

TECHNICAL REPORT

Assessment of point-of-care testing devices for infectious disease surveillance, prevention and control - a mapping exercise



ECDC TECHNICAL REPORT

Assessment of point-of-care testing devices for infectious disease surveillance, prevention and control – a mapping exercise

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Abbreviations

AIDS Acquired immune deficiency syndrome

ECDC European Centre for Disease Prevention and Control

EEA European Economic Area

EU European Union

HIV Human immunodeficiency viruses

ISO International Organization for Standardization

PCR Polymerase chain reaction POCT Point of care testing

SARS Severe Acute Respiratory Syndrome

STEC/VTEC Shiga-toxin/verocytotoxin-producing *Escherichia coli* infection

UK United Kingdom

WHO World Health Organization

Executive summary

The ability to rapidly diagnose infectious diseases is critical, not only for the appropriate and timely treatment of infected patients, but also for infectious disease surveillance, the detection of outbreaks and controlling the rapid spread of infectious diseases nationally and internationally. Point-of-care testing (POCT) for infectious diseases represents a set of technologies that can lead to the rapid detection of such diseases which can influence the way patients are treated.

This document provides the final report of a mapping exercise undertaken as part of a wider study that was commissioned by ECDC and undertaken by RAND Europe between November 2019 and April 2020. The objective of the wider project was to assess the availability, use and impact of POCT devices in European Union/European Economic Area (EU/EEA) Member States and the United Kingdom (UK) for communicable diseases under EU surveillance. Please note that the data collection was undertaken in 2019, from EU/EEA Member States, thus the UK was still a Member State of the EU at this time. This explains the inclusion of UK data in this report. The project included two parts, a scoping review and a mapping exercise. The mapping exercise, to assess the current status of the use of POCT in EU/EEA Member States and the UK, including the impact of POCT on clinical practice and on key public health functions, is the focus of this report.

The methods for this mapping exercise included the appointment of expert advisers and an initial scoping, including one expert scoping interview, a survey sent to 186 recipients, including to at least two experts per European country, a prioritisation process to identify a select number of infectious diseases for focused analysis, and follow-up research comprising interviews and desk-based research.

A total of 54 responses were received from 26 different EU/EEA Member States and the UK. The disease or health issue for which most countries reported that POCT is in use was influenza, which was reported by 19 countries (73% of countries responding to the survey). This was closely followed by HIV/AIDS, reported by 17 countries (65%), and legionnaires' disease and malaria, both reported by 13 countries (50%). At least five countries (19% of countries responding to the survey) reported that POCT is in routine clinical use for the following diseases or health issues: syphilis, chlamydia infections, hepatitis B, hepatitis C, nosocomial infections, antimicrobial resistance, tuberculosis, invasive pneumococcal disease, dengue, invasive meningococcal disease, gonorrhoea and cryptosporidiosis. The disease or health condition for which most countries reported that guidelines or similar documentation are available is HIV/AIDs, with 11 countries (65% of countries in which POCT for HIV/AIDS was reported to be in routine clinical use). The disease or health issue for which POCT is most often quality assessed is also HIV/AIDS. Evidence on the tests that have been replaced by POCT (e.g. for screening, triaging or diagnosing) was limited. Chlamydia infections, HIV/AIDS and legionnaires' disease were the diseases for which most countries reported that POCT has replaced other tests. The country in which POCT has had the most significant clinical impact, in terms of replacement, is Spain, where respondents reported that POCT had replaced existing tests across 14 diseases and health issues. Cross-analysis was conducted, exploring whether POCT has replaced other tests with whether POCT alone is sufficient for diagnosis. This analysis is based on a small number of respondents and was not asked in relation to each specific infectious disease or associated health issues, however, it does indicate that in almost all cases where POCT has replaced an existing test, that further tests would be needed to confirm a diagnosis. The public health key function which most countries (seven countries) reported POCT-derived results being used for was disease surveillance. No countries reported that POCT-derived results are used for antibiotic resistance monitoring.

Limitations of this study primarily relate to the number of responses received to the survey (n=54/186). A major consideration here was the fact that the survey implementation period coincided with the escalation of the COVID-19 pandemic, which severely affected the availability of in-country staff to participate in the survey. Similarly, there are limitations in that we received no responses from five European countries, however, for three of these, information was gathered through follow-up interviews. There are challenges of limited knowledge of any given respondent and lack of possibility for comparison across responses where only one response was received. Finally, there are also limitations relating to the way in which respondents interpreted the questions asked by the survey. We also recognise the importance and relevance of COVID-19 to this study on point of care testing, but we could not include this disease in the mapping report as the study was already underway before the pandemic occurred.

The ongoing COVID-19 pandemic has highlighted the essential role of large-scale POCT for the surveillance, prevention and control of infectious diseases. Alongside centralised laboratory-based testing, the development of rapid and reliable diagnostic tests, usable at the point of care, has quickly been recognised as a necessity in order to adequately meet public health needs. This study has provided evidence on the availability of POCT devices and the arrangements surrounding their use and their impact on clinical practice. The mapping exercise has also provided evidence on the impact of POCT in relation to clinical disease management and public health key functions. However, given the limitations outlined above, it is unlikely to be a complete picture of POCT use across EU/EEA Member States and the UK.

1 Introduction

This document provides the final report of a mapping exercise undertaken as part of a wider study on 'Assessment of point of care testing devices for infectious disease surveillance, prevention and control'. The objective of the wider project was to assess the availability, use and impact of POCT in the EU/EEA for communicable diseases under EU surveillance.

The project had two main parts:

- A scoping review, to obtain an overview of the literature available on the availability and use of POCT covering the 56 communicable diseases and related health issues currently under EU surveillance;
- A mapping exercise, to assess the current status of the use of POCT in EU/EEA Member States and the UK, including the impact of POCT on clinical practice and on key public health functions (the subject of this report); and a technical meeting was planned as a third part, however, due to the COVID-19 pandemic it was not possible to organise it.

As the final mapping exercise report, this report builds on the final mapping review protocol, the material and tools for data collection (including a survey on the EUSurvey platform), and the interim mapping exercise report. It presents a detailed description of the work undertaken on the mapping exercise and the final resultsⁱ.

1.1 Background and context

The ability to rapidly diagnose infectious diseases is critical not only for the appropriate and timely treatment of infected patients, but also for infectious disease surveillance, the detection of outbreaks and controlling the rapid spread of infectious diseases nationally and internationally. Point of care testing (POCT) for infectious diseases represents a set of technologies that can lead to the rapid detection of such diseases and can influence the way patients are treated for suspected infectious diseases. The International Organization for Standardization (ISO) defines POCT and near-patient testing as 'testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient' [1]. Throughout Europe and internationally, POCT is used across a variety of settings, including intensive care settings, neonatal and birthing units, operating theatres, general practice, nursing homes, pharmacies, outpatient and off-site clinics and in-home patient care [2], although self-testing is excluded from the ISO definition of POCT [1].

The availability and use of POCT has been increasing in recent decades, both within Europe and internationally [2]. The increased availability of POCT is partially due to technological advances that have made POCT more robust, easy-to-use and cost effective, including advances in smartphone-based technologies, paper-based assays, lab-on-chip platforms, novel assay formats, e.g. automated assays and fully integrated assays (which include all the required reagents and equipment), and advances in the long term storage of reagents needed for POCT [3-5]. Among recent developments, advancements in microfluidics have been of particular importance, allowing tests that were traditionally performed in a central laboratory setting to be performed nearer to the patient, and even in resource-limited settings lacking highly trained staff [4-5].

The immediate goal of POCT is to use the information gathered from such testing to directly influence the timely and proper care of patients [4]. As such, one of the primary benefits of POCT is that it makes testing for infectious diseases more accessible regardless of existing medical and laboratory infrastructure [3–5]. By making test results available more quickly at the site where the patient is cared for, POCT facilitates more timely and appropriate treatment, for example by reducing presumptive treatment based on clinical diagnosis rather than confirmed laboratory diagnosis [4]. POCT can also potentially facilitate more efficient care pathways, e.g. avoidance of unnecessary additional laboratory testing if a POCT is negative or admission to an appropriate isolated ward if a POCT is positive, and can also facilitate better decision-making, which should reduce complications and lead to fewer long-term hospital stays [2].

¹ Note on COVID-19: This mapping exercise was undertaken between November 2019 and April 2020, with the mapping survey, the core research method of the exercise, undertaken between January and March 2020. The study period therefore coincided directly with the escalation of the COVID-19 pandemic. It should be noted from the outset that this timing had a considerable impact on the implementation of this study. Most significantly, the COVID-19 outbreak meant that many national focal points for infectious disease surveillance – some of the principal targets of the mapping survey – were preoccupied in the co-ordination of national responses to the pandemic. This significantly affected the number of responses received by the survey. The pandemic also affected the study team's ability to conduct follow-up interviews as many with expertise in diagnostics have been fully occupied in dealing with COVID-19. The impact of the outbreak on the implementation of this study is discussed further in the limitations section of this report.

We also recognise the importance and relevance of COVID-19 to this study on point-of-care testing but we could not include this disease in the mapping report as the study was already underway before the outbreak occurred.

ⁱⁱ An assay is a type of test which identifies whether a certain substance is present and the amount of the substance in a sample.

POCT can also facilitate the effective surveillance, prevention and control of infectious disease outbreaks. For example, POCT can be useful in monitoring and containing the spread of the malaria, dengue and Ebola viruses, as there is often a lack of trained staff and reliable equipment in areas where these infectious diseases are most prevalent. POCT can also help detect and prevent the spread of infectious diseases such as HIV by ensuring that patients are diagnosed at an earlier stage, decreasing unknowing transmission to others. By making testing more readily available to patients that may be at higher risk of infection, POCT may detect diseases in patients who may otherwise be lost to follow-up if test results required multiple visits. POCT can also be used to distinguish infectious diseases such as Zika from other febrile illnesses, and can help ensure that blood supplies are safe for diseases that can be transmitted through infected blood donations [5]. This use of POCT in infectious disease surveillance, prevention and control has been supported by ECDC, for example in its guidance on infectious disease screening in migrants within EU/EEA Member States and the UK in which POCT in primary care settings is recommended, when appropriate, for HIV, hepatitis B and hepatitis C [6]. The use of POCT also helps address issues around antimicrobial stewardship by avoiding the inappropriate use of antimicrobials for presumed infectious diseases, which has been highlighted as an important strategy to help address global challenges around antimicrobial resistance [7, 8].

Although POCT for infectious diseases can be beneficial to patient-level care and public health outcomes, there are several challenges around POCT that should be considered. Compared to traditional lab-based serological tests, some POCT technologies demonstrate low diagnostic validity (e.g. sensitivity and specificity) [3, 5], particularly at low concentrations of the analyte [4]. As such, results from POCT testing need to be understood in this context, with additional confirmatory tests sometimes needed [2]ⁱ. Connectivity of POCT technology to integrate test results with hospital- and lab-based information is also a challenge [3]. Connectivity and real-time data linkages are especially important in relation to the national and international surveillance of infectious diseases, and additional efforts to standardise data and coordinate between stakeholders may open up new possibilities for rapid testing to be used to improve disease surveillance and epidemic preparedness [10].

1.2 Study objectives

The overarching objective of the mapping exercise was to map the current use of POCT in clinical infectious disease management and public health practice in EU/EEA Member States and the UK. The project aims to provide evidence on the status of POCT technologies and their potential relevance to clinical disease management and public health. It will also serve as a source of information for ECDC and key stakeholders to support decision-making in this area. The mapping exercise focuses on the EU/EEA context, including EU/EEA Member States and the UK, which was part of the EU at the time the mapping exercise began. It is designed to map the status of POCT in clinical infectious disease management and public health practice in relation to the 56 communicable diseases and related health issues currently under EU surveillance. It also provides insights into the implications for public health key functions in relation to ECDC's mandate to work with national health institutes in the EU to identify, assess and communicate about current and emerging infectious diseases. This includes implications for ECDC's disease surveillance networks and early-warning systems for potential outbreaks.

The research questions that formed the basis of the mapping exercise are presented in Table 1. This report collates evidence in the form of reference lists, data collection tables, figures and other visual representations that allows it to be readily used as a source of information for key stakeholders to support strategic decision-making. The results of the study are intended to inform how ECDC develops its activities in this increasingly important and evolving area in the future.

¹ To help address some of the challenges around differing qualities and standards for POCT devices, the World Health Organisation put together the ASSURED criteria, stating that POCT should be: Affordable; Sensitive; Specific; User-friendly; Rapid and robust; Equipment-free; and Deliverable to end-user [9].

ii European Centre for Disease Control. 2018. Diseases and special health issues under EU surveillance. Available at: https://www.ecdc.europa.eu/en/all-topics-zsurveillance-and-disease-data/diseases-and-special-health-issues-under-eusurveillance

Table 1. Research questions for mapping exercise on point of care testing devices for infectious disease surveillance, prevention and control and where in this report they are addressed

| Research question | Section(s) of this report in which the question is addressed |
|--|--|
| For which infectious diseases and related health issues do recommendations/guidelines/patient care pathways issued by national authorities, learned societies or other recognised national bodies for the use of POCT exist in the EU/EEA Member States and the UK, and for which infectious diseases and related health issues are POCT reimbursed? | Section 4.2; Section 5.2; Sections 6.4-6.14; Section 7; Annex 7 |
| For which infectious diseases and related health issues are POCTs used in routine clinical practice and to which extent have POCTs replaced traditional testing in the EU/EEA? | Section 4.1; Section 4.3; Sections 6.4-6.14; Section 7; Annex 7 |
| What are the differences between the use of POCTs in the EU/EEA Member States and the UK? | Section 4.1; Section 5.1; Sections 6.4-6.14; Section 7; Annex 6; Annex 7 |
| What are the effects of POCT use on reporting of test results and on public health key functions like outbreak detection, surveillance and response? | Section 5.3 |

1.3 Structure of this report

The remainder of the report is structured as follows:

- Section 2 describes our research approach to the mapping exercise, including a description of the primary tasks and the associated methodologies. Here, we also outline the key limitations associated with this study.
- Section 3 provides an overview of responses received by the mapping survey, the central research method
 used in this mapping exercise, including an analysis of survey responses by country, by role and experience
 of respondents.
- In Section 4, we provide high-level analysis of the results of the mapping survey, focusing on how results vary across diseases and health condition.
- In Section 5, we provide high-level analysis of the results of the mapping survey, focusing on how results vary across EU/EEA Member States and the UK.
- In Section 6, we provide detailed analysis of 11 prioritised infectious diseases. Here, we combine results from the mapping survey with findings from follow-up interviews and desk-based research.
- In Section 7, we provide summary mapping survey findings for all other diseases and associated health conditions included in the scope of this study.
- Section 8 provides a discussion of the major findings of the study.
- Finally, the annexes to the report contain a wide range of additional materials related to the design, implementation and analysis of the study, including:
 - the mapping survey as it was presented to participants;
 - the protocol used for the scoping interview;
 - the protocol used for follow-up interviews;
 - the key search terms used for follow-up desk-based research;
 - the shortlists used to select focus infectious diseases;
 - a country mapping table presenting the mapping survey results on diseases for which POCT is available in each EU/EEA country; and heatmaps presenting the mapping survey results for each infectious disease.

4

ⁱ This table presents the research questions in the request for service for this project. In the body of the text, they are presented in an order which allows the reader to more easily understand how the information fits together to best indicate POCT availability and use across EU/EEA Member States and the UK.

2 Research methods

In this section, we provide a detailed account of the approach and methodology for the mapping exercise.

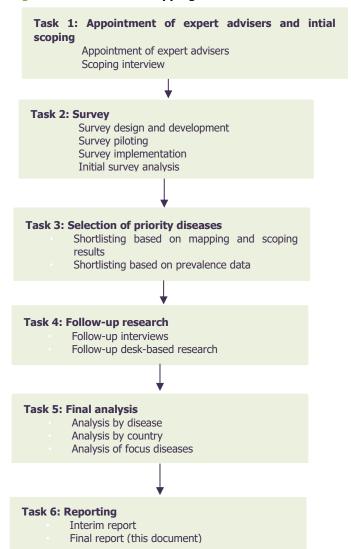
2.1 Overview of methods

The mapping exercise sought to map the current status of the use of POCT in clinical infectious disease management and public health practice in EU/EEA Member States and the UK. We designed a methodology that allowed us to assess how similar or dissimilar the availability and use of POCT is across EU/EEA Member States and the UK, as well as the public health impact of POCTEU/EEA Member States and the UK. The mapping exercise involved:

- Appointment of two expert advisers and initial scoping, including a scoping interview with one additional
 expert.
- A survey sent to 186 recipients, including to at least two experts per European country;
- A prioritisation process to a identify a select number of infectious diseases for focused analysis;
- Follow-up research comprising interviews and desk-based research;
- Analysis of evidence gathered;
- Reporting.

The methodology for each of these tasks is described in Sections 2.2 to 2.7. Figure 1 below provides a visualisation of the key tasks of the mapping exercise.

Figure 1. Overview of mapping exercise tasks



Task 1: Appointment of expert advisers and initial scoping

At inception, the study team appointed two experts in microbiology to act as advisers to the research. The expert advisers were also consulted on the plan for the mapping exercise and were consulted further at various stages of the mapping exercise where needed.

To help inform our survey development and to help us understand some of the factors which might influence the use of POCT, we also conducted one scoping interview. The interview was conducted with an expert in the field of medical microbiology and molecular diagnostics. This scoping interview was to provide the research team with a high-level understanding of the availability and extent of POCT device usage across EU and EEA countries and the UK, and to inform the development of survey questions (the protocol used for the interview can be found in Annex 2 to this report). Initially we had planned to conduct a higher number of scoping interviews (three to five). However, due to difficulties making contact with relevant individuals, we made the decision to conduct the remaining interviews as follow-up interviews after the survey had been completed. The revised approach ensured that the interviews would be of maximum assistance to our mapping review, enabling us to target interviewees that would help fill any remaining gaps in the evidence following completion of the survey (see Task 4.2 below).

Task 2: Survey

The main form of data collection for the mapping exercise was a survey of key stakeholders across EU/EEA Member States and the UK. This survey was designed to allow us to collect a large amount of data over a relatively short period of time, and to complement the information collected from the scoping review study by collecting data from a wide range of respondents, with expertise in microbiological diagnostics and the implementation of POCT. The survey process was broken down into four phases: design and development, piloting, implementation, and analysis. Each of these phases are described in more detail below.

2.1 Survey design and development

The survey questions were designed to collect information on POCT policy and use in EU/EEA Member States and the UK, along with their impact across Europe. In designing the survey questions, the study team drew upon the insights of the scoping interview. The survey was programmed using EU Survey, a platform supported by the European Commission to allow for interoperability across European-level public administrations. Where necessary, we adapted questions to the technical requirements of the EU Survey platform (e.g. by adopting the sequencing of questions to fit with EU Survey's capabilities around question visibility).

The survey questions broadly covered the following topics:

- Demographic information on the survey respondent, including their profession and how long they had worked in the field;
- The availability of POCT for infectious diseases and related health issues under ECDC's remit across EU/EEA Member States and the UK;
- The presence of official guidelines, recommendations or policy governing the use of POCT across EU/EEA countries;
- How POCT is funded or reimbursed;
- The use of POCT in clinical practice for screening, triaging or diagnosis;
- Quality assessment procedures for existing POCT devices;
- How results of POCT are used in relation to other tests to confirm diagnosis; and
- The impact of POCT for disease surveillance and other public health key functions.

A full version of the survey protocol is provided in Annex 1. The survey was designed so that only questions relating to the diseases which a respondent had indicated they were aware of POCT existing for appeared in subsequent sections. Only respondents that selected that POCT is available for all infectious diseases and related health issues would see all questions in the survey.

The survey was designed to be engaging and user-friendly and was intended to take approximately 20-30 minutes to complete. Most questions were multiple choice to allow for a shorter survey, although respondents also had the opportunity to provide additional insight through several open text questions. The survey was in English, although respondents were able to provide responses to free text questions in any language.

Task 2.2 Survey piloting

The survey was piloted extensively at RAND Europe with researchers who were outside of the POCT study team but had knowledge of infectious diseases and ECDC's remit. At this stage of piloting, both the content of the survey was tested (e.g. clarity of the questions, flow and logic of questions; appropriateness of language; time it

i

i Accessible at: https://ec.europa.eu/eusurvey/home/welcome

took to complete the survey), as well as technical functionalities within EU Survey to ensure that question visibility worked as expected when questions were dependent on previous answers in the survey.

Additionally, we piloted the survey with ECDC staff members who provided additional insight as to how the survey questions could be improved. After small refinements were made from both stages of piloting, a final survey protocol was provided to ECDC for approval.

Task 2.3 Survey implementation

We invited a range of stakeholders from across EU/EEA Member States and the UK to complete the survey, including policymakers, clinicians, European-level association members, clinical scientists and microbiologists, infectious disease specialists, representatives from national authorities and representatives from learned societies, including microbiological societies. Potential respondents were identified through preliminary desk-based research to ensure an appropriate spread across EU/EEA Member States and the UK, and across stakeholders. We ensured that we invited at least two participants from each country, often more, with the aim of securing good coverage in responses. We also asked individuals to suggest additional invitees if appropriate. Where additional names were provided, we also sent them a survey request. The survey was also sent out to ECDC National Microbiology Focal Pointsⁱ after the initial launch of the survey. In total, 186 people were invited to participate in the survey.

Surveys were sent using an email template that introduced the study, outlined the purpose of the survey, and provided contact details of the study team in case the respondent had any questions about the study or the survey. This email also included a unique link for each respondent, which was generated through EU Survey. These unique links provided a mechanism to see which links had been used and who had already filled out the survey, which allowed the study team to send reminder messages only to potential respondents that had not yet completed it. For the ECDC National Microbiology Focal Points, a different process was followed. For this group, ECDC first sent an initial email introducing them to the study and encouraging them to fill out the survey. This was followed by an email from the study team inviting them to participate in the survey, after which the process followed was the same as the rest of the potential respondents.

The survey was originally scheduled to close to new responses after two weeks. However, the deadline to complete the survey was extended twice with the aim of increasing the number of responses (particularly in view of the disruption that had been caused by the COVID-19 outbreak). In the first instance, the survey deadline was extended for two additional weeks, and in the second instance, the deadline was extended a further week and a half to allow for additional responses. In total, the survey was open for five and a half weeks.

Along with the initial invitation to participate in the survey and two emails extending the survey deadline, potential respondents received up to three reminders to participate. These reminders and extensions were only sent to respondents who had not yet provided a response and who had also not emailed the study team to decline the survey invitation. Thus, we contacted each potential participant who did not respond to us a maximum of six times during the survey's implementation period.

An Excel file was used to carefully track whether each unique link was used and when, and to log all communication with potential survey respondents.

Task 2.4 Initial survey analysis

Responses were downloaded from EU Survey and saved on password protected computers. Initial analysis explored how many and what stakeholder types had responded to the survey and analysed the countries in which POCT is available, and for which diseases. We also performed initial analysis of POCT availability, impact and use across EU/EEA Member States and the UK. For each research question, we developed an initial narrative summary of the evidence, including data tables and visuals where helpful. The analysis was performed in R, a software programme to aid in statistical analysis [11, 12].

Task 3: Prioritisation of a select number of 'focus' infectious diseases

Running alongside analysis of the survey results, the study team also decided to identify a select number of infectious diseases and associated health issues for more focussed analysis. The decision to prioritise a small number of 'focus diseases' reflected two considerations. Firstly, it reflected that fact that, within the resources available for this study, a detailed analysis of the results across all 56 diseases was not possible. For some diseases we received very little information from our mapping so it was not possible to analyse them in detail. Second, it reflected the judgement of the study team that in addition to the high-level analysis of POCT in

¹ ECDC National Microbiology Focal Points are senior microbiology experts designated by the Member States to support ECDC by providing knowledge of the technical, scientific and administrative structures of the national public health microbiology system.

relation to all 56 infectious disease categories, a more detailed consideration of the current status of POCT in relation to those diseases of particular significance in the EU/EEA context would be most useful to ECDC. The selection of focus diseases also helped to ensure a more targeted approach to the follow-up interviews and desk-based research conducted to fill gaps in the survey data (see Task 4 below).

In prioritising focus diseases, in consultation with ECDC, we used two overarching criteria: (i) those diseases for which there was evidence that POCT is available within the EU/EEA; and (ii) those diseases with highest prevalence in the EU/EEA region. For the first criterion, we used initial analysis of the results of the mapping surveyⁱ, combined with the results of the parallel RAND Europe scoping review of POCT, to give insights on those diseases for which POCT is most likely available within the EU/EEA. For the second criterion, we assessed disease prevalence using data (for both age-adjusted prevalence rate and number of cases) contained in the ECDC Surveillance Atlas of Infectious Diseases. By cross-checking the shortlists produced by these different datasets, we identified a final list of 11 focus diseases for further follow-up research and more detailed analysis. A more detailed description of the prioritisation process for focus diseases can be found in Section 6.1 below.

Task 4: Follow-up research

Once the survey analysis was completed, we identified gaps in the evidence based on which we conducted a small amount of focused follow-up research.

Task 4.1 Follow-up interviews

Follow-up interviews focused on those countries for which we did not receive survey responses, and on countries in which the single survey respondents from that country had reported that they are not aware of POCT being used for any of the infectious diseases and related health issues listed in the surveyⁱⁱⁱ. Both of these outcomes represented gaps in terms of understanding how the use of POCT varies across EU/EEA Member States and the UK. Where we conducted interviews, we focused on gathering data in relation to the 11 focus diseases prioritised during Task 3.

Interviews were conducted with EU or international experts who had knowledge of POCT in the specific geographical contexts for which gaps existed in our survey analysis. The interviews were semi-structured, providing us with the flexibility to explore areas related to POCT that the interviewee may be familiar with. The interviews were conducted by telephone and recorded, with a privacy notice and project information sheet sent to interviewees prior to the interviewi^v. The interview protocol was finalised based on the data that had been analysed from the survey (a copy of protocol used for follow-up interviews is included in Annex 3). Key areas of focus included:

- Understanding the use and impact of POCT in those EU/EEA Member States and the UK for which we did not receive survey responses. Here, we focused interviews on the 11 infectious diseases prioritised in Task 3;
- The availability of guidelines, patient pathways or other official documents concerning the use of POCT for infectious disease diagnosis, surveillance, prevention and control in those countries;
- The procedures for reimbursement for POCT devices for infectious diseases in those countries;
- The extent to which POCT has replaced other tests for screening, triaging or diagnosis in those countries;
- Whether or not POCT for infectious diseases is externally quality assessed in those countries;
- The broader applications of POCT in clinical practice and in public health activities in those countries.

The study team attempted to conduct interviews with experts in all countries for which there were gaps in the survey data. In practice, however, the challenge of making contact with relevant experts meant that interviews could not be conducted for some countries. In total, three follow-up interviews were conducted with experts in the following countries: Czechia, Lithuania and Portugal. Information relevant to the research questions was collated in an Excel file to aid analysis by EU/EEA country, alongside the data collected from the survey.

Task 4.2 Follow-up desk-based research

In addition to follow-up interviews, we conducted targeted desk-based research intended to fill gaps in the data acquired through the mapping survey. Unlike interviews, which focused on countries, desk-based research focused on those areas where survey responses had indicated that POCT was available for an infectious disease within a country, but where responses provided had also highlighted uncertainty in relation to more specific

¹ In this initial analysis of the results of the mapping survey, a POCT was taken to be available for a disease if one respondent from a country had indicated as such, regardless of the other responses from that country.

[&]quot; Accessible at: https://atlas.ecdc.europa.eu/public/index.aspx

iii Countries in this category were: Czechia, Hungary, Italy, Luxembourg, Portugal, Lithuania and Lichtenstein.

iv At the request of the interviewee from Lithuania, the interview questions were sent and responded to in written form.

^v It is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis.

questions asked by the survey, namely; those concerning the availability of guidelines for the use of POCT, whether or not POCT is externally quality assessed, arrangements for reimbursement of POCT, and the extent to which POCT has replaced other tests. Here, uncertainty meant questions to which all survey respondents from a country had provided a response of 'unsure', or questions to which not all survey respondents from the same country had provided the same answer.

To try to fill these gaps, the team used targeted Google searches for each area where the survey data had suggested uncertainty. In doing so, we focused on uncertainties pertaining to the 11 focus diseases prioritised during Task 3 above. Google searches adopted a structured approach using the same key search terms for each of the four research questions (for a list of these search terms see Annex 4 to this report). In each case, the country name and name of the disease were tailored to address the particular area where uncertainty existed. We limited each search to the first 30 results produced by each search. Any information providing clarity on the existing areas of uncertainty was collated into an Excel file to aid analysis by EU/EEA country.

As a supplement to targeted Google searches, the desk-based research also reviewed any additional information provided by survey respondents – in the form of both free text answers and links to websites, guidelines and other documentation – to see if this could provide clarity on the areas of uncertainty. Information obtained through these means was also added to our Excel file, together with the data collected from the targeted Google searching.

Task 5: Final analysis

During this phase, we conducted further analysis of the data acquired during the mapping survey. Using mapping survey data, we performed further analysis on the results of the survey with respect to each of the research questions for this study. This analysis considered the results of the survey from both a disease perspective and a country perspective, the findings of which are presented in Sections 4 and 5 of this report respectively. Analysis was performed in the software package R [11, 12]. During this phase of analysis, we also reviewed key survey findings with respect to each individual disease. We produced both a summary findings table (Section 7) and colour-coded survey 'heatmaps' summarising survey responses to key research questions for each disease by country (Annex 7).

In the case of the 11 focus diseases selected during Task 3, data collected from the mapping survey was brought together with data collected by the follow-up interviews and desk-based research. Here, we produced detailed narrative analyses combining findings of the survey, interview and desk-based research data, for each focus disease (See Section 6 of this report). We also created additional maps and visuals, including inferential colour-coded heatmaps, to help summarise the key findings of the research. Analysis was performed in R, with Excel used to assist in the production of inferential heatmaps.

Task 6: Reporting

Alongside the work undertaken in Tasks 1 to 5, the study team also conducted regular reporting on the research plans, progress and outcomes. Prior to this final report, we delivered an inception reportⁱⁱ, a finalised protocol for the mapping exercise, and an interim report presenting preliminary findings of the mapping exercise. This final mapping exercise report is the final reporting milestone. The report includes a concise discussion of the overall findings of the mapping exercise. Where relevant, it also uses these conclusions to make recommendations for potential future research.

Limitations of the analysis

As noted at the outset of this report, this study has been subject to a number of limitations (see Introduction). Here, we describe the key limitations of the mapping exercise in more detail, as well as the steps that the study team took to mitigate them.

Firstly, there are limitations due to the number of responses received to the survey. A total of 54 responses were received. A major consideration here was the fact that the survey implementation period coincided with the escalation of COVID-19, which severely affected the availability of in-country staff to participate in the survey. To increase response rates, the study team extended the deadline for the survey twice and sent several reminders to potential participants that had not yet completed the survey, including a recognition that the COVID-19

¹ The decision to focus the desk research on gaps within already acquired country data, rather than on countries where no data had been obtained, reflected: (i) the judgement of the study team that follow-up interviews were the best method to fill country gaps; and (ii) the significant number of gaps within the acquired country data.

ⁱⁱ The inception report was for the POCT study as a whole, combining the scoping review, mapping exercise and technical meeting (although the technical meeting did not go ahead).

outbreak may be impacting on respondents' ability to participate in the survey. In reminder emails, respondents were encouraged to respond to the survey even if they had limited knowledge of POCT availability, use and impact (e.g. if they only had knowledge of POCT for one or two diseases), as the study team would be collating information from across a variety of responses and information sources.

Similarly, there are limitations related to the geographical diversity of survey respondents. The mapping exercise sought to map the current status of the use of POCT testing in clinical infectious disease management and public health practice in EU/EEA Member States and the UK. As such, a single response from a well-informed respondent with knowledge of all POCT availability and use would theoretically be sufficient to create this map. However, survey responses across EU/EEA Member States and the UK varied, and we received no responses for five European countries (Czechia, Hungary, Italy, Luxembourg and Portugal). For these countries which did not respond, we attempted to arrange an interview with an expert within that country. We were able to conduct interviews with an individual from the Czechia and Portugal. In addition, the survey respondent from Lithuania reported being unaware of the use of POCT in their country, and therefore an additional interview was conducted with an expert from Lithuania to fill this gap.

There are also limitations due to the limited knowledge of any given respondent. A single response from an authoritative source in each country might be sufficient to map POCT availability and use across EU/EEA Member States and the UK. However, it is also unlikely that any single respondent has complete knowledge of POCT for all infectious diseases and related health issues within their respective countries. This creates two risks: one of collecting inaccurate information, and a second of collecting contradictory evidence from different respondents. To mitigate against these risks, where possible, the study team compared responses from within each country to assess how closely they aligned with one another. Where there was contradiction or uncertainty between survey respondents from the same country, the survey results for that question have been categorised as such. This has been distinguished from those instances in which all survey respondents from a country agreed, whether in the form of a positive or a negative response. From the survey, the significant number of mixed responses from the same country make it difficult to undertake analytical interpretation of the results. In Section 6 of this report, where we analyse the detailed findings in relation to 11 'focus diseases', we attempted to address this by providing inferential heatmaps indicating where disagreement or mixed responses nevertheless indicated the likelihood of a positive or negative response.

Another limitation relates to those countries in which we received only one survey or interview response (Austria, Belgium, Bulgaria, Cyprus, Finland, Latvia, Lithuania, Slovakia, Slovenia, Liechtenstein) and where comparison across responses was not possible. In this study, where at least one respondent from a country selected that POCT was available for a disease or health issue (and subsequently went onto answer more detailed questions), this has been considered sufficient to be included in our analysis. However, where a sole survey respondent responded to a question in a certain way – whether positive, negative or uncertain – it is not possible to know if more survey responses from that country would have given a different response. The relatively high number of countries with only one survey respondent is reflected in the low number of responses overall, as many diagnostics specialists were most likely fully engaged with the outbreak of COVID-19.^{iv}

Finally, there are also limitations relating to the way in which respondents interpreted the questions asked by the survey. In designing the mapping survey, the study team took care to ensure that POCT was clearly defined using the ISO definition. Despite this, it is possible that different survey respondents interpreted POCT in different ways. Results from some countries - France, for instance, where one survey respondent reported that POCT is available for 55 diseases and health issues, far more than in most other countries – suggest that this may have been a factor. In reviewing the results, differences between countries may reflect differences in interpretation as well as the differences in the actual uses and impacts of POCT on the ground.

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¹ Along with the initial invitation to participate in the survey and two emails extending the survey deadline, potential respondents received up to three reminders to participate (see Task 2.3 above).

^{II} For the number of responses received from each country, see Section 3.1 of this report.

^{III} One limitation of this approach is that a response was grouped as either positive or negative where it relied on only one survey respondent, the accuracy of which could not be verified.

^{iv} Due to the high number of country and information gaps within the survey data, combined with limitations on the available time and resources, we opted to focus the desk-based research on those gaps rather than on countries with one survey response.

^v The survey clarified that point of care testing (POCT) referred to testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient. The test also needed to be turned around in 90 minutes or less. Patient self-testing in a home or community environment was excluded from this definition. This follows the definition in ISO 22870:2016, accessible at: https://www.iso.org/obp/ui/#iso:std:iso:22870:ed-2:v1:en

3 Overview of survey respondents

In this section, we provide an overview of responses received by the mapping survey, including analysis of responses by country and by role and experience of respondents.

3.1 Survey respondents

The survey received 54 responses. Respondents came from 26 different EU/EEA Member States and the UK with the number of responses per country ranging from one to seven. We received no responses from Czechia, Hungary, Italy, Luxembourg and Portugal. As a result, these countries are not represented in the survey analysis. Table 2 below provides a grouping of countries based on the number of survey responses per country, and Figure 2 provides a visual representation of how responses are distributed across EU/EEA Member States and the UK.

Table 2. Number of survey responses per country

| Country | Responses |
|---|-----------|
| Denmark | 7 |
| Greece; Netherlands; Sweden | 4 |
| Estonia | 3 |
| Croatia; France; Germany; Ireland; Malta; Poland; Romania; Spain; Iceland; Norway; United Kingdom | 2 |
| Austria; Belgium; Bulgaria; Cyprus; Finland; Latvia; Lithuania; Slovakia; Slovenia; Liechtenstein | 1 |
| Czechia; Hungary; Italy; Luxembourg; Portugal | 0 |

Respondents came from a variety of professional backgrounds. Microbiologists or other laboratory staff made up the largest group of respondents (43%), followed by clinicians and other healthcare professionals (19%); academics and researchers (17%); regulators, policymakers and government workers (15%); and other roles (7%). Just over a third of respondents had between one and ten years of experience (39%), and one in three respondents had more than 20 years' experience in their respective fields (35%). Table 3 provides an overview of how survey respondents varied in terms of professional roles, and Table 4 provides an overview of how survey respondents varied in terms of years of experience.

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¹ In fact, a total of 55 responses were received. However, one respondent did not consent to participate in the study and their response was therefore removed from the analysis. As such, a total of 54 responses were analysed.

ⁱⁱ In the case of Czechia, Lithuania and Portugal, data was gathered in the form of follow-up interviews. The evidence is reported on in Section 6 of this report.

The other roles that respondents listed consisted of combinations of the other roles – for example, some respondents were clinicians and researchers.

Figure 2. Survey responses per country

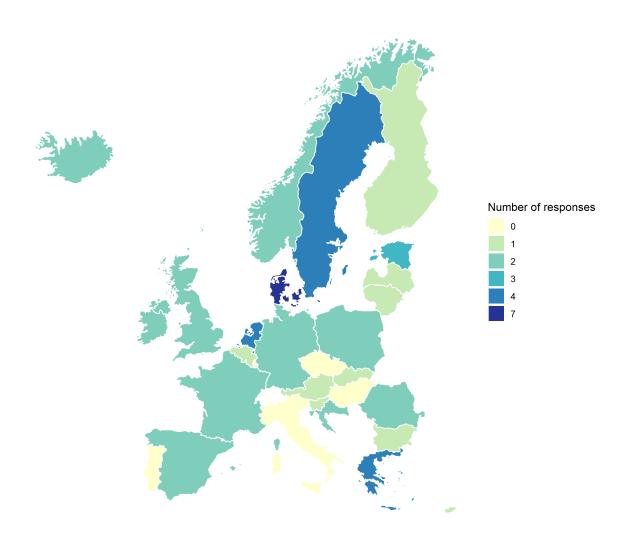


Table 3. Role of survey respondents

| Role | Respondents | Percentage of respondents (%) |
|--|-------------|-------------------------------|
| Microbiologist or other medical laboratory staff | 23 | 43 |
| Clinician or other healthcare professional | 10 | 19 |
| Academic/researcher | 9 | 17 |
| Regulator, policymaker, or government worker | 8 | 15 |
| Other | 4 | 7 |

Note: percentages do not add up to 100 due to rounding.

Table 4. Years of experience of survey respondents

| Years of experience | Respondents | Percentage of respondents (%) |
|---------------------|-------------|-------------------------------|
| None | 0 | 0 |
| Less than 1 year | 1 | 2 |
| 1-5 years | 8 | 20 |
| 6-10 years | 7 | 17 |
| 11-15 years | 11 | 27 |
| 16-20 year | 0 | 0 |
| 21-25 years | 6 | 15 |
| 26-30 years | 4 | 10 |
| 30+ years | 4 | 10 |

Note: percentages may not add up to 100 due to rounding.

4 Survey results by disease

In this section, we provide a summary analysis of the results of the mapping survey, focusing on the way in which results vary by disease or health condition. In the first section, we analyse survey responses to questions concerning the diseases and health issues for which POCT is in routine clinical use. In section two, we analyse survey responses to questions concerning the availability of official documentation concerning the use of POCT, the reimbursement procedures in place for POCT, and the extent to which POCT is quality assessed. In section three, we analyse the responses to questions concerning the extent to which POCT for specific diseases has replaced other diagnostic tests for screening, triaging or diagnosis. Using the limited survey data on POCT replacement of existing tests, we also examine the types of diagnostic test which POCT has replaced.

4.1 POCT availability and use in routine clinical practice

Respondents to the survey were asked to select the infectious diseases and related health issues for which POCT is routinely used in clinical practice within their respective countries. Responses to this question addressed the following research questions:

- For which of the 56 infectious diseases and related health issues are POCTs used in routine clinical practice?
- what are the differences between the use of POCTs in EU/EEA Member States and the UK?

The study team examined the number of countries reporting that POCT is available for each disease or health issue. The disease or health issue for which the most countries reported that POCT was in use was influenza, which was reported by 19 countries (73% of countries responding to the survey). This was closely followed by HIV/AIDS, reported by 17 countries (65%), and legionnaires' disease and malaria, both reported by 13 countries (50%). At least five countries (19% of countries responding to the survey) reported that POCTs is in routine clinical use for the following diseases or health issues: syphilis, chlamydia infections, hepatitis B, hepatitis C, nosocomial infections, antimicrobial resistance, tuberculosis, invasive pneumococcal disease, dengue, invasive meningococcal disease, gonorrhoea and cryptosporidiosis. Forty diseases were reported as having POCT in routine clinical use by fewer than five countries. Table 5 provides the number of countries that reported POCT being used in routine clinical practice for each infectious disease or health issue. It should be noted that in some cases there was variation in whether respondents from the same country reported that POCT is available. Such variance is not necessarily unexpected, given that most survey respondents would have an expert knowledge of some diseases, but not of others. The above reflects those countries in which at least one survey respondent selected that POCT is in routine clinical use for a given disease or health issue.

¹ It is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis.

ⁱⁱ This second question, though partly addressed in this section, is also addressed in more detail in the next section, where the results of the survey are analysed on a country-by-country basis.

iii Here, a single survey response reporting that POCT is in routine clinical use for a disease or health condition within a country was taken as evidence, regardless of other survey responses from that country.

^{iv} In the tables within this report, we refer to 'influenza – including influenza A(H1N1)', which was the specific terminology used in the mapping survey. When referring to the disease in textual commentary throughout the report, however, we have used the descriptor influenza.

^v In the tables within this report, we refer to 'HIV infection and AIDS', which was the specific terminology used in the mapping survey. When referring to the disease in textual commentary throughout the report, however, we have used the descriptor HIV/AIDs.

Table 5. Number of countries that reported POCT was used for each infectious disease and related health issue

Survey question: For which diseases or other health-related issue are you aware that POCT is routinely used in clinical practice in your country?

| Disease | Number of countries |
|--|---------------------|
| Influenza – including influenza A(H1N1) | 19 |
| HIV infection and AIDS | 17 |
| Malaria | 13 |
| Legionnaires' disease | 13 |
| Syphilis | 8 |
| | 8 |
| Chlamydia infections | |
| Hepatitis B | 7 |
| Hepatitis C | 7 |
| Nosocomial infections | 7 |
| Antimicrobial resistance | 7 |
| Tuberculosis | 7 |
| Invasive pneumococcal disease | 7 |
| Dengue | 5 |
| Invasive meningococcal disease | 5 |
| Gonorrhoea | 5 |
| Cryptosporidiosis | 5 |
| Infections with Haemophilus influenzae group B | 4 |
| Giardiasis | 4 |
| Shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection | 4 |
| Hepatitis A | 3 |
| Listeriosis | 3 |
| Lyme neuroborreliosis | 3 |
| Measles | 3 |
| Mumps | 3 |
| Rubella | 3 |
| Toxoplasmosis, congenital | 3 |
| Viral haemorrhagic fevers | 3 |
| West Nile virus infection | 3 |
| Brucellosis | 3 |
| Campylobacteriosis | 3 |
| Cholera | 3 |
| | |
| Salmonellosis | 3 |
| Shigellosis | 3 |
| Typhoid and paratyphoid | 3 |
| Yersiniosis | 3 |
| Leptospirosis | 2 |
| Tetanus | 2 |
| Pertussis | 2 |
| Anthrax | 2 |
| Botulism | 2 |
| Chikungunya virus disease | 2 |
| Diphtheria | 2 |
| Echinococcosis | 2 |
| Plague | 2 |
| Poliomyelitis | 2 |
| Q fever | 2 |
| Severe Acute Respiratory Syndrome (SARS) | 2 |
| Tick borne encephalitis | 2 |
| Tularaemia | 2 |
| Zika virus disease | 2 |
| Smallpox | 1 |
| Rabies | 1 |
| Transmissible spongiform encephalopathies | 1 |
| Trichinellosis | 1 |
| Variant Creutzfeldt–Jakob's disease | 1 |
| | 1 |
| Yellow fever | <u> </u> |

4.2 POCT guidelines, funding and quality assessment

In addition to the question of whether or not POCT was available for routine clinical use, survey respondents were also asked about the following areas for each disease: the availability of POCT recommendations and guidelines at the national level; how POCT is reimbursed within the healthcare system; and whether POCT is quality assessed. Analysing responses to these questions addresses the following research question: for which of the 56 infectious diseases and related health issues do recommendations/guidelines/patient care pathways issued by national authorities, learned societies or other recognised national bodies for the use of POCT exist in the EU/EEA Member States and the UK, and for which infectious diseases and related health issues are POCT reimbursed?

Table 6 below presents the number of countries reporting that guidelines, recommendations, patient care pathways and other official documents are available for each infectious disease and associated health issue. The table (and all subsequent tables in this section) has been structured by the number of affirmative responses to this question for each disease.

Tables 6-9 present information on the number of countries reporting whether guidelines, reimbursement and quality assessment are available for POCT, as well as the number of countries reporting that POCT has replaced other diagnostic tests. In all cases, the tables group country responses into one of three categories: positive, negative or uncertain. Positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question. Negative responses represent instances in which all survey respondents from a country provided a 'no' answer. 'Uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses. sing these tables, it should be noted that the grouping of a country into one of the three categories will, in some cases, be based on the answers provided by only one survey respondent. At the same time, it should also be noted that a county in which several respondents provided either a positive or a negative response to a question will nevertheless be grouped as uncertain where one respondent from the same country provided an unsure or contradictory response.

HIV/AIDs was the disease or health condition for which most countries (11 countries) reported that guidelines or similar documentation was available (65% of countries in which POCT for HIV/AIDS was reported to be in routine clinical use). The second highest recording disease or health issue in this respect was influenza, with nine countries reporting that guidelines or similar documentation are available (47% of countries in which POCT for influenza was reported to be in routine clinical use). According to the results of the survey, there is only one other disease or health issue for which guidelines or similar exist in at least five countries. This is legionnaires' disease, with five countries reporting that guidelines are available (38% of countries in which POCT for legionnaires was reported to be in routine clinical use). Four countries reported that guidelines are available for syphilis and tuberculosis, while three countries reported the existence of guidelines for the following diseases or health conditions: antimicrobial resistance chlamydia infections; hepatitis B; hepatitis C; invasive meningococcal disease; and malaria. Across all the above diseases or health issues, there was considerable uncertainty about the existence of guidelines. Across the aforementioned diseases (i.e those for which at least three countries reported that guidelines are available), 25% of country responses indicated uncertainty as to whether or not guidelines existed. Later in this report, we examine what survey responses revealed about the availability of guidelines for POCT within different EU/EEA Member States and the UK (see Section 5.1).

Table 6. Number of countries reporting the presence of guidelines, recommendations, patient care pathways and other official documentations available for POCT, by diseaseⁱ

Survey question: For [name of disease or health issue], are official guidelines, recommendations, patient care pathways or other official documents available for practitioners to use?

| Disease | Number of countries reporting availability of guidelines or other official documentation | Number of countries reporting that guidelines or other official documentation not available | Number of countries for which responses indicated uncertainty | Total number of countries for which responses to this question were received |
|--|--|--|---|--|
| HIV infection and AIDS | 11 | 3 | 3 | 17 |
| Influenza – including influenza A(H1N1) | 9 | 5 | 5 | 19 |
| Legionnaires' disease | 5 | 2 | 6 | 13 |
| Invasive pneumococcal disease | 4 | 1 | 2 | 7 |
| Syphilis | 4 | 2 | 2 | 8 |
| Tuberculosis | 4 | 2 | 1 | 7 |
| Antimicrobial resistance | 3 | 4 | 0 | 7 |
| Chlamydia infections | 3 | 3 | 2 | 8 |
| Hepatitis B | 3 | 3 | 1 | 7 |
| Hepatitis C | 3 | 3 | 1 | 7 |
| Invasive meningococcal disease | 3 | 2 | 0 | 5 |
| Malaria | 3 | 4 | 6 | 13 |
| Botulism | 2 | 0 | 0 | 2 |
| Brucellosis | 2 | 0 | 1 | 3 |
| Campylobacteriosis | 2 | 0 | 1 | 3 |
| Chikungunya virus disease | 2 | 0 | 0 | 2 |
| Dengue | 2 | 1 | 2 | 5 |
| Diphtheria | 2 | 0 | 0 | 2 |
| Echinococcosis | 2 | 0 | 0 | 2 |
| Gonorrhoea | 2 | 2 | 1 | 5 |
| Hepatitis A | 2 | 1 | 0 | 3 |
| Infections with Haemophilus influenzae group B | 2 | 0 | 2 | 4 |
| Listeriosis | 2 | 1 | 0 | 3 |
| Lyme neuroborreliosis | 2 | 1 | 0 | 3 |
| Measles | 2 | 1 | 0 | 3 |
| Mumps | 2 | 1 | 0 | 3 |
| Nosocomial infections | 2 | 3 | 2 | 7 |
| Plague | 2 | 0 | 0 | 2 |
| Poliomyelitis | 2 | 0 | 0 | 2 |
| Q fever | 2 | 0 | 0 | 2 |
| Rubella | 2 | 1 | 0 | 3 |
| Salmonellosis | 2 | 0 | 1 | 3 |
| Severe Acute Respiratory Syndrome (SARS) | 2 | 0 | 0 | 2 |
| Shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection | 2 | 0 | 2 | 4 |
| Shigellosis | 2 | 0 | 1 | 3 |
| Tick borne encephalitis | 2 | 0 | 0 | 2 |
| Toxoplasmosis, congenital | 2 | 1 | 0 | 3 |
| Tularaemia | 2 | 0 | 0 | 2 |
| Typhoid and paratyphoid | 2 | 0 | 1 | 3 |
| Viral haemorrhagic fevers | 2 | 0 | 1 | 3 |
| West Nile virus infection | 2 | 1 | 0 | 3 |
| Yersiniosis | 2 | 0 | 1 | 3 |
| Zika virus disease | 2 | 0 | 0 | 2 |

¹ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question; negative responses represent instances in which all survey respondents from a country provided a 'no' answer; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses.

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| Anthrax | 1 | 0 | 1 | 2 |
|---|---|---|---|---|
| Cholera | 1 | 1 | 1 | 3 |
| Giardiasis | 1 | 1 | 2 | 4 |
| Leptospirosis | 1 | 1 | 0 | 2 |
| Pertussis | 1 | 1 | 0 | 2 |
| Rabies | 1 | 0 | 0 | 1 |
| Smallpox | 1 | 0 | 0 | 1 |
| Tetanus | 1 | 1 | 0 | 2 |
| Transmissible spongiform encephalopathies | 1 | 0 | 0 | 1 |
| Trichinellosis | 1 | 0 | 0 | 1 |
| Variant Creutzfeldt–Jakob's disease | 1 | 1 | 1 | 3 |
| Yellow fever | 1 | 0 | 0 | 1 |
| Cryptosporidiosis | 0 | 1 | 4 | 5 |

Table 7 presents the number of countries that POCT is either fully or partially reimbursed through the healthcare system for each infectious disease and associated health issue. The table shows that HIV/AIDS was again the disease or health issue for which most countries (15 countries) provided a positive response. This represents 88% of countries in which POCT for HIV/AIDs is reported to be in routine clinical use, indicating a high likelihood that POCT for this disease will be at least partially reimbursed in EU/EEA Member States and the UK. No country responding to the survey reported that POCT for HIV/AIDS was not reimbursed. Influenza received the second highest number of positive responses, with 13 countries reporting that POCT for influenza is either fully or partially reimbursed, 68% of those countries in which POCT for influenza is reported to be available. There were also three countries reporting that POCT for influenza is not reimbursed. In the case of both legionnaires' disease and malaria, respondents from 11 countries reported that POCT is either fully or partially reimbursed. In both cases, this represented 85% of countries in which POCT was in routine clinical use for those diseases. As can be seen from the table, for several diseases or health issues, survey responses suggest that POCT is fully or partially reimbursed in all countries where it is in routine clinical use. Notable examples of this include syphilis, hepatitis B, hepatitis C, cryptosporidiosis and shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection. Later in this report, we examine what survey responses revealed about the reimbursement of POCT within different EU/EEA Member States and the UK (see Section 5.1)

¹ Here, in order to provide a summary overview of survey responses on reimbursement, we have chosen to collapse fully and partially reimbursed together. For information on differences between full and partial reimbursement across diseases, and across countries, see Section 6 of this report.

Table 7. Number of countries reporting that POCT is either fully or partially reimbursed through the healthcare system, by diseaseⁱ

Survey question: For [name of disease or health issue], how is POCT paid for?

| Survey question: For [name of disease or | nealth issue], now | is POCT paid for: | | |
|--|---|---|---|--|
| Disease | Number of countries reporting that POCT is either fully or partially reimbursed | Number of countries reporting that POCT is not reimbursed | Number of countries for which responses indicated uncertainty | Total number of countries for which responses to this question were received |
| HIV infection and AIDS | 15 | 0 | 2 | 17 |
| Influenza – including influenza A(H1N1) | 13 | 3 | 3 | 19 |
| Legionnaires' disease | 11 | 0 | 2 | 13 |
| Malaria | 11 | 0 | 2 | 13 |
| Syphilis | 8 | 0 | 0 | 8 |
| Chlamydia infections | 7 | 1 | 0 | 8 |
| Hepatitis B | 7 | 0 | 0 | 7 |
| Hepatitis C | 7 | 0 | 0 | 7 |
| Invasive pneumococcal disease | 6 | 0 | 1 | 7 |
| Nosocomial infections | 6 | 0 | 1 | 7 |
| Antimicrobial resistance | 5 | 1 | 1 | 7 |
| Cryptosporidiosis | 5 | 0 | 0 | 5 |
| Tuberculosis | 5 | 1 | 1 | 7 |
| Dengue | 4 | 0 | 1 | 5 |
| Giardiasis | 4 | 0 | 0 | 4 |
| Gonorrhoea | 4 | 0 | 1 | 5 |
| Invasive meningococcal disease | 4 | 0 | 1 | 5 |
| Shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection | 4 | 0 | 0 | 4 |
| Brucellosis | 3 | 0 | 0 | 3 |
| Campylobacteriosis | 3 | 0 | 0 | 3 |
| Cholera | 3 | 0 | 0 | 3 |
| Hepatitis A | 3 | 0 | 0 | 3 |
| Infections with Haemophilus influenzae group B | 3 | 0 | 1 | 4 |
| Listeriosis | 3 | 0 | 0 | 3 |
| Lyme neuroborreliosis | 3 | 0 | 0 | 3 |
| Measles | 3 | 0 | 0 | 3 |
| Mumps | 3 | 0 | 0 | 3 |
| Rubella | 3 | 0 | 0 | 3 |
| Salmonellosis | 3 | 0 | 0 | 3 |
| Shigellosis | 3 | 0 | 0 | 3 |
| Toxoplasmosis, congenital | 3 | 0 | 0 | 3 |
| Typhoid and paratyphoid | 3 | 0 | 0 | 3 |
| Viral haemorrhagic fevers | 3 | 0 | 0 | 3 |
| West Nile virus infection | 3 | 0 | 0 | 3 |
| Yersiniosis | 3 | 0 | 0 | 3 |
| Anthrax | 2 | 0 | 0 | 2 |
| Botulism | 2 | 0 | 0 | 2 |
| Chikungunya virus disease | 2 | 0 | 0 | 2 |
| Diphtheria | 2 | 0 | 0 | 2 |
| Echinococcosis | 2 | 0 | 0 | 2 |
| Pertussis | 2 | 0 | 0 | 2 |
| Plague | 2 | 0 | 0 | 2 |
| Poliomyelitis | 2 | 0 | 0 | 2 |
| | | | | |
| Q fever | 2 | 0 | 0 | 2 |

¹ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question; negative responses represent instances in which all survey respondents from a country provided a 'no' answer; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses.

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| Tularaemia | 2 | 0 | 0 | 2 |
|---|---|---|---|---|
| Zika virus disease | 2 | 0 | 0 | 2 |
| Leptospirosis | 1 | 1 | 0 | 2 |
| Rabies | 1 | 0 | 0 | 1 |
| Smallpox | 1 | 0 | 0 | 1 |
| Tetanus | 1 | 1 | 0 | 2 |
| Transmissible spongiform encephalopathies | 1 | 0 | 0 | 1 |
| Trichinellosis | 1 | 0 | 0 | 1 |
| Variant Creutzfeldt–Jakob's disease | 1 | 0 | 0 | 1 |
| Yellow fever | 1 | 0 | 0 | 1 |

Table 8 presents survey data on the number of countries reporting that POCT is externally quality assessed for each infectious disease and associated health issue. Consistent with the findings for guidelines and reimbursement, the table shows that the disease or health issue for which POCT is most often quality assessed is HIV/AIDS. Overall, however, the number of countries reporting the existence of quality assessment procedures is lower than the number of countries reporting either guidelines or reimbursement mechanisms for HIV/AIDS. Of the 17 countries in which POCT is in routine clinical use for HIV/AIDS, seven reported that POCT is externally quality assessed (41%). Similarly, of the 19 countries reporting that POCT is in routine clinical use for influenza, four of these reported that POCT is externally quality assessed (21%). In addition to HIV/AIDS and influenza, a number of other diseases or health issues have POCT quality assessed in at least three countries, according to the results of the mapping survey. Those fitting this category are antimicrobial resistance; legionnaires' diseases and tuberculosis (for which POCT is quality assessed in at least 4 countries); and hepatitis C; invasive meningococcal disease; invasive pneumococcal disease; and malaria (for which POCT is quality assessed in at least with three countries). It should also be noted, however, that across all diseases there appears to be significant uncertainty surrounding the question of POCT quality assessment. For example, while four countries reported that POCT quality assessment measures are in place for legionnaires' disease, respondents from seven countries (54% of those in which POCT for legionnaires' disease is in use) were unsure on this point.

Table 8. Number of countries reporting that POCT is externally quality assessed, by diseasei

Survey question: To your knowledge, are POCTs for [name of disease or health issue] externally quality assessed?

| Disease | Number of countries reporting that POCT is externally quality assessed | Number of countries reporting that POCT is not externally quality assessed | Number of countries for which responses indicated uncertainty | Total number of countries for which responses to this question were received |
|---|--|---|---|--|
| HIV infection and AIDS | 7 | 3 | 7 | 17 |
| Antimicrobial resistance | 4 | 1 | 2 | 7 |
| Influenza – including influenza A(H1N1) | 4 | 5 | 10 | 19 |
| Legionnaires' disease | 4 | 0 | 9 | 13 |
| Tuberculosis | 4 | 1 | 2 | 7 |
| Hepatitis C | 3 | 1 | 3 | 7 |
| Invasive meningococcal disease | 3 | 0 | 2 | 5 |
| Invasive pneumococcal disease | 3 | 1 | 3 | 7 |
| Malaria | 3 | 3 | 7 | 13 |
| Chlamydia infections | 2 | 1 | 5 | 8 |
| Gonorrhoea | 2 | 0 | 3 | 5 |
| Hepatitis B | 2 | 1 | 4 | 7 |
| Measles | 2 | 0 | 1 | 3 |
| Mumps | 2 | 0 | 1 | 3 |
| Rubella | 2 | 0 | 1 | 3 |
| Syphilis | 2 | 1 | 5 | 8 |
| Anthrax | 1 | 0 | 1 | 2 |
| Brucellosis | 1 | 0 | 2 | 3 |
| Campylobacteriosis | 1 | 0 | 2 | 3 |
| Cryptosporidiosis | 1 | 0 | 4 | 5 |
| Dengue | 1 | 0 | 4 | 5 |
| Diphtheria | 1 | 0 | 1 | 2 |
| Giardiasis | 1 | 0 | 3 | 4 |
| Hepatitis A | 1 | 0 | 2 | 3 |

¹ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question; negative responses represent instances in which all survey respondents from a country provided a 'no' answer; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses.

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| Infections with haemophilus influenzae group B | 1 | 0 | 3 | 4 |
|---|---|---|---|---|
| Listeriosis | 1 | 0 | 2 | 3 |
| Lyme neuroborreliosis | 1 | 0 | 2 | 3 |
| Nosocomial infections | 1 | 1 | 5 | 7 |
| Pertussis | 1 | 0 | 1 | 2 |
| Plague | 1 | 0 | 1 | 2 |
| Poliomyelitis | 1 | 0 | 1 | 2 |
| Q fever | 1 | 0 | 1 | 2 |
| Salmonellosis | 1 | 0 | 2 | 3 |
| Shiga-toxin/verocytotoxin-producing <i>Escherichia coli</i> (STEC/VTEC) infection | 1 | 0 | 3 | 4 |
| Shigellosis | 1 | 0 | 2 | 3 |
| Toxoplasmosis, congenital | 1 | 0 | 2 | 3 |
| Tularaemia | 1 | 0 | 1 | 2 |
| Typhoid and paratyphoid | 1 | 0 | 2 | 3 |
| Viral haemorrhagic fevers | 1 | 1 | 1 | 3 |
| Botulism | 0 | 0 | 2 | 2 |
| Chikungunya virus disease | 0 | 0 | 2 | 2 |
| Cholera | 0 | 0 | 3 | 3 |
| Echinococcosis | 0 | 0 | 2 | 2 |
| Leptospirosis | 0 | 1 | 1 | 2 |
| Rabies | 0 | 0 | 1 | 1 |
| Severe Acute Respiratory Syndrome (SARS) | 0 | 0 | 2 | 2 |
| Smallpox | 0 | 1 | 0 | 1 |
| Tetanus | 0 | 1 | 1 | 2 |
| Tick borne encephalitis | 0 | 0 | 2 | 2 |
| Transmissible spongiform encephalopathies | 0 | 0 | 1 | 1 |
| Trichinellosis | 0 | 0 | 1 | 1 |
| Variant Creutzfeldt–Jakob's disease | 0 | 0 | 1 | 1 |
| West Nile virus infection | 0 | 1 | 2 | 3 |
| Yellow fever | 0 | 0 | 1 | 1 |
| Yersiniosis | 0 | 0 | 3 | 3 |
| Zika virus disease | 0 | 0 | 2 | 2 |

4.3 Impact of POCT on clinical practice

Survey respondents were asked about whether POCT has replaced other tests for screening, triaging or diagnosis of infectious diseases and which tests were previously used for diagnosis. These questions addressed the following research question: to what extent have POCTs replaced traditional testing in the EU/EEA? However, it is important to note that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis (see later in this section for further detail).

Table 9 shows the number of countries reporting that POCT has replaced other tests for the screening, triaging or diagnosis for each infectious disease and associated health issue. As with tables in the previous section, the table has been structured in order of the number of affirmative responses to this question for each disease. The table demonstrates the very low number of cases in which POCT has replaced other forms of test, a finding common across all diseases. Chlamydia infections, HIV/AIDS and legionnaires' disease were the diseases for which most countries reported that POCT has replaced other tests. In all three cases, however, only two countries (different countries in each case) reported that this was the case. In some cases, there is clearly some uncertainty concerning this question of whether or not POCT has replaced other tests. In the case of influenza, for example, respondents from eight countries (42% of countries in which POCT for influenza was reported to be in use) were either unsure or disagreed on this point. In other cases, however, the results appear to provide confirmation that in most countries, POCT has not replaced other tests. For example, of the 17 countries reporting that POCT for HIV/AIDS is in routine use, 13 of these (76%) reported that no such replacement had taken place. Other diseases or health issues for which a high proportion of countries provided a confirmed negative response on replacement include legionnaires' disease, hepatitis B, hepatitis C, invasive pneumococcal disease, syphilis and tuberculosis.

Table 9. Number of countries reporting that POCT has replaced other tests for screening, triaging or diagnosis, by diseaseⁱ

Survey question: For [name of disease or health issue], has POCT replaced a previously used test, e.g. for screening, triaging or diagnosing?

| Disease | Number of countries reporting that POCT has replaced other tests | Number of countries reporting that POCT has not replaced other tests | Number of countries for which responses indicated uncertainty | Total number of countries for which responses to this question were received |
|--|---|---|---|--|
| Chlamydia infections | 2 | 3 | 3 | 8 |
| HIV infection and AIDS | 2 | 13 | 2 | 17 |
| Legionnaires' disease | 2 | 9 | 2 | 13 |
| Antimicrobial resistance | 1 | 3 | 3 | 7 |
| Campylobacteriosis | 1 | 0 | 2 | 3 |
| Cholera | 1 | 0 | 2 | 3 |
| Cryptosporidiosis | 1 | 2 | 2 | 5 |
| Dengue | 1 | 1 | 3 | 5 |
| Giardiasis | 1 | 2 | 1 | 4 |
| Gonorrhoea | 1 | 2 | 2 | 5 |
| Hepatitis B | 1 | 5 | 1 | 7 |
| Hepatitis C | 1 | 5 | 1 | 7 |
| Influenza – including influenza A(H1N1) | 1 | 10 | 8 | 19 |
| Invasive meningococcal disease | 1 | 3 | 1 | 5 |
| Invasive pneumococcal disease | 1 | 5 | 1 | 7 |
| Nosocomial infections | 1 | 2 | 4 | 7 |
| Q fever | 1 | 0 | 1 | 2 |
| Salmonellosis | 1 | 0 | 2 | 3 |
| Shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection | 1 | 2 | 1 | 4 |
| Shigellosis | 1 | 1 | 1 | 3 |
| Tetanus | 1 | 0 | 1 | 2 |
| Typhoid and paratyphoid | 1 | 1 | 1 | 3 |
| Viral haemorrhagic fevers | 1 | 1 | 1 | 3 |
| Yersiniosis | 1 | 1 | 1 | 3 |
| Anthrax | 0 | 1 | 1 | 2 |
| Botulism | 0 | 1 | 1 | 2 |
| Brucellosis | 0 | 1 | 2 | 3 |
| Chikungunya virus disease | 0 | 1 | 1 | 2 |
| Diphtheria | 0 | 1 | 1 | 2 |
| Echinococcosis | 0 | 0 | 2 | 2 |
| Hepatitis A | 0 | 2 | 1 | 3 |
| Infections with Haemophilus influenzae group B | 0 | 1 | 3 | 4 |
| Leptospirosis | 0 | 1 | 1 | 2 |
| Listeriosis | 0 | 2 | 1 | 3 |
| Lyme neuroborreliosis | 0 | 1 | 2 | 3 |
| Malaria | 0 | 7 | 6 | 13 |
| Measles | 0 | 2 | 1 | 3 |
| Mumps | 0 | 2 | 1 | 3 |
| Pertussis | 0 | 1 | 1 | 2 |
| Plague | 0 | 0 | 2 | 2 |
| Poliomyelitis | 0 | 1 | 1 | 2 |
| Rabies | 0 | 0 | 1 | 1 |
| **** | | | | • |

¹ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question; negative responses represent instances in which all survey respondents from a country provided a 'no' answer; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses.

It is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis.

| 0 | 2 | 1 | 3 |
|---|--|---|---|
| 0 | 0 | 2 | 2 |
| 0 | 0 | 1 | 1 |
| 0 | 7 | 1 | 8 |
| 0 | 0 | 2 | 2 |
| 0 | 1 | 2 | 3 |
| 0 | 0 | 1 | 1 |
| 0 | 0 | 1 | 1 |
| 0 | 5 | 2 | 7 |
| 0 | 1 | 1 | 2 |
| 0 | 0 | 1 | 1 |
| 0 | 1 | 2 | 3 |
| 0 | 0 | 1 | 1 |
| 0 | 1 | 1 | 2 |
| | 0 0 0 0 0 0 0 0 0 0 0 0 | 0 2 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 1 0 0 0 1 0 0 0 1 0 0 0 1 0 0 0 1 | 0 2 1 0 0 2 0 0 1 0 7 1 0 0 2 0 1 2 0 0 1 0 0 1 0 5 2 0 1 1 0 0 1 0 0 1 0 0 1 0 0 1 0 0 1 0 1 1 0 1 1 |

The results of this question were cross-analysed with the question exploring whether POCT alone is sufficient for diagnosis (which was asked as a general, rather than disease-specific question). For the 27 infectious diseases or associated health issues in which at least one respondent reported that POCT had replaced another test, only three were reported by respondents to not require further testing to confirm a diagnosis (chlamydia infections, gonorrhoea and influenza). However, for each of these, an equal number or more respondents reported that further testing would be needed for a confirmation of a diagnosis. For the other infectious diseases or associated health issues, respondents reported that further testing would be needed in addition to the POCT to confirm a diagnosis (except for tetanus in which the respondent was unsure whether further testing would be needed). This analysis is based on a small number of respondents and was not asked in relation to each specific infectious disease or associated health issues, and so should be interpreted with care. However, it does indicate that in almost all cases where POCT has replaced an existing test, that further tests would be needed to confirm a diagnosis.

Diagnostic tests replaced by POCT

Where respondents reported that POCT had replaced existing tests for the screening, triaging or diagnosis of an infectious disease or associated health issue, the survey also asked about the specific forms of diagnostic test that had been replaced. Responses to this question provided additional information on the replacement of traditional testing by POCTs within the EU/EEA and the UK.

Evidence on the diagnostic tests that have been replaced by POCT was limited. A major reason for this, of course, was the small number of countries reporting that POCT has replaced existing tests, a finding common across all infectious diseases and health issues (see Section 4.3 above). Nevertheless, in those limited instances where respondents did report that POCT had replaced other tests, most also provided details on the types of test that had been replaced. Table 10 below lists the types of test which respondents reported that POCT had replaced for each disease or health issue.

Table 10. Tests replaced by POCT, by disease

Survey question: Which diagnostic test was used previously?

| Disease | Tests replaced by POCT |
|---|---|
| Anthrax | Bacterial or viral culture; PCR |
| Antimicrobial resistance | Bacterial or viral culture; PCR |
| Campylobacteriosis | Bacterial or viral culture |
| Chlamydia infection | Antigen testing; bacterial or viral culture; microscopy |
| Cholera | Bacterial or viral culture; microscopy |
| Cryptosporidiosis | Microscopy |
| Dengue | Serological testing |
| Giardiasis | Microscopy |
| Gonorrhoea | Bacterial or viral culture; microscopy |
| Hepatitis B | Serological testing |
| Hepatitis C | Serological testing |
| HIV infection and AIDS | Serological testing |
| Influenza – including influenza A(H1N1) | Bacterial or viral culture; PCR |
| Invasive meningococcal disease | Bacterial or viral culture |
| Invasive pneumococcal disease | Bacterial or viral culture |
| | |

| Disease | Tests replaced by POCT |
|--|---|
| Legionnaires' disease | Bacterial or viral culture; serological testing |
| Malaria | Microscopy |
| Nosocomial infections | Bacterial or viral culture; PCR |
| Q fever | Other |
| Salmonellosis | Bacterial or viral culture |
| Shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection | Bacterial or viral culture; antigen testing |
| Shigellosis | Bacterial or viral culture |
| Tetanus | Serological testing |
| Tuberculosis | Bacterial or viral culture; microscopy |
| Tularaemia | Bacterial or viral culture |
| Typhoid and paratyphoid | Bacterial or viral culture |
| Viral haemorrhagic fevers | Other |
| Yersiniosis | Bacterial or viral culture |

As can be seen from the table, according to survey respondents, the form of test most replaced by POCT is bacterial or viral culture. Across 18 different diseases or health conditions, at least one respondent reported that bacterial or viral culture had been replaced by POCT. Other tests which respondents reported had been replaced by POCT were PCR, serological testing, microscopy and antigen testing. For two diseases (Q fever and viral haemorrhagic fevers), a survey respondent selected 'other' and reported that, prior to POCT, diagnostic testing was performed abroad.

5 Survey results by country

In the previous section, we analysed survey responses to questions concerning POCT availability, use, guidelines, reimbursement, quality assessment in EU/EEA Member States and the UK. In doing so, we examined the way in which the use and impact of POCT differ across different diseases. In this section, we analyse the same core questions with a view to understanding difference in POCT use and impact across countries. In the first section, we use the survey results to analyse which countries use POCT most commonly for infectious diseases or associated health issues. From here, mirroring the structure of the previous section, we analyse survey responses to questions concerning the availability of official guidelines and documentation, the reimbursement procedures in place for POCT, and the extent to which POCT is externally quality assessed, this time on a country-by-country basis. The section then analyses the responses to questions concerning the extent to which POCT for specific diseases has replaced other diagnostic tests for screening, triaging or diagnosis. In the section's final section, we analyse the study findings concerning the way in which POCT results are used in public health functions related to infectious disease within EU/EEA Member States and the UK, including surveillance, outbreak investigation and infection control. Here, we draw upon responses to country level questions about the public health uses of POCT-derived results posed within the mapping survey.

5.1 POCT availability and use in routine clinical practice

The study team examined the number of diseases for which each country reported that POCT is available. This analysis directly addresses the research question: What are the differences between the use of POCTs in EU/EEA Member States and the UK? According to the findings of the mapping survey, the country with POCT in use for the highest number of infectious diseases or associated health issues is France (55), closely followed by Norway (48). In Cyprus and Spain, survey respondents reported that POCT is in routine clinical use for 25 diseases. In Denmark, POCT was reported to be available for seven diseases. Eight other countries reported that POCT was available for at least five diseases or health issues: Austria; Germany; Greece; Sweden; Croatia; Malta; Estonia; and the Netherlands.

Table 11 below provides the number of diseases or health issues for which POCT was reported to be in routine clinical use in each country. The table only includes those countries for which the mapping survey provided evidence that POCT is available for at least one disease or health issue.ⁱⁱ

ⁱ This second question, though partly addressed in this section, is also addressed in more detail in the next section, where the results of the survey are analysed on a country-by-country basis.

ⁱⁱ While this table presents survey data only, follow-up interviews provided evidence regarding the use of POCT in three additional countries: Czechia, Lithania and Portugal. Information on the diseases for which POCT is available in those countries can be found in Section 6 of this report.

Table 11. Number of diseases or related health issues for which POCT is available, by countryi

Survey question: For which diseases or other health-related issue are you aware that POCT is routinely used in clinical practice in your country?

| Country | Number of diseases |
|----------------|--------------------|
| France | 55 |
| Norway | 48 |
| Cyprus | 25 |
| Spain | 25 |
| Denmark | 9 |
| Austria | 7 |
| Germany | 7 |
| Greece | 7 |
| Sweden | 7 |
| Croatia | 6 |
| Malta | 6 |
| Estonia | 5 |
| Netherlands | 5 |
| Belgium | 4 |
| Finland | 4 |
| Latvia | 4 |
| Romania | 4 |
| Slovenia | 4 |
| United Kingdom | 3 |
| Bulgaria | 2 |
| Ireland | 2 |
| Slovakia | 2 |
| Poland | 1 |
| Iceland | 1 |

The results in the above table should be treated with some caution. In both France and Norway, for example, the high number of diseases for which POCT was reported to be available reflected, in large part, the response of a single survey respondent who selected nearly every listed disease as having POCT used in routine clinical practice. The considerable difference between the number of POCT use diseases reported in these two countries and the number reported elsewhere may reflect differences in the respondents' interpretation of what constitutes POCT (despite the definition given within the survey), rather than an accurate representation of the state of POCT in those countries."

Figure 3 below provides a graphical representation of the diseases for which respondents from each country reported that POCT is available. The figure can be used to easily identify which diseases are covered by POCT in which country, according the results of the mapping survey. Taking gonorrhoea as an example, the figure shows five coloured tabs indicating that, according to the results of the mapping survey, POCT is available for gonorrhoea in five EU/EEA Member States and the UK. Cross-referencing of the colour tabs against the figure legend reveals that the five countries in question are: Cyprus, France, Malta, Norway, Spain.

In Annex 6 to this report, these same data are presented in the form of a mapping table.

¹ Diseases in this table are those for which at least one survey respondent from the country reported that POCT is in routine clinical use.

^{II} The survey specified that the ISO definition of POCT (ISO 22870:2016) was to be used. Accessible at: https://www.iso.org/obp/ui/#iso:std:iso:22870:ed-2:v1:en

iii The figure does not include data on those countries for which no survey response was received, or for those cases where a survey respondent reported that POCT is not used for any infectious disease of health issue. Data gathered on the state of POCT in three other countries, Czechia, Lithuania and Portugal, acquired through follow-up interviews, is reported on in Section 6 of this report.

Influenza – including influenza A(H1N1) – HIV infection and AIDS – Malaria – Legionnaires' disease – Legionnaires' disease Syphilis -Chlamydia infections -Tuberculosis Nosocomial infectio Invasive pneumococcal disease Hepatitis C Hepatitis B Antimicrobial resistance Invasive meningococcal disease Gonorrhoed Dengue Cryptosportidiosis Shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection Infections with haemophilus influenzae group B Yersiniosis — Yersiniosis — Viral haemorrhagic fevers — Typhoid and paratyphoid — Toxoplasmosis, congenital — Shigellosis — Salmonellosis — Salmonellosis — Yersiniosis nonellosis = Rubella = Mumps = Measles = Orreliosis = Listeriosis = Nonellosis = Nonellosi = Nonellosis = Nonellosis = Nonellosis = Nonellosis = Nonellosi = Nonellosis = Nonellosis = Nonellosis = Nonellosis = Nonellosi = Nonellosis = Nonellosis = Nonellosis = Nonellosis = Nonellosi = N ne neuroborreliosis Listeriosis Hepatitis A Cholera Listeriosis
Hepatitis A —
Cholera
Campylobacteriosis
Brucellosis
Zika virus disease
Tularaemia
k borne encephalitis
Tetanus Severe Acute Respiratory Syndrome (SARS)
Q fever Q fever Policy Plague Pertussis Leptospirosis Chinococcosis Diphtheria virus disease Botulism Leptospirosis Echinococcosis Diphtheria Chikungunya virus disease Botulism Anthrax Yellow fever Variant Creutzfeldt–Jakob's disease Trichinellosis

Transmissible spongiform encephalopathies

Smallpox 10 15 Count Slovenia Denmark Greece Netherland: Iceland Estonia Belaium Norway Spain Finland Ireland Country Bulgaria Poland United Kingdom Croatia France Latvia Romania Cyprus

Figure 3. Availability of POCT for infectious diseases and associated health conditions in EU/EEA Member States and the UK

5.2 POCT guidelines, funding and quality assessment

As noted above (see Section 4.2), survey respondents were also asked about the following areas: the availability of POCT recommendations and guidelines at the national level; how POCT is reimbursed within the healthcare system; and how POCT is externally quality assessed. These questions address the following research question: For which of the 56 infectious diseases and related health issues do recommendations/guidelines/patient care pathways issued by national authorities, learned societies or other recognised national bodies for the use of POCT exist in the EU/EEA Member States and the UK, and for which infectious diseases and related health issues are POCT reimbursed? In this section, we analyse responses to these questions on a country-by-country basis.

Tables 12-15 present information on the number of diseases for which each country reported that guidelines, reimbursement and quality assessment are available for POCT, as well as the number of diseases for which each country reported that POCT has replaced other diagnostic tests. In all cases, the tables group diseases into one of three categories: positive, negative or uncertain. Positive responses represent instances in which all survey respondents from a country provided a 'yes' answer for the disease. Negative responses represent instances in which all survey respondents from a country provided a 'no' answer for the disease. 'Uncertain' responses

indicate where survey respondents were either all unsure or provided mixed responses for the disease. In using these tables, it should be noted that the grouping of a disease into one of the three aforementioned categories will, in some cases, be based on the answers provided by only one survey respondent. At the same time, it should also be noted that a disease for which several respondents from a country provided either positive or negative responses, will nevertheless be grouped as uncertain where one respondent from the same country provided an unsure or contradictory response.

Table 12 shows the number of diseases or health issues for which guidelines or similar documentation were reported to be available in each country. The table (and all subsequent tables in this section) has been structured by the number of diseases for which this question was answered affirmatively in each country. The countries in which the highest number of diseases have guidelines in place covering POCT for infectious diseases, according to the mapping survey, are France and Norway, with 50 and 47 diseases reported to be covered by guidelines respectively (91% and 96% of diseases for which POCT was reported to be in clinical use). Again, these results should be treated with caution, given their high reliance on the responses of single individuals. Beyond these two countries, other countries in which respondents reported availability of POCT-related guidelines across multiple diseases or health issues were Spain, with seven diseases, representing 28% of the diseases for which POCT was reported to be in routine clinical use, and Cyprus, with four diseases, representing 15% of the diseases for which POCT was reported to be in routine clinical use. In Finland, survey respondents indicated that guidelines were available for all four diseases for which POCT was reported to be in use. Other countries reporting a 100% coverage by guidelines were: Ireland (with one diseases); Slovakia (with two diseases); and Poland (one disease). Conversely, countries in which none of the POCT-covered diseases had guidelines in place were Austria, Iceland, Latvia, Malta and Romania.

Table 12. Number of diseases or related health issues for which guidelines, recommendations, patient care pathways and other official documentations available, by countryⁱⁱ

Survey question: For [name of disease or health issue], are official guidelines, recommendations, patient care pathways or other official documents available for practitioners to use?

| Country | Number of diseases for which guidelines or other official documentation are available | Number of diseases for which guidelines or other official documentation are not available | Number of diseases for which responses indicated uncertainty | Total number of diseases for which responses to this question were received |
|----------------|---|---|--|---|
| France | 50 | 0 | 5 | 55 |
| Norway | 47 | 1 | 1 | 49 |
| Spain | 7 | 2 | 16 | 25 |
| Cyprus | 4 | 22 | 0 | 26 |
| Finland | 4 | 0 | 0 | 4 |
| Denmark | 3 | 1 | 0 | 4 |
| Slovenia | 3 | 1 | 0 | 4 |
| Ireland | 2 | 0 | 0 | 2 |
| Slovakia | 2 | 0 | 0 | 2 |
| United Kingdom | 2 | 0 | 1 | 3 |
| Croatia | 1 | 0 | 5 | 6 |
| Estonia | 1 | 0 | 4 | 5 |
| Germany | 1 | 0 | 6 | 7 |
| Netherlands | 1 | 3 | 1 | 5 |
| Poland | 1 | 0 | 0 | 1 |
| Austria | 0 | 0 | 7 | 7 |
| Belgium | 0 | 3 | 1 | 4 |
| Bulgaria | 0 | 1 | 1 | 2 |
| Greece | 0 | 5 | 2 | 7 |
| Iceland | 0 | 1 | 0 | 1 |
| Latvia | 0 | 4 | 0 | 4 |
| Liechtenstein | 0 | 0 | 0 | 0 |

ⁱ In both cases, however, respondents also provided links to official guidelines in most of the instances where they reported guidelines to be available.

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ⁱⁱ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question for the disease; negative responses represent instances in which all survey respondents from a country provided a 'no' answer for the disease; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses for a disease.

| Lithuania | 0 | 0 | 0 | 0 |
|-----------|---|---|---|---|
| Malta | 0 | 6 | 0 | 6 |
| Romania | 0 | 4 | 0 | 4 |
| Sweden | 0 | 1 | 4 | 5 |

Table 13 shows the number of diseases or associated health issues for which POCT is either fully or partially reimbursed through the healthcare system in each country, according to the results of the mapping survey. On the whole, the table suggests a strong tendency for POCT for infectious diseases to be either fully or partially reimbursed in EU/EEA Member States and the UK. In many countries, including France, Cyprus, Austria, Croatia, Malta, Sweden, Romania, Slovenia, the United Kingdom, Ireland and Slovakia, survey respondents reported that in all instances where POCT was in routine clinical use for a disease or health issue, POCT was either fully or partially reimbursed through the healthcare system. In many other countries, survey respondents reported that POCT was reimbursed for a high proportion of the diseases for which it was available, but there was uncertainty or disagreement regarding a small number of other diseases. There were only six countries in which respondents reported that a POCT was not reimbursed. These countries were Finland, Latvia, Netherlands, Belgium, Bulgaria and Iceland.

Table 13. Number of diseases or related health issues for which POCT is either fully or partially reimbursed, by countryⁱ

Survey guestion: For [name of disease or health issue], how is POCT paid for?

| Country | Number of diseases for which POCT is either fully or partially reimbursed | Number of diseases for which POCT is not reimbursed | Number of diseases for which responses indicated uncertainty | Total number of diseases for which responses to this question were received |
|----------------|--|---|---|--|
| France | 54 | 0 | 0 | 54 |
| Norway | 47 | 0 | 0 | 47 |
| Cyprus | 25 | 0 | 0 | 25 |
| Spain | 20 | 0 | 5 | 25 |
| Austria | 7 | 0 | 0 | 7 |
| Croatia | 6 | 0 | 0 | 6 |
| Malta | 6 | 0 | 0 | 6 |
| Sweden | 5 | 0 | 0 | 5 |
| Estonia | 4 | 0 | 1 | 5 |
| Greece | 4 | 0 | 3 | 7 |
| Romania | 4 | 0 | 0 | 4 |
| Slovenia | 4 | 0 | 0 | 4 |
| Denmark | 3 | 0 | 1 | 4 |
| Finland | 3 | 1 | 0 | 4 |
| Latvia | 3 | 1 | 0 | 4 |
| Netherlands | 3 | 2 | 0 | 5 |
| United Kingdom | 3 | 0 | 0 | 3 |
| Germany | 2 | 0 | 5 | 7 |
| Ireland | 2 | 0 | 0 | 2 |
| Slovakia | 2 | 0 | 0 | 2 |
| Belgium | 1 | 2 | 1 | 4 |
| Bulgaria | 1 | 1 | 0 | 2 |
| Iceland | 0 | 1 | 0 | 1 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 1 | 1 |

Table 14 presents data on the number of infectious diseases or associated health issues for which POCT is externally quality assessed in each country, according to the results of the mapping survey. The table shows that the countries in which the most quality assessment of POCT takes place externally, according to the mapping

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¹ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question for the disease; negative responses represent instances in which all survey respondents from a country provided a 'no' answer for the disease; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses for a disease.

survey, are Norway (29 diseases, representing 60% of diseases for which POCT was reported to be in routine clinical use) and Cyprus (23 diseases, representing 92% of diseases for which POCT was reported to be in routine clinical use). In the Netherlands and Finland, survey respondents reported that POCT is quality assessed across five and four diseases, respectively. In both cases, this suggests that POCT is quality assessed across all diseases for which it is in routine use in those countries. In some countries, respondents demonstrated a high degree of uncertainty concerning whether or not POCT is quality assessed. In Spain, for example, responses indicated uncertainty for 24 of the 25 diseases (96%) for which POCT was reported to be in use. In France, meanwhile, responses indicated uncertainty for all 55 diseases for which POCT was reported to be in use. It is also notable that in some countries, POCT does not seem to be quality assessed for any of the diseases or health issues for which it is available. Examples of this include Iceland, Ireland, Romania and Slovakia. In Greece, survey respondents reported that POCT was not quality assessed for five of the seven diseases for which it is in use, and were uncertain regarding the other two.

Table 14. Number of diseases or related health issues for which POCT is externally quality assessed, by countryⁱ

Survey question: To your knowledge, are POCTs for [name of disease or health issue] externally quality assessed?

| Country | Number of diseases for which POCT is externally quality assessed | Number of diseases for which POCT is not externally quality assessed | Number of diseases for which responses indicated uncertainty | Total number of diseases for which responses to this question were received |
|----------------|---|---|--|---|
| Norway | 29 | 1 | 18 | 48 |
| Cyprus | 23 | 2 | 0 | 25 |
| Netherlands | 5 | 0 | 0 | 5 |
| Finland | 4 | 0 | 0 | 4 |
| Estonia | 2 | 0 | 3 | 5 |
| Latvia | 2 | 2 | 0 | 4 |
| Slovenia | 2 | 1 | 1 | 4 |
| Sweden | 2 | 0 | 3 | 5 |
| Belgium | 1 | 2 | 1 | 4 |
| Malta | 1 | 0 | 5 | 6 |
| Spain | 1 | 0 | 24 | 25 |
| Austria | 0 | 0 | 7 | 7 |
| Bulgaria | 0 | 1 | 1 | 2 |
| Croatia | 0 | 0 | 6 | 6 |
| Denmark | 0 | 1 | 3 | 4 |
| France | 0 | 0 | 55 | 55 |
| Germany | 0 | 0 | 7 | 7 |
| Greece | 0 | 5 | 2 | 7 |
| Iceland | 0 | 1 | 0 | 1 |
| Ireland | 0 | 2 | 0 | 2 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 1 | 1 |
| Romania | 0 | 4 | 0 | 4 |
| Slovakia | 0 | 2 | 0 | 2 |
| United Kingdom | 0 | 0 | 3 | 3 |

i

¹ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question for the disease; negative responses represent instances in which all survey respondents from a country provided a 'no' answer for the disease; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses for a disease.

5.3 Impact of POCT on clinical practice

This section reports on survey findings concerning the question of whether POCT has replaced other tests for screening, triaging or diagnosis of infectious diseases, and more specifically how this varies between countries. It also reports on country-by-country responses to the question of whether POCT is sufficient to make final diagnoses for infectious diseases.

Table 15 provides data on the number of diseases for which POCT has replaced existing tests in each country. Broadly, the results mirror those of Table 9 in highlighting the low number of instances in which POCT has replaced other forms of test. According to survey data, the country in which POCT has had the most significant clinical impact, in terms of replacement, is Spain, where respondents reported that POCT had replaced existing tests across 14 diseases and health issues. Notably, only eight countries reported that POCT has replaced other tests for at least one infectious disease or health condition. In addition to Spain, these were Slovenia, Austria, Cyprus, Norway, Belgium, Denmark and Sweden. In Cyprus, survey respondents indicated a high level of certainty that POCT has not replaced existing tests across many diseases and health issues (92% of diseases for which POCT is available). Other countries in which respondents confirmed that a high proportion of diseases were still tested by non-POCT tests included Austria, Sweden, Norway, Bulgaria, Croatia, Estonia and Finland. Notably, in France, responses demonstrated uncertainty concerning whether or not POCT has replaced existing tests across all diseases and health issues for which POCT was said to be in routine use. However, it is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis, as described earlier.

Table 15. Number of diseases or related health issues for which POCT has replaced other tests for screening, triaging or diagnosis, by countryⁱ

Survey question: For [name of disease or health issue], has POCT replaced a previously used test, e.g. for screening, triaging or diagnosing?

| Country | Number of diseases for which POCT has replaced other tests | Number of diseases for which POCT has not replaced other tests | Number of diseases for which responses indicated uncertainty | Total number of diseases for which responses to this question were received |
|---------------|--|---|--|---|
| Spain | 14 | 6 | 5 | 25 |
| Slovenia | 4 | 0 | 0 | 4 |
| Austria | 2 | 5 | 0 | 7 |
| Cyprus | 2 | 23 | 0 | 25 |
| Norway | 2 | 28 | 18 | 48 |
| Belgium | 1 | 2 | 1 | 4 |
| Denmark | 1 | 1 | 2 | 4 |
| Sweden | 1 | 3 | 1 | 5 |
| Bulgaria | 0 | 2 | 0 | 2 |
| Croatia | 0 | 6 | 0 | 6 |
| Estonia | 0 | 4 | 1 | 5 |
| Finland | 0 | 3 | 1 | 4 |
| France | 0 | 0 | 55 | 55 |
| Germany | 0 | 0 | 7 | 7 |
| Greece | 0 | 3 | 4 | 7 |
| Iceland | 0 | 1 | 0 | 1 |
| Ireland | 0 | 2 | 0 | 2 |
| Latvia | 0 | 4 | 0 | 4 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 6 | 0 | 6 |
| Netherlands | 0 | 5 | 0 | 5 |

¹ In this table, positive responses represent instances in which all survey respondents from a country provided a 'yes' answer to the question for the disease; negative responses represent instances in which all survey respondents from a country provided a 'no' answer for the disease; 'uncertain' responses indicate where survey respondents were either all unsure or provided mixed responses for a disease.

It is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis.

29

| Poland | 0 | 1 | 0 | 1 |
|----------------|---|---|---|---|
| Romania | 0 | 4 | 0 | 4 |
| Slovakia | 0 | 2 | 0 | 2 |
| United Kingdom | 0 | 3 | 0 | 3 |

POCT and sufficiency for diagnosis

Survey respondents were asked whether the results obtained through a POCT device were sufficient to make a final diagnosis for any of the infectious diseases for which they had listed POCT as being in routine clinical use. Responses to this question provided additional, country-level evidence on the extent to which POCTs used in routine clinical practice have replaced traditional testing in the EU/EEA.

Overall, responses to this question indicated a low likelihood that POCT results are sufficient to make a final diagnosis of infectious diseases or associated health issues. In 11 countries, all respondents answering this question reported that across all infectious diseases, further tests are needed, in addition to POCT results, in order to confirm diagnosis. The countries in this category were: Croatia; Lichtenstein; Iceland; Malta; Finland; Slovenia; Spain; France; Latvia; Slovakia; and Austria. In two countries (Bulgaria and Cyprus), respondents only provided positive responses to this question. In both cases this was based on only one respondent from the country.

It is notable that there was considerable uncertainty on this question, with 12 countries providing survey responses of either unsure or mixed responses. In three countries (Sweden, Denmark and Greece), for example, separate survey respondents provided answers of 'yes', 'no' and 'unsure' to the question of whether POCT is sufficient for final diagnosis of any infectious disease. In five of the countries where responses suggested uncertainty (Netherlands, Romania, United Kingdom, Norway, Ireland), responses comprised a mixture of negative and unsure responses, thereby suggesting that POCT is unlikely to be used for final diagnosis of any infectious diseases in those countries.

POCT and public health key functions

Survey respondents were asked about how POCT results are used in their country for the purposes of public health key functions, for example in disease surveillance, national surveillance, outbreak investigation, infection control, antibiotic resistance monitoring, nosocomial infection monitoring, national reporting of infectious diseases and other purposes. These questions, developed in consultation with ECDC, addressed the following research question: What are the effects of POCT use on reporting of test results and on public health key functions like outbreak detection, surveillance and response?

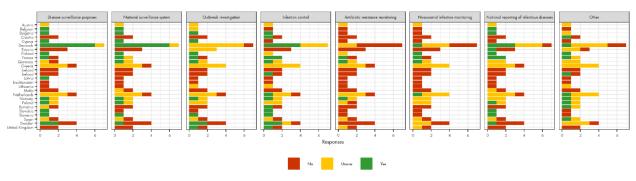
Table 16 provides an overview of the number of countries that reported that POCT-derived results are used in different public health functions. For all the public health functions listed, countries were more likely to report that POCT-derived results were not used rather than used. However, it is also clear that there was considerable uncertainty about the role of POCT across all of these public health functions. Disease surveillance is the public health key function which most countries (seven) reported POCT-derived results being used for. Respondents from six countries reported that POCT results are used for national reporting of infectious disease surveillance, while five countries reported that POCT results are used in national surveillance systems. Notably, no countries reported that POCT-derived results are used for antibiotic resistance monitoring.

Table 16. POCT impact on public health functions, by countryi

| Survey question | Yes | No | Uncertainty | Total number of countries for which answers to this question were provided |
|---|-----|----|-------------|--|
| Are POCT-derived results used in your country for disease surveillance purposes? | 7 | 8 | 11 | 26 |
| Are POCT-derived results used in your country for national reporting of infectious diseases? | 6 | 9 | 11 | 26 |
| Are POCT-derived results fed into the national surveillance system in your country? | 5 | 10 | 11 | 26 |
| Are POCT-derived results used in your country for outbreak investigation? | 4 | 8 | 14 | 26 |
| Are POCT-derived results used in your country for infection control? | 4 | 7 | 15 | 26 |
| Are POCT-derived results used in your country for nosocomial infection monitoring? | 1 | 14 | 11 | 26 |
| Are POCT-derived results used in your country for other purposes besides the ones listed above? | 1 | 9 | 16 | 26 |
| Are POCT-derived results used in your country for antibiotic resistance monitoring? | 0 | 15 | 11 | 26 |

Due to the limited number of responses from any given country, building a clear picture of POCT use for public health functions within each EU/EEA country is not yet possible. In Table 16, countries included in the 'yes' column were those in which there was full agreement between respondents from the same country that POCT-derived results are used for this purpose. As shown in Figure 4 below, however, this may reflect a situation in which only one survey respondent has provided an answer to the question. By indicating country responses to the public health question by respondent, Figure 4 helps to identify areas where there were more respondents within a country, and therefore where there may be better clues to the actual situation on the ground. It also shows how countries where a unanimous positive response to a question was not provided by respondents, may nevertheless in practice likely be using POCT for the health function in question. The best example of this is Denmark, where it seems likely, despite the lack of unanimity from survey respondents, that POCT is used for both disease surveillance and for national surveillance systems.

Figure 4. POCT use for public health functions by country



¹ In this table, the yes column provides the number of countries in which all survey respondents from the same country provided a positive answer to the question; the no column provides the number of countries in which all survey respondents from a country provided a negative answer; and the uncertainty column provides the number of countries in which survey respondents were either all unsure or provided mixed responses.

6 Analysis of focus infectious diseases

In this section, we analyse the study findings on the uses and impact of POCT in relation to 11 focus infectious diseases. In the first section, we explain the rationale for conducting a more focused analysis on a limited number of diseases and provide more detail on the methodology used to select focus diseases. We also provide an explanation of the 'inferential heatmaps' used throughout the section to present key findings for each disease. From this point, the section proceeds to analyse each of the 11 focus diseases in turn. In each case, we analyse the study findings for the number of countries that report POCT is in routine clinical use, as well as the broader questions surrounding POCT, including the availability of guidelines, reimbursement, replacement of other diagnostic tests and quality assessment. Distinct from other sections of the mapping report, this section combines the findings of the mapping survey with the findings of follow-up interviews and desk-based research conducted by the study team.

6.1 Selection of focus diseases

The decision to include a section focusing on a select number of diseases was taken during the initial data analysis phase of the mapping exercise (see Sections 2.4 and 2.5 for the rationale for this approach).

In deciding to focus on selected diseases, the study team faced the question of how to choose which diseases to prioritise. One option was to focus only on those diseases for which the most mapping survey respondents indicated that POCT was available. In consultation with expert advisers, however, the study team chose to use a more comprehensive approach to the identification of focus diseases, one that drew not just on the preliminary findings of the mapping study but also on other sources, including disease prevalence data.

The starting point for this selection process was a basic quantitative assessment of the results of both our scoping reviewⁱ and our mapping survey. For the mapping survey, we assessed the number of countries that that had reported that POCT was in use for each disease. For the scoping review results, we assessed the number of times POCT had been applied to each disease within the studies reviewed. The results gave us an indication of the diseases for which the use of POCT is likely to be most prominent within the EU/EEA region, as determined by the two research methods. For both sets of results, we shortlisted the top 12 diseases for further consideration in our selection process.ii

In addition to the scoping and mapping results, our selection process also incorporated a broader assessment of which infectious diseases are most prevalent in the EU/EEA context.iii For this purpose, we consulted data contained within ECDC's Surveillance Atlas of Infectious Diseases. iv Specifically, we examined ECDC Surveillance Atlas data on both age-adjusted rates and number of reported cases for each disease. Year both data sets, we again shortlisted the top 12 diseases for further consideration.vi

Using the above four shortlists (scoping review data; mapping review data; ECDC Surveillance Atlas age-adjusted rate data; ECDC Surveillance Atlas case number data, all of which are reproduced in Annex 5 to this report), the disease selection process comprised the following steps. Firstly, diseases that appeared in either the scoping or mapping shortlists and either of the ECDC Atlas data shortlists were selected. This step ensured the inclusion of diseases for which there is clear evidence regarding both prevalence and the availability of POCT. Secondly, any diseases which appeared in both the scoping and mapping shortlists were also selected. The rationale for this step was that the results of the scoping and the mapping reviews provide relatively strong evidence that POCT exists for these diseases. It was the judgement of the study team that such diseases were more suitable for

¹ The scoping review, undertaken for ECDC alongside this mapping exercise, aims to provide an overview of the literature available on the availability and use of POCT covering the 56 communicable diseases and related health issues currently under FU surveillance

ii The decision to shortlist 12 diseases was based on the results of the basic quantitative analysis of the mapping exercise and scoping reviews; more specifically, an observed drop-off in both the number of references to diseases within the scoping literature and the number of countries reporting POCT availability after the first 12 diseases.

iii Prevalence is not the only way to analyse the threat posed by infectious diseases. 'Incidence', being the spread of a disease within a specific time period, would be another approach. For this study, the study team decided to use prevalence due to both the greater availability of data in this area and the fact that some of the diseases or associated health conditions included in this study have endemic characteristics, rather than high incidence.

iv Available at: https://www.ecdc.europa.eu/en/surveillance-atlas-infectious-diseases

v In both cases, we used data for the year 2018 where this was available, or 2017 where it was not. For 'number of cases', we used data on 'confirmed' reported cases where this was available, and 'all' reported cases where it was not. It should be noted that the two ECDC Atlas datasets contained some gaps, more details on which can be found in Annex 5 to this report.

vi It is also to be noted that ECDC Atlas data reports microbiological data rather than syndromic surveillance.

further analysis than those for which ECDC data showed high prevalence, but for which there is little evidence that POCT is being used.i

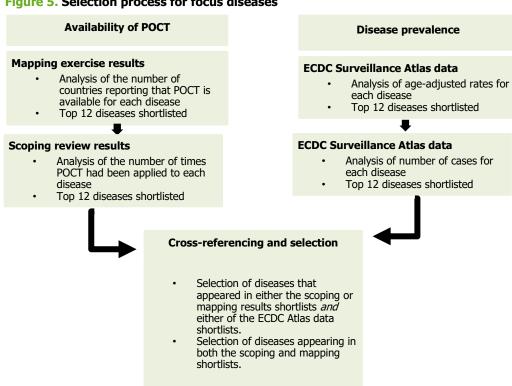
In some cases, owing to differences in the way in which ECDC records prevalence data for certain diseases, we found that the two ECDC datasets (age-adjusted rates and number of cases) did not contain data for diseases which have a high prevalence within the EU/EEA. The second step in the selection process (i.e of including diseases that appeared in both mapping exercise and scoping review shortlists) helped to ensure the inclusion of two diseases fitting this description: influenza and chlamydia infections. Overall, the two steps described above gave us a list of 11 infectious diseases for further in-depth analysis. The selected focus diseases are listed in Table 17 below.

Figure 5, we present a flow diagram outlining the selection process for focus diseases.

Table 17. Selected focus diseases

| Disease | |
|--|--|
| Chlamydia infections | |
| Cryptosporidiosis | |
| Gonorrhoea | |
| lepatitis B | |
| lepatitis C | |
| IIV infection and AIDS | |
| nfluenza – including influenza A(H1N1) | |
| nvasive pneumococcal disease | |
| Malaria Malaria | |
| Syphilis | |
| uberculosis | |

Figure 5. Selection process for focus diseases



i Four diseases – campylobacteriosis, salmonellosis, giardiasis and hepatitis A – appeared in both the ECDC Atlas data shortlists but did not appear in either the scoping or mapping shortlists. It also worth noting that three diseases - nosocomial infections, legionnaires' disease and group A streptococcus – appeared in one of the scoping and mapping shortlists, but in neither of the ECDC Surveillance Atlas data shortlists.

6.2 Data sources for focus disease analysis

As noted above, the prioritisation of a select number of diseases provided focus for the study team's follow-up research. Follow-up interviews and desk-based research focused on filling evidence gaps in the survey data – both in terms of countries and in terms of unanswered research questions – in relation to the selected focus diseases (see Section 2.5 above). In analysing the study findings for each of the 11 focus diseases, this section of the report draws on a combination of all three data sources (mapping survey, interviews and desk-based research). In this respect, it is distinct from other sections, which report on mapping survey findings alone.

6.3 Inferential heatmaps

In analysing the study findings in relation to each focus disease, this section uses 'heatmaps' to visualise the data gathered by the study. Heatmaps combine a tabular format with colour coded cells to indicate the nature of a study finding in relation to a specific field. In the hypothetical example presented in Figure 6 below, a green square under 'Reimbursement' indicates a study finding that POCT is either fully or partially reimbursed in Country X, while a red cell under 'Replacement' indicates that POCT has not replaced other diagnostic tests. Yellow cells for 'Quality assessment' and 'Guidelines' indicate uncertainty in the study findings for these areas.

Figure 6. Example heatmap

| | Quality assessment | Reimbursement | Replacement | Guidelines |
|-----------|--------------------|---------------|-------------|------------|
| Country X | | | | |

Heatmaps have been used in other sections of this report (see Annex 7) to provide a visual representation of the basic findings of the mapping survey. The heatmaps presented in this section, however, are unique from those presented in other sections of the report as they adopt an inferential approach to the colour coding of study findings. Rather than presenting findings in a three-tier colour code – i.e. green for 'yes'; red for 'no'; yellow for 'uncertainty or mixed/evidence' – as is done elsewhere, the inferential heatmaps presented here go further in separating findings, where possible, into two further colour codes. The first of these colour codes, indicated by a light green cell, shows where the evidence, though inconclusive, was suggestive of a positive finding. The second of the additional colour codes, indicated by a light red cell, shows where evidence, though inconclusive, was suggestive of negative finding.

In using this inferential approach, we have adopted a systematic approach towards the five different levels of colour coding. In Figure 7 below, the properties of each colour code are described.

Figure 7. Assumptions underpinning classification for inferential heatmaps

| Positive finding | All survey respondents from the same country who answered the question provided a positive response; or Interviewee who answered this question provided a clear positive response. |
|--|--|
| Negative finding | All survey respondents from the same country who answered the question provided a negative response; or Interviewee who answered this question provided a clear negative response. |
| Mixed or unclear finding | Survey respondents from the same country who answered the question were either all 'unsure' or directly contradicted each other in their responses, with at least one reporting 'yes' and at least one reporting 'no'. Desk-based research yielded either no information or tangential information only, with no clarification provided; or Interviewee who answered this question was unsure |
| Mixed evidence suggesting positive finding | Of survey respondents answering this question from the same country, at least one reported 'yes' and was not directly contradicted by others, e.g. all other respondents were 'unsure'; or Survey responses provided mixed or unclear findings, but follow-up desk-research provided information that suggested positive finding. |
| Mixed evidence suggesting negative finding | Of survey respondents answering this question from the same country, at least one reported 'no' and was not directly contradicted by others, e.g. all other respondents were 'unsure'. Field not applicable to interviewees. Survey responses provided mixed or unclear findings, but follow-up desk-research provided information that suggested negative finding. |

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¹ It is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis.

6.4 Chlamydia infections

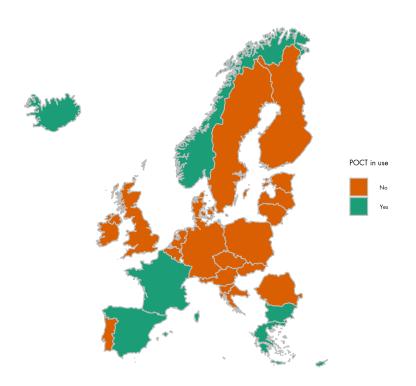
6.4.1 Overview

Chlamydia infection was identified as one of the focus diseases for this study. Chlamydia appeared in the shortlists of most referenced diseases within both the scoping review and mapping survey. Chlamydia infections also have a high prevalence compared with other infectious diseases in Europe. A summary of the mapping exercise findings with respect to POCT for chlamydia infections is below:

- POCT is in routine clinical use for chlamydia infections in at least eight EU/EEA Member States and the UK;
- Three of these countries have official guidelines covering use of POCT for chlamydia infections;
- In seven countries where it is in routine clinical use, POCT for chlamydia infections is either fully or partially reimbursed through the healthcare system;
- In two countries where it is in routine clinical use, POCT has replaced other tests for the screening, triaging or diagnosis of chlamydia infections. Of these, one reported that POCT alone is sufficient for a diagnosis and the other reported that further tests are needed to confirm a diagnosis;
- POCT for chlamydia infections is externally quality assessed in two countries.

Figure 8 below shows countries where POCT for chlamydia infections is in routine clinical use, based on the findings from this study.

Figure 8. EU/EEA Member States and the UK in which POCT for chlamydia infections is in routine clinical use



6.4.2 Detailed findings

Mapping survey respondents from eight different EU/EEA Member States and the UK reported that there is POCT in routine clinical use for chlamydia infections. Those countries where POCT was reported as available are Bulgaria, Cyprus, France, Greece, Iceland, Malta, Norway and Spain. Figure 9 shows the inferential heatmap for chlamydia infections.

Of the eight countries where respondents reported that POCT is in routine clinical use for chlamydia infections, respondents from three countries (France, Norway and Spain) reported that official guidelines are in place.

¹ Chlamydia infections did not appear in either of the ECDC Atlas data shortlists prepared by the study team. This, however, was due to differences in the reporting format used to monitor chlamydia infection within the Atlas database. The notification rate for chlamydia (145.89) within the EU/EEA is indicative of a high prevalence relative to other infectious diseases in this study.

Survey respondents from three countries (Cyprus, Iceland and Malta) reported that there are no official guidelines available for POCT for chlamydia infections. In Bulgaria, a survey respondent was unsure whether guidelines covering the use POCT for chlamydia exist. In Greece, one respondent reported that guidelines are not available, while another respondent was unsure on this point. Follow-up desk research revealed that Greece has guidelines in place for the case management of chlamydia infection, as well as a national chlamydia surveillance system, though it is not clear whether these cover the use of POCT [13]

In most countries where it is in routine clinical use, POCT for chlamydia infections appears to be either fully or partially reimbursed through the healthcare system. In Bulgaria, Cyprus, France, Greece, Malta and Spain, survey respondents reported that POCT is fully reimbursed. In Norway, a survey respondent reported that POCT is either fully or partially reimbursed. In Iceland, a survey respondent reported POCT for chlamydia infections is entirely paid for by patients and not reimbursed.

Survey respondents from two countries (Cyprus and Spain) reported that POCT had replaced previous tests for the screening, triaging or diagnosis of chlamydia infections. Of these, Cyprus reported that POCT alone is sufficient for a diagnosis and Spain reported that further tests are needed to confirm a POCT diagnosis. In most cases, however, it does not appear that POCT for chlamydia infections has replaced existing tests. In three countries (Bulgaria, Iceland and Malta), survey respondents reported that POCT has not replaced existing tests. In Norway, the survey respondent was unsure on this point. In both France and Greece, one survey respondent reported that POCT has not replaced existing tests, while another was unsure.

There is limited evidence that POCT for chlamydia infections is externally quality assessed in EU/EEA Member States and the UK. Respondents from two countries (Cyprus and Norway) reported that external quality assessment measures are in place. In Iceland, however, it was reported that POCT for chlamydia infections has not been externally quality assessed. Survey respondents from Bulgaria and Spain were unsure whether POCT for chlamydia infections has been externally quality assessed. In both France and Greece, one respondent reported that POCT was not externally quality assessed, while another was unsure. In Malta, a survey respondent selected 'other' in response to this question, but also indicated that some quality assessment had been undertaken 'in collaboration with WHO studies'.

Guidelines Reimbursement Replacement Quality assessment

Bulgaria
Cyprus
France
Greece
Iceland
Malta
Norway
Spain

Figure 9. Inferential heatmap for chlamydia infections

6.5 Cryptosporidiosis

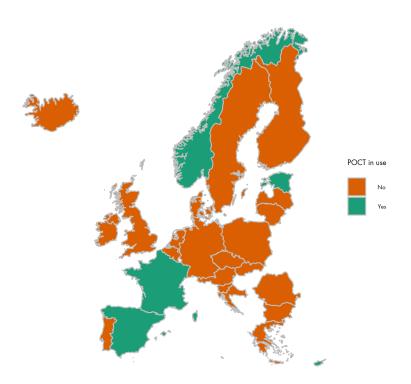
6.5.1 Overview

Cryptosporidiosis was included in the list of focus diseases for this study due to its appearance in one ECDC prevalence data shortlist (number of cases) and the scoping review. A summary of the mapping exercise findings with respect to POCT for cryptosporidiosis is below:

- POCT is in routine clinical use for cryptosporidiosis in at least five EU/EEA Member States and the UK.
- There is no firm evidence that any of these countries have official guidelines covering use of POCT for cryptosporidiosis.
- In all countries where it is in routine clinical use, POCT for cryptosporidiosis is either fully or partially reimbursed through the healthcare system.
- POCT has replaced other tests for the screening, triaging or diagnosis of cryptosporidiosis in one country.
 However, this country also reported that POCT is not sufficient alone and further tests are needed to confirm a diagnosis.
- POCT for cryptosporidiosis is externally quality assessed in one country.

Figure 10 below shows countries where POCT for cryptosporidiosis is in routine clinical use, based on the findings from this study.

Figure 10. EU/EEA Member States and the UK in which POCT for cryptosporidiosis is in routine clinical use



6.5.2 Detailed findings

Mapping survey respondents from five different EU/EEA Member States and the UK reported that there is POCT in routine clinical use for cryptosporidiosis. Those countries where POCT was reported as available are Cyprus, Estonia, France, Norway, Spain. Figure 11 shows the inferential heatmap for cryptosporidiosis.

There is no firm evidence that official guidelines covering the use of POCT for cryptosporidiosis exist in any country. In Cyprus, a survey respondent reported that no official guidelines exist. In three countries (Estonia, Norway and Spain) respondents were unsure whether guidelines existed. In France, one respondent reported that guidelines covering the use of POCT for cryptosporidiosis are available, while another was unsure on this point.

In all countries where it is in routine clinical use, POCT for cryptosporidiosis appears to be either fully or partially reimbursed through the healthcare system. In Cyprus, Estonia, France and Spain, survey respondents reported that POCT for cryptosporidiosis is fully reimbursed. In Norway, a survey respondent reported that POCT for cryptosporidiosis is either fully or partially reimbursed.

In Spain, a survey respondent reported that POCT has replaced existing tests for the screening, triaging or diagnosis of cryptosporidiosis. However, this respondent also reported that POCT is not sufficient alone and further tests are needed to confirm a diagnosis. On the whole, however, there is limited evidence that POCT has replaced other tests. In two countries (Cyprus and Estonia), survey respondents reported that POCT has not replaced existing tests. In Norway, a survey respondent was unsure whether POCT has replaced exiting tests. In France, one respondent reported that POCT has not replaced other tests, while another respondent was unsure on this point.

There is limited evidence that POCT for cryptosporidiosis is externally quality assessed in EU/EEA Member States and the UK. In Cyprus, a survey respondent reported that POCT for cryptosporidiosis is externally quality assessed. In all other countries reporting the use of POCT for cryptosporidiosis, however, survey respondents were unsure whether POCT is externally quality assessed.

Figure 11. Inferential heatmap for cryptosporidiosis

| | Guidelines | Reimbursement | Replacement | Quality assessment |
|---------|------------|---------------|-------------|--------------------|
| Cyprus | | | | |
| Estonia | | | | |
| France | | | | |
| Norway | | | | |
| Spain | | | | |

6.6 Gonorrhoea

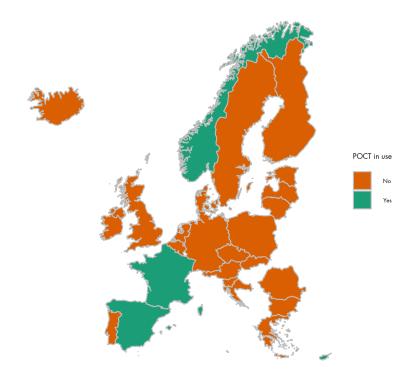
6.6.1 Overview

Gonorrhoea was included in the list of focus diseases for this study due to its appearance in one of the two ECDC prevalence data shortlist (number of cases) and the scoping review). A summary of the mapping exercise findings with respect to POCT for gonorrhoea is below:

- POCT is in routine clinical use for gonorrhoea in at least five EU/EEA Member States and the UK;
- Two countries have official guidelines covering use of POCT for gonorrhoea;
- POCT for gonorrhoea is likely partially or fully reimbursed through the healthcare system in five countries;
- POCT has replaced other tests for the screening, triaging or diagnosis of gonorrhoea in one country. Of
 these, one reported that POCT alone is sufficient for a diagnosis and the other reported that further tests
 are needed to confirm a diagnosis;
- POCT for gonorrhoea is likely externally quality assessed in two countries.

Figure 12 below shows countries where POCT for gonorrhoea is in routine clinical use, based on the findings from this study.

Figure 12. EU/EEA Member States and the UK in which POCT for gonorrhoea is in routine clinical use



6.6.2 Detailed findings

Mapping survey respondents from five different EU/EEA Member States and the UK reported that there is POCT in routine clinical use for gonorrhoea. Those countries where POCT was reported as available are Cyprus, France, Malta, Norway and Spain. Figure 13 shows the inferential heatmap for gonorrhoea.

Of the five countries where respondents reported that POCT is in routine clinical use for gonorrhoea, respondents from two countries (France and Norway) reported that official guidelines are in place. In Cyprus and Malta, survey respondents reported that guidelines covering the use of POCT for gonorrhoea are not in place. In Spain, one survey respondent reported that guidelines are available, while another reported that they are not. Follow-up desk research revealed that Spain does have guidelines in place for the diagnosis of all sextually transmitted infections, including gonorrhoea, which include guidance concerning the use of POCT. However, these guidelines do not recommend use of POCT for gonorrhoea specifically, due to the low sensitivity and specificity of POCT devices [14].

According to the evidence of the mapping survey, in all countries where POCT for gonorrhoea is used, it is either fully or partially reimbursed through the healthcare system. In Cyprus, France, Malta and Norway, survey respondents reported that POCT for gonorrhoea is fully reimbursed. In Spain, one survey respondent reported

that POCT is fully reimbursed, while another selected 'other' and reported that POCT is included in the general budget of the clinical microbiological laboratory.

There is mixed evidence that POCT has replaced existing tests for the screening, triaging or diagnosis of gonorrhoea. In Cyprus, the survey respondent reported that POCT has replaced other tests and that POCT results are sufficient to make a diagnosis alone. In Malta and Norway, however, survey respondents reported that POCT has not replaced other tests. In Spain, the survey respondent was unsure on this point. In France, one respondent reported that POCT for gonorrhoea has not replaced other tests, while the other was unsure.

There is some evidence that POCT for gonorrhoea is externally quality assessed in those countries where it is in routine clinical use. In Cyprus and Norway, survey respondents reported that POCT for gonorrhoea is subject to external quality assessment. In Spain, one respondent reported that POCT is externally quality assessed, while another respondent was unsure on this point. In France, both survey respondents were unsure whether POCT for gonorrhoea is externally quality assessed. In Malta, a survey respondent selected 'other' in response to this question, but also indicated that quality assessment had been undertaken 'in collaboration with WHO studies'.

Figure 13. Inferential heatmap for gonorrhoea

| | Guidelines | Reimbursement | Replacement | Quality assessment |
|--------|------------|---------------|-------------|--------------------|
| Cyprus | | | | |
| France | | | | |
| Malta | | | | |
| Norway | | | | |
| Spain | | | | |

6.7 Hepatitis B

6.7.1 Overview

Hepatitis B was included in the list of focus diseases for this study due to its appearance in one of the two ECDC prevalence data shortlists (age-standardised rate) and the scoping review and mapping survey. A summary of the mapping exercise findings with respect to POCT for hepatitis B is provided below:

- POCT is in routine clinical use for hepatitis B in at least eight EU/EEA Member States and the UK;
- Three of these countries have official guidelines covering use of POCT for hepatitis B;
- In all countries where it is in routine clinical use, POCT for hepatitis B is either fully or partially reimbursed through the healthcare system;
- POCT has replaced other tests for the screening, triaging or diagnosis of hepatitis B in one country; However, this country reported that further testing would be needed after a POCT to confirm a diagnosis;
- POCT for hepatitis B is externally quality assessed in three countries.

Figure 14 below shows countries where POCT for hepatitis B is in routine clinical use, based on the findings from this study.

POCT in use

No
Yes

Figure 14. EU/EEA Member States and the UK in which POCT for hepatitis B is in routine clinical use

6.7.2 Detailed findings

Mapping survey respondents from seven different EU/EEA Member States and the UK reported that POCT is in routine clinical use for hepatitis B. Those countries where POCT for hepatitis B was reported as available are Croatia, Cyprus, France, Malta, Norway, Romania, Spain. In follow-up interviews, an interviewee from Portugal reported that POCT for hepatitis B is also in routine clinical use in that country. Figure 15 shows the inferential heatmap for hepatitis B.

Of the eight countries where respondents reported that POCT is in routine clinical use for hepatitis B, respondents from three countries (France, Norway and Spain) reported that official guidelines are in place. Respondents from three countries (Cyprus, Malta and Romania) reported that there are no official guidelines covering POCT for hepatitis B. A survey respondent from Croatia was unsure on this point, as was an interviewee from Portugal.

From the evidence of the mapping survey, it appears that POCT for hepatitis B is either fully or partially reimbursed in all countries where it is in routine clinical use. In Croatia, Cyprus, France, Norway, Romania and Spain, respondents reported that POCT for hepatitis B is fully reimbursed through the healthcare system. In Malta, the survey respondent reported that POCT is partially reimbursed and partially paid for by patients. An interviewee from Portugal reported that POCT for hepatitis B is fully reimbursed in the context of hospitals, and partially reimbursed in other clinical settings, e.g. pharmacies.

On balance, there is limited evidence that POCT has replaced other tests for the screening, triaging or diagnosis of hepatitis B in EU/EEA Member States and the UK. In Spain, a survey respondent reported that POCT for hepatitis B has replaced other tests, although also reported that further testing is required to confirm a POCT diagnosis. However, in Croatia, Cyprus, Malta, Norway and Romania, survey respondents reported that POCT has not replaced other tests. In Portugal, an interviewee also reported that POCT for hepatitis B has not replaced other tests. In France, meanwhile, one survey respondent reported that POCT has not replaced other tests, while another respondent was unsure. Desk-based research also found evidence to suggest that POCT has not replaced serological screening, which remains the standard for diagnosing hepatitis B in France [15].

There is mixed evidence regarding whether POCT for hepatitis B is externally quality assessed in EU/EEA Member States and the UK. In Cyprus and Norway, survey respondents reported that externally quality assessment measures are in place for POCT. In Portugal, an interviewee also reported that POCT is externally quality assessed. In Romania, the survey respondent reported that POCT for hepatitis B is not quality assessed. In Croatia, France, Malta and Spain, survey respondents were unsure on this point.

Figure 15. Inferential heatmap for hepatitis B

| | Guidelines | Reimbursement | Replacement | Quality assessment |
|----------|------------|---------------|-------------|--------------------|
| Croatia | | | | |
| Cyprus | | | | |
| France | | | | |
| Malta | | | | |
| Norway | | | | |
| Portugal | | | | |
| Romania | | | | |
| Spain | | | | |

6.8 Hepatitis C

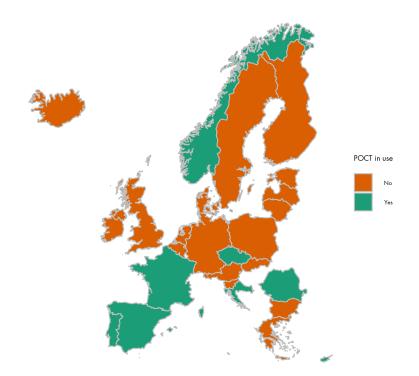
6.8.1 Overview

Hepatitis C was included in the list of focus diseases for this study due to its appearance in both of the ECDC prevalence data shortlists (age-standardised rate and number of cases) and the scoping review and mapping survey. A summary of the mapping exercise findings with respect to POCT for hepatitis C is provided below:

- POCT is in routine clinical use for hepatitis C in at least nine EU/EEA Member States and the UK;
- Three of these countries have official guidelines covering use of POCT for hepatitis C;
- In eight countries, POCT for hepatitis C is either fully or partially reimbursed through the healthcare system;
- POCT has replaced other tests for the screening, triaging or diagnosis of hepatitis C in one country; However, this country reported that further testing would be needed after a POCT to confirm a diagnosis;
- POCT for hepatitis C is externally quality assessed in four countries.

Figure 16 below shows countries where POCT for hepatitis C is in routine clinical use, based on the findings from this study.

Figure 16. EU/EEA Member States and the UK in which POCT for hepatitis C is in routine clinical use



6.8.2 Detailed findings

Mapping survey respondents from seven different EU/EEA Member States and the UK reported that POCT is in routine clinical use for hepatitis C. Countries where POCT for hepatitis C was reported as available are Croatia, Cyprus, France, Malta, Norway, Romania, Spain. In follow-up interviews, interviewees from Czechia and Portugal also reported that POCT for hepatitis C is in routine clinical use. Figure 17 shows the inferential heatmap for hepatitis C.

There is mixed evidence concerning the availability of official guidelines covering the use of POCT for hepatitis C. In France, Norway and Spain, survey respondents reported that guidelines are available. In Cyprus, Czechia, Malta and Romania, survey respondents reported that guidelines are not available. An interviewee from Czechia also reported that there are no guidelines covering POCT for hepatitis C. A survey respondent from Croatia and an interviewee from Portugal were unsure on this point.

In most countries where it is in routine clinical use, POCT for hepatitis C appears to be either fully or partially reimbursed through the healthcare system. In Croatia, Cyprus, France, Norway, Romania, Spain, survey respondents reported that POCT for hepatitis C is fully reimbursed. In Malta, the survey respondent reported that POCT is partially reimbursed and partially paid for by patients. In Portugal, meanwhile, an interviewee reported that POCT is fully reimbursed in the context of hospitals, and partially reimbursed in other clinical settings, e.g. pharmacies. In the Czechia, an interviewee reported that there are no specific arrangements in place for the reimbursement of POCT.

In most countries, it seems that POCT has not replaced other tests for the screening, triaging or diagnosis of hepatitis C. One exception to this was in Spain, where it was reported that POCT for hepatitis C has replaced other tests, although the respondent also reported that further testing is required to confirm a POCT diagnosis. In France, one survey respondent reported that POCT has not replaced other tests, while another respondent was unsure. In Croatia, Cyprus, Malta, Norway and Romania, however, survey respondents reported that POCT has not replaced other tests. In Portugal, an interviewee also reported that POCT has not replaced existing tests for hepatitis C. In Czechia, an interviewee also reported that POCT has replaced other tests in some hospitals but was unsure whether this was the case more broadly.

There is mixed evidence regarding whether or not POCT for hepatitis C is externally quality assessed in EU/EEA Member States and the UK. In Cyprus, Malta and Norway, survey respondents reported that POCT for hepatitis C is externally quality assessed. In Portugal, an interviewee also reported that external quality assessment measures for POCT are in place. In Croatia, France and Spain, respondents were unsure on this point. An interviewee from Czechia was also unsure. In Romania, a survey respondent reported that POCT for hepatitis C is not externally quality assessed.

Guidelines Reimbursement Replacement Quality assessment

Croatia

Cyprus

Czechia

France

Malta

Norway

Portugal

Romania

Spain

Figure 17. Inferential heatmap for hepatitis C

6.9 HIV/AIDS

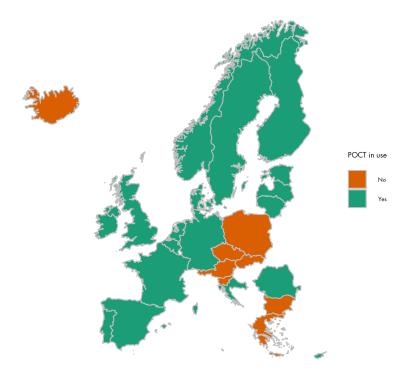
6.9.1 Overview

HIV/AIDS was included in the list of focus diseases for this study due to its appearance in both of the ECDC prevalence data shortlists (age-standardised rate and number of cases) and the scoping review and mapping survey. A summary of the mapping exercise findings with respect to POCT for HIV/AIDS is provided below:

- POCT is in routine clinical use for HIV/AIDS in at least nineteen EU/EEA Member States and the UK:
- Twelve countries have official guidelines covering the use of POCT for HIV/AIDS;
- POCT for HIV/AIDS is either fully or partially reimbursed through the healthcare system in sixteen countries;
- POCT has replaced other tests for the screening, triaging or diagnosis of HIV/AIDS in two countries;
 However, both countries reported that further testing is needed to confirm a diagnosis;
- POCT for HIV/AIDS is externally quality assessed in eight countries.

Figure 18 below shows countries where POCT for HIV/AIDS is in routine clinical use, based on the findings from this study.

Figure 18. EU/EEA Member States and the UK in which POCT for HIV/AIDS is in routine clinical use



6.9.2 Detailed findings

Mapping survey respondents from 17 different EU/EEA Member States and the UK reported that POCT is in routine clinical use for HIV/AIDS. Those countries where POCT was reported as available are Belgium, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Ireland, Latvia, Malta, the Netherlands, Norway, Romania, Spain, Sweden and the United Kingdom. In follow-up interviews, interviewees from two countries (Lithuania and Portugal) also reported that POCT for HIV/AIDS is in routine clinical use. Figure 19 shows the inferential heatmap for HIV/AIDS.

In most countries where POCT for HIV/AIDS is in routine clinical use, it appears that official guidelines are in place. Survey respondents from eleven countries (Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Ireland, Norway, Spain and the United Kingdom) reported that guidelines are available. An interviewee from Lithuania also reported that guidelines are available. In three countries (Latvia, Malta and Romania), survey respondents reported that guidelines covering POCT for HIV/AIDS are not available. In Belgium, the Netherlands and Sweden, survey respondents were unsure about the availability of guidelines. An interviewee from Portugal was also unsure on this point.

Based on the evidence collected from the survey and interviews, in those EU/EEA Member States and the UK where POCT for HIV/AIDS is in routine clinical use, it is highly likely to be either fully or partially reimbursed through the health system. Survey respondents from twelve countries (Belgium, Croatia, Cyprus, Denmark, France, Ireland, Netherlands, Norway, Romania, Spain, Sweden, United Kingdom) reported that POCT is fully reimbursed through the healthcare system. In Finland, the survey respondent reported that POCT is fully reimbursed through either the national healthcare system, municipal authorities or non-governmental organisation. An interviewee from Portugal reported that POCT for HIV/AIDS is fully reimbursed in the context of hospitals, and partially reimbursed in other clinical settings, e.g. pharmacies. In Latvia, the survey respondent reported that POCT is partially reimbursed and partially paid for by patients. In Estonia, the survey respondent that POCT is covered by state budgets but in only in the specific setting of anonymous HIV testing sites; in general health care, POCT is covered from national health insurance for those patients who are insured. In Germany, the survey respondent was unsure about whether or not POCT is reimbursed. Follow-up desk research found that in German hospitals, POCT costs are reimbursed within the daily hospital rate, but also suggested that

¹ In Lithuania, an interviewee reported that POCT has been used in routine clinical use for HIV infection, but that thus far this took place through a temporary EU project.

[&]quot;The respondent referred to 'private sector organisations' and the 'Finnish Red Cross'.

there are limited options for full reimbursement [16, 17] In Lithuania, an interviewee reported that POCT for HIV/AIDS is not reimbursed through the healthcare system ⁱ

In most countries, it seems, POCT has not replaced other tests for the screening, triaging or diagnosis of HIV/AIDS. The only two countries where survey respondents reported that POCT has replaced other tests were Spain and Sweden, but in both cases the respondents reported that further tests are needed to confirm a POCT diagnosis. In Belgium, Croatia, Cyprus, Denmark, Estonia, Finland, Ireland, Latvia, Malta, the Netherlands, Norway, Romania and the United Kingdom, survey respondents reported that POCT for HIV/AIDS has not replaced other tests. In Portugal, an interviewee also reported that POCT has not replaced existing tests. In France, one survey respondent reported that POCT has not replaced other tests, while another was unsure. Survey respondents and interviewees from Germany and Lithuania were also unsure whether POCT has replaced existing tests.

There is mixed evidence regarding whether or not POCT for HIV/AIDS is externally quality assessed. In seven countries (Belgium, Cyprus, Estonia, Finland, Latvia, the Netherlands and Norway, survey respondents reported that quality assessment measures for POCT are in place. In Portugal, an interviewee also reported that POCT for HIV/AIDS is externally quality assessed. In Denmark, Ireland and Romania, however, survey respondents reported that POCT is not quality assessed. In Malta, survey respondents provided different answers to this question; one reporting that POCT was in place and the other that it was not. Respondents from Croatia, France, Germany, Spain, Sweden and the United Kingdom were unsure whether or not quality assessment of POCT takes place. In the case of Germany, follow-up desk research found evidence that a German Medical Association Directive on the Quality Assurance of Tests in Laboratory Medicine does not stipulate any special regulations for POCT in comparison to those for a medical laboratory [16].

Guidelines Reimbursement Replacement Quality assessment Belgium Croatia Cyprus Denmark Estonia Finland France Germany Ireland Latvia Lithuania Malta Netherlands Norway Portugal Romania Spain Sweden United Kingdom

Figure 19. Inferential heatmap for HIV/AIDS

6.10 Influenza

6.10.1 Overview

Influenza – including A(H1N1) – was identified as a focus disease for this study. Influenza appeared in the shortlists of most referenced diseases within both the scoping review and mapping survey. Influenza also has a high prevalence compared with other infectious diseases within Europe. A summary of the mapping exercise findings with respect to POCT for influenza is provided below:

- POCT is in routine clinical use for influenza in at least twenty-one EU/EEA Member States and the UK;
- Nine countries have official guidelines covering the use of POCT for influenza;
- POCT for influenza is likely either fully or partially reimbursed through the healthcare system in sixteen countries;
- POCT has replaced other tests for the screening, triaging or diagnosis of influenza in one country. However
 it was reported that further tests are needed to confirm a POCT diagnosis in this country;

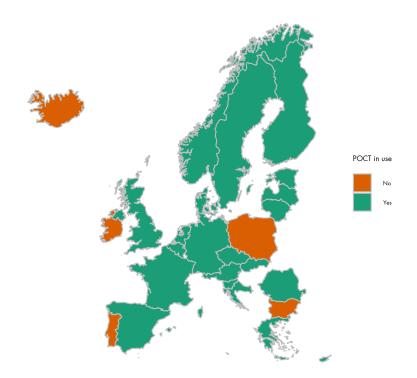
¹ Here, it was reiterated that the use of POCT for HIV infection in Lithuania has thus far been EU project based.

ii Like chlamydia infections, influenza did not appear in either of the ECDC Atlas data shortlists prepared by the study team. Again, however, this was due to differences in the reporting format used to monitor influenza within the Atlas database, rather than low prevalence. On the prevalence of influenza in Europe see the annual epidemiological reports on seasonal influenza produced by ECDC: https://www.ecdc.europa.eu/en/seasonal-influenza/surveillance-reports-and-disease-data

POCT for influenza is likely externally quality assessed in eight countries.

Figure 20 below shows countries where POCT for influenza is in routine clinical use, based on the findings from this study.

Figure 20. EU/EEA Member States and the UK in which POCT for influenza is in routine clinical use



6.10.2 Detailed findings

Mapping survey respondents from nineteen different EU/EEA Member States and the UK reported that POCT is in routine clinical use for influenza. Those countries where POCT was reported as available are Austria, Belgium, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Latvia, the Netherlands, Norway, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom. In follow-up interviews, interviewees from two countries (Lithuania and Czechia) also reported that POCT for influenza is in routine clinical use. Figure 21 shows the inferential heatmap for influenza.

In nine countries where POCT for influenza is in routine clinical use (Cyprus, Denmark, Finland, France, the Netherlands, Norway, Slovakia, Spain and the United Kingdom), survey respondents reported that guidelines are available. However, survey respondents from five countries (Belgium, Greece, Latvia, Romania and Slovenia), reported that no such guidelines are available. Interviewees from Lithuania and Czechia also reported that no guidelines covering POCT for influenza exist in those countries. In four countries (Austria, Croatia, Estonia and Germany) survey respondents were unsure on the availability of guidelines. In Sweden, two survey respondents reported that guidelines are available, while one reported that they are not.

According to the evidence, where POCT for influenza is in routine clinical use, it is often either fully or partially reimbursed through the healthcare system. In Austria, Croatia, Cyprus, Estonia, France, the Netherlands, Romania, Slovenia, Spain, Sweden and the United Kingdom, survey respondents reported that POCT is fully reimbursed. In the Slovakia, a survey respondent reported that POCT is fully reimbursed under the general hospitalisation budget. In Denmark, meanwhile, all survey respondents reported that POCT is fully reimbursed, with the exception of one who selected 'other' but reported that reimbursement is only available in hospitals. In Norway and Finland, survey respondents reported that POCT is either fully or partially reimbursed. In Estonia, survey respondents reported that POCT is partially reimbursed. In Greece, one survey respondent reported that POCT is partially reimbursed, while another was unsure. Survey respondents and interviewees from four countries (Belgium, Czechia, Latvia, Lithuania) reported that POCT for influenza is not reimbursed. In Germany, the survey respondent was unsure on this question.

¹ One Swedish respondent also reported that reporting of use of POCT was mandatory under the country's Communicable Diseases Act.

In most cases, it seems, POCT has not replaced other tests for the screening, triaging or diagnosis of influenza. Survey respondents from nine countries (Austria, Belgium, Croatia, Cyprus, Latvia, the Netherlands, Norway, Romania, Slovakia and the United Kingdom) reported that no such replacement has occurred. In both France and Greece, one respondent reported that POCT has not replaced other tests, while another respondent was unsure. In Sweden, two respondents reported that POCT has not replaced other tests, while one was unsure. The only country in which a respondent reported that POCT has replaced existing tests for influenza was Slovenia, however it was reported that further tests are needed to confirm a POCT diagnosis in Slovenia. In Denmark, survey respondents disagreed on this question, with three reporting that POCT had replaced existing tests, two reporting that it had not, and one unsure. Survey respondents from Finland, Germany and Spain were all unsure on this point, as were interviewees from Lithuania and Czechia. In follow-up desk research, we found evidence to suggest that many German hospitals continue to rely on centralised laboratory testing for influenza [18].

The evidence concerning external quality assessment for influenza POCT is mixed. In five countries (Cyprus, Denmark, Finland, Netherlands and Norway), survey respondents reported that POCT for influenza is externally quality assessed. In the United Kingdom, meanwhile, a survey respondent selected 'other' and reported that institution-specific quality assurance and control schemes are in place for POCT. In another five countries (Greece, Latvia, Romania, Slovakia and Slovenia), respondents reported that there is no quality assessment in place. In Estonia, one respondent reported that POCT is quality assessed, while one was unsure. In both Sweden and France, at least one respondent reported that POCT is quality assessed, while others were unsure. In all remaining countries (Austria, Belgium, Croatia, Czechia, Germany, Lithuania and Spain), survey respondents and interviewees were unsure whether POCT for influenza is subject to quality assessment.

Guidelines Reimbursement Replacement Quality assessment Austria Belgium Croatia Cyprus Czechia Denmark Estonia Finland France Germany Greece Latvia Lithuania Netherlands Norway Romania Slovakia Slovenia Spain Sweden United Kingdom

Figure 21. Inferential heatmap for influenza

6.11 Invasive pneumococcal disease

6.11.1 Overview

POCT for invasive pneumococcal disease is externally quality assessed in three countries.

Invasive pneumococcal disease was included in the list of focus diseases for this study due to its appearance in both of the ECDC prevalence data shortlists (age-standardised rate and number of cases) and the mapping survey. A summary of the mapping exercise findings with respect to POCT for invasive pneumococcal disease is provided below:

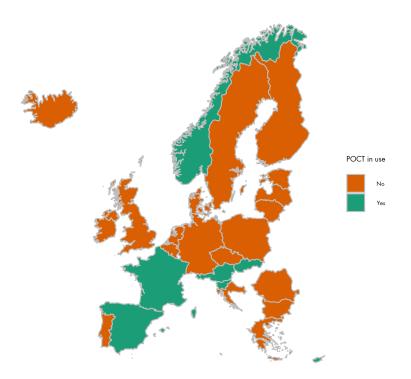
- POCT is in routine clinical use for invasive pneumococcal disease in at least seven EU/EEA Member States and the UK;
- It is likely that four countries have official guidelines covering the use of POCT for invasive pneumococcal disease;
- POCT for invasive pneumococcal disease is likely to be either fully or partially reimbursed through the healthcare system in seven countries;

¹ As noted above, follow-up desk research found evidence that a German Medical Association Directive on the Quality Assurance of Tests in Laboratory Medicine does not stipulate any special regulations for POCT in comparison to those for a medical laboratory.

 POCT has replaced other tests for the screening, triaging or diagnosis of invasive pneumococcal disease in one country. However, it was also reported that further tests are needed to confirm a POCT diagnosis in this country.

Figure 22 below shows countries where POCT for invasive pneumococcal disease is in routine clinical use, based on the findings from this study.

Figure 22. EU/EEA Member States and the UK in which POCT for invasive pneumococcal disease is in routine clinical use



6.11.2 Detailed findings

Mapping survey respondents from seven different EU/EEA Member States and the UK reported that POCT is in routine clinical use for invasive pneumococcal disease. Countries where POCT was reported as available are Austria, Cyprus, France, Norway, Slovakia, Slovenia and Spain. Figure 23 shows the inferential heatmap for invasive pneumococcal disease.

In four countries (France, Norway, Slovenia and Spain), survey respondents reported that POCT for invasive pneumococcal disease is covered by relevant guidelines. In one country (Cyprus), the survey respondent reported that no such guidelines are available. In Austria, the survey respondent was unsure whether or not guidelines were in place. In Spain, survey respondents provided different answers to this question, with one reporting that guidelines are available, and another reporting that they are not. Follow-up desk-research found evidence that guidelines covering the application of rapid diagnostic tests for pneumonia are available in Spain, which include reference to POCT devices [19].

According to the findings of the mapping survey, where POCT for invasive pneumococcal disease is in routine clinical use, it is likely that it is fully reimbursed by the healthcare system. In Austria, Cyprus, France, Norway, Slovakia, Slovenia and Spain, survey respondents reported that POCT for invasive pneumococcal disease is fully reimbursed. In Spain, one survey respondent reported that POCT is fully reimbursed, while another selected 'other' and reported that it is included in the general budget of the clinical microbiology laboratory.

In most cases, it seems that POCT for has not replaced existing tests for the screening, triaging or diagnosis of invasive pneumococcal disease. In Austria, Cyprus, Norway, Slovakia and Spain, survey respondents reported that no such replacement has occurred. In France, meanwhile one respondent reported that POCT has not replaced existing tests (although this respondent also reported that further tests are required to confirm a diagnosis), while another respondent was unsure. In Slovenia, a survey respondent reported that POCT has replaced other tests.

There is mixed evidence concerning the extent to which POCT for invasive pneumococcal disease is externally quality assessed. In three countries (Cyprus, Norway and Slovenia, survey respondents reported that external quality assessment procedures are in place. In Slovakia, the survey respondent reported that POCT is not quality

assessed. In France, one survey respondent reported that there was no quality assessment, while another was unsure. In Austria and Spain, survey respondents were unsure about the existence of procedures for quality assessment.

Figure 23. Inferential heatmap for invasive pneumococcal disease

| | Guidelines | Reimbursement | Replacement | Quality assessment |
|----------|------------|---------------|-------------|--------------------|
| Austria | | | | |
| Cyprus | | | | |
| France | | | | |
| Norway | | | | |
| Slovakia | | | | |
| Slovenia | | | | |
| Spain | | | | |

6.12 Malaria

6.12.1 Overview

Malaria was included in the list of focus diseases for this study due to its appearance in the scoping review and mapping survey. While malaria did not feature in either of the ECDC prevalence data shortlists, it has a high prevalence in many countries outside of Europe and therefore represents a potential threat through travellers either visiting or returning to the EU/EEA region from those countries. A summary of the mapping exercise findings with respect to POCT for malaria follow:

- POCT is in routine clinical use for malaria in at least 13 EU/EEA Member States and the UK;
- Three countries have official guidelines covering the use of POCT for malaria;
- POCT for malaria is likely to be either fully or partially reimbursed through the healthcare system in twelve countries;
- There is no firm evidence that POCT has replaced other tests for the screening, triaging or diagnosis of malaria in any country;
- POCT for malaria is likely externally quality assessed in four countries.

Figure 24 below shows countries where POCT for malaria is in routine clinical use, based on the findings from this study.

¹ The prevalence of malaria within EU/EEA countries may also increase in the future due to climate change and shifts in movement of vector species. Available at: https://www.ecdc.europa.eu/en/climate-change/climate-change-europe

POCT in use
No
Yes

Figure 24. EU/EEA Member States and the UK in which POCT for malaria is in routine clinical use

6.12.2 Detailed findings

Mapping survey respondents from thirteen different EU/EEA Member States and the UK reported that POCT is in routine clinical use for malaria. Those countries where POCT was reported as available are Austria, Belgium, Croatia, Denmark, Estonia, France, Germany, Greece, Latvia, Norway, Spain and Sweden. Figure 25 shows the inferential heatmap for malaria.

Of those thirteen countries in which POCT is used for malaria, respondents from only three countries (Denmark, France and Norway) reported that official guidelines are in place. In four countries (Belgium, Cyprus, Greece and Latvia), respondents reported that no guidelines are available. In Austria, Croatia, Estonia, Germany and Spain, survey respondents were unsure about the availability of guidelines. In Sweden, one respondent reported that guidelines are available, while another reported that they are not.

In most countries where is in use, it seems, POCT for malaria is either fully or partially reimbursed through the healthcare system. In Austria, Croatia, Cyprus, Denmark, Estonia, France, Germany, Norway, Spain and Sweden, survey respondents reported that POCT for malaria is fully reimbursed. In Latvia, the survey respondent reported that POCT is partially reimbursed by the healthcare system and partially paid for by patients. In Greece, one survey respondent reported that POCT is fully reimbursed, while another was unsure. In Belgium, the survey respondent was unsure whether or not POCT for malaria is reimbursed.

There is no firm evidence that POCT has replaced other tests for the screening, triaging or diagnosis of malaria in any context. In Austria, Croatia, Cyprus, Estonia, Latvia, Norway and Sweden, survey respondents reported that POCT for malaria has not replaced other tests. In France, one respondent reported that it has not replaced other tests, while another was unsure. In Belgium, Germany and Spain, survey respondents were unsure whether or not POCT for malaria has replaced existing tests. In both Denmark and Greece, one survey respondent reported that POCT has replaced existing tests (although also reported that further testing is needed to confirm a POCT diagnosis), while another reported that it has not. In the case of Greece, follow-up desk research found evidence that rapid diagnostic tests, aimed at prompt point-of-care diagnosis of malaria cases, have been distributed to health units and facilities nationwide [20-21].

There is mixed evidence regarding whether POCT for malaria is externally quality assessed. In Cyprus, Norway and Sweden, respondents reported that quality assessment procedures are in place. In Denmark, one respondent reported that POCT for malaria is quality assessed, while another was unsure on this point. In three countries (Belgium, Greece and Latvia), survey respondents reported that POCT for malaria is not quality assessed. In all other countries (Austria, Croatia, Estonia, France, Germany and Spain), survey respondents were unsure on the point.¹

Figure 25. Inferential heatmap for malaria

| | Guidelines | Reimbursement | Replacement | Quality assessment |
|---------|------------|---------------|-------------|--------------------|
| Austria | | | | |
| Belgium | | | | |
| Croatia | | | | |
| Cyprus | | | | |
| Denmark | | | | |
| Estonia | | | | |
| France | | | | |
| Germany | | | | |
| Greece | | | | |
| Latvia | | | | |
| Norway | | | | |
| Spain | | | | |
| Sweden | | | | |

6.13 Syphilis

6.13.1 Overview

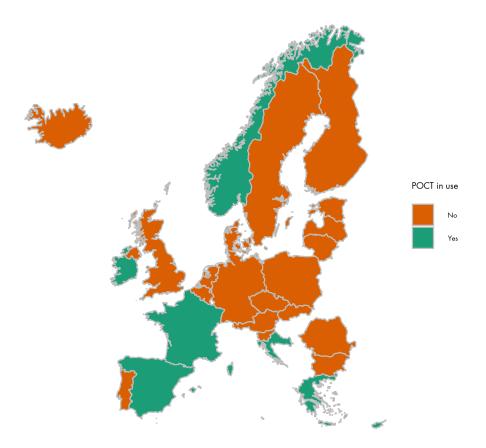
Syphilis was included in the list of focus diseases for this study due to its appearance in both of the ECDC prevalence data shortlists (age-standardised rate and number of cases) and both the scoping review and mapping survey study shortlists. A summary of the mapping exercise findings with respect to POCT for syphilis is provided below:

- POCT is in routine clinical use for syphilis in at least eight EU/EEA Member States and the UK;
- Four of these countries have official guidelines covering the use of POCT for syphilis;
- In all countries where it is in routine clinical use, POCT for syphilis is either fully or partially reimbursed through the healthcare system;
- There is no firm evidence that POCT has replaced other tests for the screening, triaging or diagnosis of syphilis in any country;
- POCT for syphilis is externally quality assessed in two countries.

Figure 26 below shows countries where POCT for syphilis is in routine clinical use, based on the findings from this study.

¹ As noted above, in the German case, follow-up desk research found evidence that a German Medical Association Directive on the Quality Assurance of Tests in Laboratory Medicine does not stipulate any special regulations for POCT in comparison to those for a medical laboratory.

Figure 26. EU/EEA Member States and the UK in which POCT for syphilis is in routine clinical use



6.13.2 Detailed findings

Mapping survey respondents from eight different EU/EEA Member States and the UK reported that POCT is in routine clinical use for syphilis. Those countries where POCT was reported as available are Croatia, Cyprus, France, Greece, Ireland, Malta, Norway and Spain. Figure 27 shows the inferential heatmap for syphilis.

In four countries where POCT is in routine clinical use for syphilis (France, Ireland, Norway and Spain), survey respondents reported that guidelines are available. In two countries (Cyprus and Malta), survey respondents reported that no such guidelines are available. Respondents from two countries (Croatia and Greece), were unsure on this point.

According to the evidence, in all countries where POCT for syphilis is in routine clinical use, it is either fully or partially reimbursed by the healthcare system. Respondents from seven countries (Cyprus, France, Greece, Ireland, Malta, Norway and Spain) reported that POCT for syphilis is fully reimbursed. In Croatia, the survey respondent reported that POCT is partially reimbursed by the healthcare system and partially paid for by patients.

The mapping survey produced no evidence that POCT has replaced other tests for the screening, triaging or diagnosis of syphilis in any country. In seven countries (Croatia, Cyprus, Greece, Ireland, Malta, Norway and Spain), respondents reported that POCT has not replaced other tests. In France, the survey respondent was unsure on this point.

There is mixed evidence regarding whether POCT for syphilis is externally quality assessed in EU/EEA Member States and the UK. Survey respondents in two countries (Cyprus and Norway) reported that POCT for syphilis is externally quality assessed. In Ireland, the survey respondent reported that no external quality assessment procedures are in place. In Croatia, France, Greece and Spain, survey respondents were unsure whether or not POCT for syphilis is externally quality assessed. In Malta, a survey respondent selected 'other' in response to this question, but also indicated that quality assessment had been undertaken 'in collaboration with WHO studies'.

Figure 27. Inferential heatmap for syphilis

| | Guidelines | Reimbursement | Replacement | Quality assessment |
|---------|------------|---------------|-------------|--------------------|
| Croatia | | | | |
| Cyprus | | | | |
| France | | | | |
| Greece | | | | |
| Ireland | | | | |
| Malta | | | | |
| Norway | | | | |
| Spain | | | | |

6.14 Tuberculosis

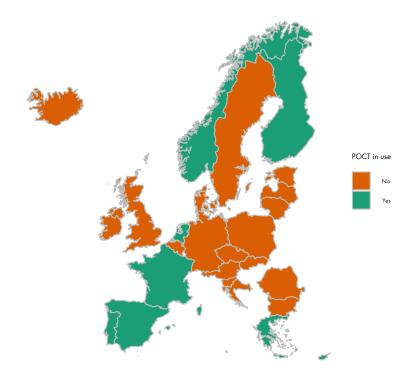
6.14.1 Overview of findings

Tuberculosis was included in the list of focus diseases for this study due to its appearance in both of the ECDC prevalence data shortlists (age-standardised rate and number of cases) and both scoping review and mapping survey study shortlists. A summary of the mapping exercise findings for POCT for tuberculosis is provided below:

- POCT is in routine clinical use for tuberculosis in at least eight EU/EEA Member States and the UK;
- It is likely that four of these countries have official guidelines covering POCT for tuberculosis;
- POCT for tuberculosis is partially or fully reimbursed through the healthcare system in seven countries;
- There is no firm evidence that POCT has replaced other tests for the screening, triaging or diagnosis of tuberculosis in any setting;
- POCT for tuberculosis is likely externally quality assessed in six countries.

Figure 28 below shows countries where POCT for tuberculosis is in routine clinical use, based on the findings from this study.

Figure 28. EU/EEA Member States and the UK in which POCT for tuberculosis is in routine clinical use



6.14.2 Detailed findings

Respondents from seven different EU/EEA Member States and the UK reported that there is POCT in routine clinical use for tuberculosis in the mapping survey. Those countries where POCT for tuberculosis was reported as available are Cyprus, Finland, France, Greece, the Netherlands, Spain and Norway. In follow-up interviews, an interviewee from Portugal reported that POCT for tuberculosis is also in routine clinical use in that country. Figure 29 shows the inferential heatmap for tuberculosis.

Of the eight countries where mapping survey respondents reported that POCT is in routine clinical use for tuberculosis, respondents from four countries (Cyprus, Finland, France and Norway) reported that official guidelines are in place. Respondents from two countries (Greece and Netherlands) reported that there are no official guidelines available for POCT for tuberculosis. In Portugal, an interviewee was unsure whether guidelines for the application of POCT to tuberculosis are available. In Spain, one survey respondent reported that guidelines are available, while the other reported that they are not. Follow-up desk research revealed that Spain does have a national plan for the prevention and control of tuberculosis, and that this recommends use of rapid immunochromatographic tests which could include POCT [22].

Based on the information collected from the survey and interviews, in those EU/EEA Member States and the UK where POCT for tuberculosis is in routine clinical use, it is likely that it is either fully or partially reimbursed through the health system. Respondents from six countries (Cyprus, Finland, France, Greece and Norway) reported that POCT for tuberculosis is fully reimbursed through the healthcare system. In the Netherlands, meanwhile, the survey respondent reported that POCT for tuberculosis is partially reimbursed and partially paid for by patients. In Spain, one respondent reported that it was fully reimbursed, while the another selected 'other' and reported that it is included within the general budget of the clinical microbiology laboratory. An interviewee from Portugal reported that POCT for tuberculosis is fully reimbursed in the context of hospitals, and partially reimbursed in other clinical settings, e.g., pharmacies.

According to evidence from the mapping survey and interviews, it does not appear that POCT has replaced previous tests for the screening, triaging or diagnosis of tuberculosis in EU/EEA Member States and the UK. Respondents from five countries (Cyprus, Finland, Greece, Netherlands and Norway) reported that it has not replaced other tests. In France, one respondent reported that it has not replaced other tests, while another was unsure. In the case of Portugal, a follow-up interview highlighted that POCT is still used alongside centralised laboratory tests. In Spain respondents to the survey disagreed as to whether or not POCT has replaced other tests for tuberculosis, with one respondent reporting that it has (although also reporting that further testing is needed to confirm a POCT diagnosis), and another reporting that it has not.

On balance, it appears that POCT for tuberculosis is often externally quality assessed. Survey respondents from four countries (Cyprus, Finland, Netherlands and Norway) reported that it is externally quality assessed. In Portugal, a follow-up interview confirmed that POCT for tuberculosis is also externally quality assessed. In Spain, one survey respondent reported that POCT for tuberculosis is quality assessed, while another was unsure. Greece, meanwhile, was the only country in which a survey respondent reported that tuberculosis has not been externally quality assessed. Survey respondents from France were unsure as to whether POCT for tuberculosis had been externally quality assessed.

Guidelines Reimbursement Replacement Quality assessment

Cyprus
Finland
France
Greece
Netherlands
Norway
Portugal
Spain

Figure 29. Inferential heatmap for tuberculosis

7 Summary analysis of other diseases

In this section, we summarise the key mapping survey findings for all other diseases included within the scope of this study.ⁱ

Table 18. Summary findings for all other infectious diseases

| Disease | Number of EU/EEA | Names of countries (and | Key findings | | | | |
|-------------------------------|--|--|---|---|--|--|--|
| the UK reporting POCT was rep | Member States and the UK reporting POCT was reported to be in routine clinical use | number of respondents reporting POCT is used in each case) | Guidelines | Reimbursement | Replacement ⁱⁱ | Quality assessment | |
| Anthrax | 2 | France (2); Norway (1) | In Norway, the survey respondent reported that guidelines covering the application of POCT to anthrax are available. In France, survey responses indicated uncertainty concerning the availability of guidelines. | In France and Norway, survey respondents reported that POCT for anthrax is fully reimbursed through the healthcare system. | In Norway, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of anthrax. In France, survey responses indicated uncertainty about the extent to which existing diagnostic procedures has been replaced. | respondent reported that POC for anthrax is externally quality assessed. In France, survey respondents were unsure whether POCT for anthrax is externally quality assessed. | |
| Antimicrobial resistance | 7 | Cyprus (1); France (2); Greece (1); Netherlands (1); Norway (1); Spain (1); Sweden (1) | In France, Norway and Spain, survey respondents reported that guidelines covering the application of POCT to antimicrobial resistance are available. In Cyprus, Greece, the Netherlands and Sweden, survey respondents reported that guidelines covering the use of POCT for antimicrobial resistance are not available. | In Cyprus, France, Spain and Sweden, survey respondents reported that POCT for antimicrobial resistance is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for antimicrobial resistance is either fully or partially reimbursed through the healthcare system. In the Netherlands, the survey respondent reported that POCT for antimicrobial resistance is partially reimbursed. | respondents reported that POCT has not replaced other tests. In Germany and Norway, survey respondents were | In Cyprus, the Netherlands, Norway and Sweden, survey respondents reported that POCT for antimicrobial resistance is externally quality assessed. In Greece, the survey respondent reported that POCT for antimicrobial resistance is externally quality assessed. In Spain, the survey respondent was unsure whether POCT for antimicrobial resistance is quality assessed. In France, survey responses also indicated uncertainty on this point. | |

¹ Summary findings for each individual disease can also be viewed in the form of heatmaps – see Annex 7 of this report.

ii It is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis.

| Botulism | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for botulism are available. | In France and Norway, survey respondents reported that POCT for botulism is fully reimbursed through the healthcare system. | In Norway, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of botulism. In France, the respondent was unsure whether POCT for botulism has replaced other tests. | In France and Norway, survey respondents were unsure whether POCT for botulism is externally quality assessed. |
|------------------------------|---|------------------------|---|---|--|---|
| Brucellosis | 3 | | In France and Norway, survey respondents reported that guidelines covering the use of POCT for brucellosis are available. In Spain, the survey respondent was unsure whether guidelines existed. | In France and Spain, survey respondents reported that POCT for brucellosis is fully or reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for brucellosis is either fully or partially reimbursed through the healthcare system. | In France and Norway, survey respondents were unsure whether POCT for brucellosis | In Norway, the survey respondent reported that POCT for brucellosis is externally quality assessed. In France and Spain, survey respondents were unsure whether POCT for brucellosis is externally quality assessed. |
| Campylobacteriosis | 3 | | In France and Norway, survey respondents reported that guidelines covering the use of POCT for campylobacteriosis are available. In Spain, the survey respondent was unsure about the availability of guidelines. | In France and Spain, survey respondents reported that the POCT for campylobacteriosis is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for campylobacteriosis is either fully or partially reimbursed through the healthcare system. | screening, triaging or diagnosis of campylobacteriosis. In Norway, the survey | In Norway, the survey respondent reported that POCT for campylobacteriosis is externally quality assessed. In Spain, the survey respondent was unsure whether POCT for campylobacteriosis is externally quality assessed. In France, survey respondents also indicated uncertainty on this point. |
| Chikungunya virus disease | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for chikungunya virus disease are available. | In France, the survey respondent reported that POCT for chikungunya virus disease is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for chikungunya virus disease is either fully or partially reimbursed through the healthcare system. | respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of chikungunya virus disease. In France, the survey | In France and Norway, survey respondents were unsure whether POCT for botulism is externally quality assessed. |
| Cholera | 3 | | In France, survey respondents reported that guidelines covering the use of POCT for cholera are available. In Norway, the survey respondent reported that guidelines covering the use of POCT for cholera are not available. | In France, Norway and Spain, survey respondents reported that POCT for cholera is fully reimbursed through the healthcare system. | In Spain, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of cholera. | In Norway and Spain, respondents were unsure whether POCT for cholera is externally quality assessed. |

| | | | In Spain, the survey respondent was unsure on this point. | | In Norway, the respondent was unsure whether POCT has replaced other tests for the screening, triaging or diagnosis of cholera. In France, survey respondents also indicated uncertainty on this point. | In France, responses also indicated uncertainty on this point. |
|--|---|---|---|--|--|---|
| Dengue | 5 | Austria (1); France (1); Germany (1); Norway (1); Spain (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for dengue are available. In Spain, the survey respondent reported that guidelines covering the use of POCT for dengue are not available. In Germany and Austria, respondents were unsure on this point. | In Austria, France, Germany and Norway, survey respondents reported that POCT for cholera is fully reimbursed through the healthcare system. In Spain, the survey respondent reported that the cost of POCT for dengue is included in the general budget of the clinical microbiology laboratory. | In Austria, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of dengue. In Spain, the survey respondent reported that POCT for dengue has not replaced other tests. In France, Germany and Norway, survey respondents were unsure on this point. | In Spain, the survey respondent reported that POCT for dengue is externally quality assessed. In Austria, France, Germany and Norway, respondents were unsure whether POCT for dengue is externally quality assessed. |
| Diphtheria | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for diphtheria are available. | In France and Norway, survey respondents reported that POCT for diphtheria is fully reimbursed through the healthcare system. | In Norway, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of diphtheria. In France, the survey respondent was unsure whether POCT for diphtheria has replaced other tests. | In Norway, the survey respondent reported that POCT for diphtheria is externally quality assessed. In France, the survey respondent was unsure whether POCT for diphtheria is externally quality assessed. |
| Echinococcosis | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for echinococcosis are available. | In France and Norway, survey respondents reported that POCT for echinococcosis is fully reimbursed through the healthcare system. | In France and Norway, survey respondents reported that POCT has not replaced other tests for the screening, triaging or diagnosis of echinococcosis. | In France and Norway, survey respondents reported that POCT for echinococcosis is not externally quality assessed. |
| Shiga-toxin-producing Escherichia coli (STEC/VTEC) infection | 4 | Austria (1); France (2); Norway (1); Spain (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for shigatoxin-producing Escherichia coli (STEC/VTEC) infection are available. In Austria and Spain, survey respondents were unsure about the availability of guidelines. | In Austria, France and Spain, survey respondents reported that POCT for shiga-toxin-producing Escherichia coli (STEC/VTEC) infection is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for shiga-toxin-producing Escherichia coli (STEC/VTEC) infection is either fully or partially reimbursed through the healthcare system. | for shiga-toxin-producing Escherichia coli (STEC/VTEC) has not replaced other tests. | In Norway, the survey respondent reported that POCT for shiga-toxin-producing Escherichia coli (STEC/VTEC) infection is externally quality assessed. In Austria and Spain, survey responses were unsure whether POCT for shiga-toxin-producing Escherichia coli (STEC/VTEC) infection is externally quality assessed. In France, survey respondents also indicated uncertainty on this point. |

| Giardiasis | 4 | Cyprus (1); France (2); Norway (1); Spain (1) | In Norway, the survey respondent reported that guidelines covering the use of POCT for giardiasis are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for giardiasis are not available. In Spain, the survey respondent was unsure on this point. In France, survey respondents also indicated uncertainty on this point. | In Cyprus, France, Norway and Spain, survey respondents reported that POCT for giardiasis is fully reimbursed through the health system. | In Spain, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of giardiasis. In Cyprus, the survey respondent reported that POCT for giardiasis is externally quality assessed. In France, Norway and Spain survey respondents reported that POCT for giardiasis has not replaced other tests. In France, survey responses indicated uncertainty on this point. |
|--|----|---|---|--|--|
| Hepatitis A | 3 | Cyprus (1); France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for hepatitis A are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for hepatitis A are not available. | that POCT for hepatitis A is fully reimbursed through the | In Cyprus and Norway, survey respondents reported that POCT has not replaced other tests for the screening, triaging or diagnosis of hepatitis A. In France, the survey respondent was unsure whether POCT for hepatitis A has replaced other tests. In Cyprus, the survey respondent reported that PO for hepatitis A is externally quality assessed. In France and Norway, surver respondents were unsure whether POCT for hepatitis A externally quality assessed. |
| Infections with haemophilus influenzae group B | 4 | Austria (1); France (2); Germany (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for infections with haemophilus influenzae group B are available. In Austria and Germany, survey respondents were unsure about the availability of guidelines. | In Austria, France and Norway, survey respondents reported that POCT for infections with haemophilus influenzae group B is fully reimbursed through the healthcare system. In Germany, the survey respondent was unsure on this point. | In Austria, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of infections with haemophilus influenzae group B. In Germany and Norway, survey respondents were unsure whether POCT for infections with haemophilus influenzae group B is external quality assessed. In Austria and Germany, survey respondents were unsure whether POCT for infections with haemophilus influenzae group B is externally quality assessed. In France, survey respondent also indicated uncertainty on this point. |
| Legionnaires' disease | 11 | Austria (1); Cyprus (1); Estonia (1); Finland (1); France (2); Germany (1); Latvia (1); Norway (1); Poland (1); Slovenia (1); Spain (1); Sweden (2); United Kingdom (1) | In Finland, France, Norway, Poland and Slovenia, survey respondents reported that guidelines covering the use of POCT for legionnaires' disease are available In Cyprus and Latvia, survey respondents reported that guidelines covering the use of POCT for legionnaires' disease are not available. In Austria, Estonia, Germany, Spain, Sweden and the United Kingdom, survey respondents were unsure on this point. | | In Austria and Slovenia, survey respondents reported that POCT has replaced other tests for the screening, triaging or diagnosis of legionnaires' disease. In Cyprus, Estonia, Finland, Latvia, Norway, Poland, Spain, Sweden and the United Kingdom, survey respondents reported that POCT for legionnaires' disease has not replaced other tests. In Cyprus, Estonia, Finland a Latvia, survey respondents reported that POCT for legionnaires' disease is externally quality assessed. |

| | | | | reimbursed through the healthcare system. In Latvia, the survey respondent reported that POCT for legionnaires' disease is partially reimbursed. In Germany and Poland, survey respondents were unsure on this point. | respondent was unsure on this point. In France, survey respondents also indicated uncertainty on this point. | In France and Sweden, survey respondents also indicated uncertainty on this point. In Poland, the survey respondent left this field blank. |
|-----------------------|---|------------------------------------|--|--|--|--|
| Leptospirosis | 2 | Bulgaria (1); France (1) | In France, the survey respondent reported that guidelines covering the use of POCT for leptospirosis are available. In Bulgaria, the survey respondent reported that guidelines covering the use of POCT for leptospirosis are not available. | In France, the survey respondent reported that POCT for leptospirosis is fully reimbursed through the healthcare system. In Bulgaria, the survey respondent reported that POCT for leptospirosis is paid for entirely by patients and not reimbursed. | respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of leptospirosis. In France, the survey | In Bulgaria, the survey respondent reported that POCT for leptospirosis has not been externally quality assessed. In France, the survey respondent was unsure whether POCT for leptospirosis has been externally quality assessed. |
| Listeriosis | 3 | Cyprus (1); France (2); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for listeriosis are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for listeriosis are not available. | In Cyprus and France, survey respondents reported that POCT for listeriosis is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for listeriosis is either fully or partially reimbursed through the healthcare system. | In France, survey responses indicated uncertainty on this point. | In Cyprus, the survey respondent reported that POCT for listeriosis is externally quality assessed. In Norway, the survey respondent was unsure whether POCT for listeriosis is externally quality assessed. In France, survey respondents also indicated uncertainty on this point. |
| Lyme neuroborreliosis | 3 | Cyprus (1); France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for lyme neuroborreliosis are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT of lyme neuroborreliosis are not available. | In Cyprus and France, survey respondents reported that POCT for lyme neuroborreliosis is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for lyme neuroborreliosis is either fully or partially reimbursed through the healthcare system. | respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of lyme neuroborreliosis. | In Cyprus, the survey respondent reported that POCT for lyme neuroborreliosis is externally quality assessed. In France and Norway, survey respondents whether POCT for lyme neuroborreliosis is externally quality assessed. |
| Measles | 3 | Cyprus (1); France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for measles are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for measles are not available. | In Cyprus, France and Norway, survey respondents reported that POCT for measles is fully reimbursed through the healthcare system. | respondents reported that POCT has not replaced other tests for the screening, triaging or | In Cyprus and Norway, survey respondents reported that POCT for measles is externally quality assessed. In France, the survey respondent was unsure whether POCT for measles is externally quality assessed. |

| | | | | | other tests. | |
|--------------------------------|---|---|--|---|---|---|
| Invasive meningococcal disease | 5 | Cyprus (1); France (2); Norway (1); Slovenia (1); Spain (1) | In France, Norway and Slovenia, survey respondents reported that guidelines covering the use of POCT for invasive meningococcal disease are available. In Cyprus and Spain, survey respondents reported that guidelines covering the use of POCT for invasive meningococcal disease are not available. | In Cyprus, France, Norway and Slovenia, survey respondents reported that POCT for invasive meningococcal disease is fully reimbursed through the healthcare system. In Spain, the survey respondent reported that POCT for invasive meningococcal disease is included in the general budget of the clinical microbiology laboratory. | In Slovenia, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of invasive meningococcal disease. In Cyprus, Norway and Spain, survey respondents reported that POCT for invasive meningococcal disease has not replaced other tests. In France, survey responses indicated uncertainty on this point. | In Cyprus, Norway and Slovenia, survey respondents reported that POCT for invasive meningococcal disease is externally quality assessed. In Spain, the survey respondent was unsure whether POCT for invasive meningococcal disease is externally quality assessed. In France, survey responses also indicated uncertainty on this point. |
| Mumps | 3 | Cyprus (1); France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for mumps are available. In Cyprus, survey respondents reported that guidelines covering the use of POCT for mumps are not available. | In Cyprus, France and Norway, survey respondents reported that POCT for mumps is fully reimbursed through the healthcare system. | In Cyprus and Norway, survey respondents reported that POCT has not replaced other tests for the screening, triaging or diagnosis of mumps. In France, the survey respondent was unsure whether POCT for mumps has replaced other tests. | In Cyprus and Norway, survey respondents reported that POCT for mumps is externally quality assessed. In France, the survey respondent was unsure whether POCT for mumps is externally quality assessed. |
| Nosocomial infections | 7 | Denmark (1); France (1); Germany (1); Greece (1); Netherlands (1); Norway (1); Spain (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for nosocomial infections are available. In Denmark, Greece and the Netherlands, survey respondents reported that guidelines covering the use of POCT for nosocomial infections are not available. In Greece and Spain, survey respondents were unsure on this point. | In Denmark, France, Greece, Norway and Spain, survey respondents reported that POCT for nosocomial infections is fully reimbursed through the healthcare system. In the Netherlands, the survey respondent reported that POCT for nosocomial infections is partially reimbursed through the healthcare system. In Germany, the survey respondent was unsure on this point. | In Denmark, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of nosocomial infections. In Greece and the Netherlands, survey respondents reported that POCT for nosocomial infections has not replaced other tests. In France, Germany, Norway and Spain, survey respondents were unsure on this point. | In the Netherlands, the survey respondent reported that POCT for nosocomial infections is externally quality assessed. In Greece, the survey respondent reported that POCT for nosocomial infections is not externally quality assessed. In Denmark, France, Germany, Norway and Spain, survey respondents were unsure on this point. |
| Pertussis | 2 | Cyprus (1); France (2) | In France, survey respondents reported that guidelines covering the use of POCT for pertussis are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for pertussis are not available. | In Cyprus and France, survey respondents reported that POCT for pertussis is fully reimbursed through the healthcare system. | In Cyprus, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of pertussis. In France, survey responses indicated uncertainty on this point. | In Cyprus, the survey respondent reported that POCT for pertussis is externally quality assessed. In France, survey respondents were unsure whether POCT for pertussis is externally quality assessed. |

| Plague | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for plague are available. | In France and Norway, survey respondents reported that POCT for plague is fully reimbursed through the healthcare system. | In France and Norway, survey respondents reported that POCT has not replaced other tests for the screening, triaging or diagnosis of plague. | In Norway, the survey respondent reported that POCT for plague is externally quality assessed. In France, the survey respondent reported that POCT for plague is not externally quality assessed. |
|---------------|---|------------------------------------|--|---|--|---|
| Poliomyelitis | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for poliomyelitis are available. | In France and Norway, survey respondents reported that POCT for poliomyelitis is fully reimbursed through the healthcare system. | In Norway, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of poliomyelitis. In France, the survey respondent was unsure whether POCT for poliomyelitis has replaced other tests. | In Norway, the survey respondent reported that POCT for poliomyelitis is externally quality assessed. In France, the survey respondent was unsure whether POCT for poliomyelitis is externally quality assessed. |
| Q fever | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for Q fever are available. | In France, the survey respondent reported that POCT for Q fever is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for Q fever is either fully or partially reimbursed through the healthcare system. | respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of Q fever. In France, the survey respondent reported that POCT | In Norway, the survey respondent reported that POCT for Q fever is externally quality assessed. In France, the survey respondent reported that POCT for Q fever is not externally quality assessed. |
| Rabies | 1 | France (1) | In France, the survey respondent reported that guidelines covering the use of POCT for rabies are available. | In France, the survey respondent reported that POCT for rabies is fully reimbursed through the healthcare system. | respondent reported that POCT has not replaced other tests for | In France, the survey respondent reported that POCT for rabies is not externally quality assessed. |
| Rubella | 3 | Cyprus (1); France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for rubella are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for rubella are not available. | In Cyprus, France and Norway, survey respondents reported that POCT for rubella is fully reimbursed through the healthcare system. | respondents reported that POCT has not replaced other tests for the screening, triaging or | In Cyprus and Norway, survey respondents reported that POCT for rubella is externally quality assessed. In France, the survey respondent was unsure whether POCT for rubella is externally quality assessed. |
| Salmonellosis | 3 | France (2); Norway (1); Spain (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for salmonellosis are available. In Spain, the survey respondent was unsure whether guidelines covering the use of POCT for salmonellosis are available. | In France and Spain, survey respondents reported that POCT for salmonellosis is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT | In Spain, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of salmonellosis. In France, survey respondents reported that POCT has not | In Norway, the survey respondent reported that POCT for salmonellosis is externally quality assessed. In France, survey respondents reported that POCT for salmonellosis is not externally |

| | | | | for salmonellosis either fully or partially reimbursed thorough the healthcare system. | replaced other tests for the screening, triaging or diagnosis of salmonellosis. In Norway, the survey respondent was unsure on this point. | quality assessed. In Spain, the survey respondent was unsure on this point. |
|---|---|------------------------|--|---|--|---|
| Severe Acute Respiratory Syndrome (SARS) | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for Severe Acute Respiratory Syndrome (SARS) are available. | In France and Norway, survey respondents reported that POCT for Severe Acute Respiratory Syndrome (SARS) is fully reimbursed through the healthcare system. | In France and Norway, survey respondents reported that POCT has not replaced other tests for the screening, triaging or diagnosis of Severe Acute Respiratory Syndrome (SARS). | In France, survey respondents reported that POCT for Severe Acute Respiratory Syndrome (SARS) is not externally quality assessed. |
| Shigellosis | 3 | | In France and Norway, survey respondents reported that guidelines covering the use of POCT for shigellosis are available. In Spain, the survey respondent was unsure whether guidelines covering the use of POCT for shigellosis are available. | In France and Spain, survey respondents reported that POCT for shigellosis is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for shigellosis is either fully or partially reimbursed through the healthcare system. | In Norway, the survey respondent reported that POCT has not replaced other tests for | In Norway, the survey respondent reported that POCT for shigellosis is externally quality assessed. In Spain, the survey respondent was unsure whether POCT for shigellosis is externally quality assessed. In France, survey respondents also indicated uncertainty on this point. |
| Smallpox | 1 | Norway (1) | In Norway, the survey respondent reported that guidelines covering the use of POCT for smallpox are available. | In Norway, the survey respondent reported that POCT for smallpox is fully reimbursed through the healthcare system. | In Norway, the survey respondent was unsure whether POCT has replaced other tests for the screening, triaging or diagnosis of smallpox. | In Norway, the survey respondent reported that POCT for smallpox is not externally quality assessed. |
| Tick borne encephalitis | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for tick borne encephalitis are available. | No responses were received. | In France and Norway, survey respondents reported that POCT has not replaced other tests for the screening, triaging or diagnosis of tick borne encephalitis. | In France and Norway, survey respondents reported that POCT for tick borne encephalitis is not quality assessed. |
| Tetanus | 2 | | In France, the survey respondent reported that guidelines covering the use of POCT for tetanus are available. In Belgium, the survey respondent reported that guidelines covering the use of POCT for tetanus are not available. | In France, the survey respondent reported that POCT for tetanus is fully reimbursed through the healthcare system. In Belgium, the survey respondent reported that POCT for tetanus is paid for entirely by patients and not reimbursed. | In Belgium, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of tetanus. In France, the survey respondent was unsure whether POCT for tetanus has replaced other tests. | In Belgium, the survey respondent reported that POCT for tetanus is not externally quality assessed. In France, the survey respondent was unsure whether POCT for tetanus is externally quality assessed. |

¹ Due to an error in the survey, respondents were not asked about arrangements for reimbursement of POCT for tick borne encephalitis.

| Toxoplasmosis, congenital | 3 | Cyprus (1); France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for toxoplasmosis, congenital are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for toxoplasmosis, congenital are not available. | In Cyprus, France and Norway, survey respondents reported that POCT for toxoplasmosis, congenital is fully reimbursed through the healthcare system. | In Cyprus, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of toxoplasmosis, congenital. In France and Norway, survey respondents were unsure whether POCT for toxoplasmosis, congenital has replaced other tests. | In Cyprus, the survey respondent reported that POCT for toxoplasmosis, congenital is externally quality assessed. In France and Norway, survey respondents were unsure whether POCT for toxoplasmosis, congenital is quality assessed. |
|---|---|------------------------------------|--|---|---|---|
| Trichinellosis | 1 | France | In France, the survey respondent reported that guidelines covering the use of POCT for trichinellosis are available. | In France, the survey respondent reported that POCT for trichinellosis is fully reimbursed through the healthcare system. | In France, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of trichinellosis. | In France, the survey respondent reported that POCT for trichinellosis is not externally quality assessed. |
| Transmissible spongiform encephalopathies | 1 | France | In France, the survey respondent reported that guidelines covering the use of POCT for transmissible spongiform encephalopathies are available. | In France, the survey respondent reported that POCT for transmissible spongiform encephalopathies is fully reimbursed through the healthcare system. | In France, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of transmissible spongiform encephalopathies. | In France, the survey respondent reported that POCT for transmissible spongiform encephalopathies is not externally quality assessed. |
| Tularaemia | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for tularaemia are available. | In France, the survey respondent reported that POCT for tularaemia is fully reimbursed through the healthcare system. Norway, the survey respondent reported that POCT for tularaemia is either fully or partially reimbursed through the healthcare system. | has not replaced other tests for the screening, triaging or diagnosis of tularaemia. In France, the survey respondent was unsure whether POCT for tularaemia has | In Norway, the survey respondent reported that POCT for tularaemia is externally quality assessed. In France, the survey respondent was unsure whether POCT for tularaemia is externally quality assessed. |
| Typhoid and paratyphoid | 3 | France (1); Norway (1); Spain (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for typhoid and paratyphoid are available. In Spain, the survey respondent was unsure whether guidelines covering the use of POCT for typhoid and paratyphoid are available. | In France, Norway and Spain, survey respondents reported that POCT for typhoid and paratyphoid is fully reimbursed through the healthcare system. | In Spain, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of typhoid and paratyphoid. In Norway, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of typhoid and paratyphoid. In France, the survey respondent was unsure whether POCT for typhoid and paratyphoid has replaced other tests. | In Norway, the survey respondent reported that POCT for typhoid and paratyphoid is externally quality assessed. In France and Spain, survey respondents were unsure whether POCT for typhoid and paratyphoid is externally quality assessed. |

| Variant Creutzfeldt- Jakob's disease | 3 | Cyprus (1); France (1); Norway (1) | In Norway, the survey respondent reported that guidelines covering the use of POCT for Variant Creutzfeldt-Jakob's disease are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for Variant Creutzfeldt-Jakob's disease are not available. In France, survey responses indicated uncertainty on this point. | In France, the survey respondent reported that POCT for Variant Creutzfeldt-Jakob's disease is fully reimbursed through the healthcare system. In Cyprus and Norway, survey respondents left this field blank. | respondent was unsure whether POCT has replaced other tests for the screening, triaging or diagnosis of Variant Creutzfeldt-Jakob's disease. | In France, the survey respondent was unsure whether POCT for Variant Creutzfeldt-Jakob's disease is externally quality assessed. In Cyprus and Norway, survey respondents left this field blank. |
|---|---|------------------------------------|--|---|---|--|
| Viral haemorrhagic fevers | 3 | Cyprus (1); France (2); Norway (1) | In Cyprus and Norway, survey respondents reported that guidelines covering the use of POCT for viral haemorrhagic fevers are available. In France, survey responses indicated uncertainty regarding the availability of guidelines. | In Cyprus, France and Norway, survey respondents reported that POCT for viral haemorrhagic fevers is fully reimbursed through the healthcare system. | respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of viral haemorrhagic fevers. In Cyprus, the survey respondent reported that POCT has not replaced other tests for | In Norway, the survey respondent reported that POCT for viral haemorrhagic fevers is externally quality assessed. In Cyprus, the survey respondent reported that POCT for viral haemorrhagic fevers is not externally quality assessed. In France, survey responses indicated uncertainty on this point. |
| West Nile virus infection | 3 | Cyprus (1); France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for West Nile virus infection are available. In Cyprus, the survey respondent reported that guidelines covering the use of POCT for West Nile virus infection are not available. | In Cyprus, France and Norway, survey respondents reported that POCT for West Nile virus infection is fully reimbursed through the healthcare system. | respondent reported that POCT for West Nile virus infection has not replaced other tests for the | In Cyprus, the survey respondent reported that POCT for West Nile infection virus is externally quality assessed. In France and Norway, survey respondents were unsure whether POCT for West Nile infection virus is externally quality assessed. |
| Yellow fever | 1 | France (1) | In France, the survey respondent reported that guidelines covering the use of POCT for yellow fever are available. | In France, the survey respondent reported that POCT for yellow fever is fully reimbursed through the healthcare system. | In France, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of yellow fever. | In France, the survey respondent reported that POCT for yellow fever is not externally quality assessed. |
| Yersinosis | 3 | France (2); Norway (1); Spain (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for yersinosis are available. In Spain, the survey respondent was unsure whether guidelines covering the use of POCT for yersinosis are available. | In France and Spain, survey respondents reported that POCT for yersinosis is fully reimbursed through the healthcare system. In Norway, the survey respondent reported that POCT for yersinosis is either fully or partially reimbursed. | In Spain, the survey respondent reported that POCT has replaced other tests for the screening, triaging or diagnosis of yersinosis. In Norway, the survey respondent reported that POCT has not replaced other tests for the screening, triaging or diagnosis of yersinosis. In France, survey responses indicated uncertainty on this point. | In Norway and Spain, survey respondents were uncertain whether POCT for yersinosis is externally quality assessed. France, survey respondents also indicated uncertainty on this point. |

| Zika virus disease | 2 | France (1); Norway (1) | In France and Norway, survey respondents reported that guidelines covering the use of POCT for zika virus disease are available | In France and Norway, survey respondents reported that POCT for zika virus diseases is fully reimbursed through the healthcare system. | respondent reported that POCT | In France and Norway, survey respondents were unsure whether POCT for zika virus disease is externally quality assessed. |
|--------------------|---|------------------------|---|--|-------------------------------|--|
|--------------------|---|------------------------|---|--|-------------------------------|--|

8 Conclusion

The recent COVID-19 pandemic highlighted the essential role of large-scale POCT for the surveillance, prevention and control of infectious diseases. Alongside centralised laboratory-based testing, the development of rapid and reliable diagnostic tests, usable at the point of care, has been recognised as necessary to adequately meet public health needs.¹

The aim of this mapping exercise was to map the current use of POCT and near-patient testing in clinical infectious disease management and public health practice in EU/EEA Member States and the UK. Using a mapping survey of key stakeholders and experts across EU/EEA Member States and the UK, combined with follow-up interviews and desk-based research, the study has provided evidence on the availability of POCT devices, the arrangements surrounding their use (guidelines, reimbursement, quality assessment) and their impact on clinical practice. The mapping exercise has also provided evidence on the impact of POCT in relation to clinical disease management and public health key functions.

Given the limitations outlined in Section 2.1, the evidence it has presented is unlikely to be a complete picture of POCT use across the EU/EEA Member States and the UK. While the low number of responses to the survey has been one factor here, it evident that there are also more fundamental challenges associated with the use of a survey methodology to collect factual data on the state of POCT across 56 diseases and related health issues. Most notably, mixed responses to survey questions provided by respondents from the same country has made it difficult to reach firm conclusions about the uses of POCT in some countries. Related to this, the significant amount of uncertainty throughout the survey results suggests that many of those who responded, while perhaps having expert knowledge in specific areas of clinical practice, may have been unsure about the uses of POCT in other areas. Variations in the reported use of POCT across different countries also raise questions about the extent to which all respondents understood the questions in the same way. Notwithstanding these limitations, the findings of this mapping exercise should nevertheless serve as a source of information for ECDC and key stakeholders to support future decision-making in this area.

Below we summarise the key findings of this research. First, we provide key findings on the infectious diseases or health issues for which most EU/EEA Member States and the UK have POCT in routine clinical use, together with findings on which countries have POCT in place for the highest number or infectious diseases or health issues. Second, we summarise the mapping exercise findings regarding the extent to which POCT for infectious diseases is covered by guidelines, reimbursement mechanisms and quality assessment procedures, viewed from both a disease and a country perspective. Then, we summarise key findings of the mapping exercise regarding the extent to which POCT has replaced other diagnostic tests, again from a disease and a country perspective. Finally, we review key findings concerning the use of POCT in public health key functions within EU/EEA Member States and the UK.

Availability of POCT in routine clinical use

Infectious diseases and associated health issues for which POCT is in routine clinical use in EU/EEA Member States and the UK

- According to the results of the mapping exercise, influenza is the disease or health issue for which most countries have POCT in routine clinical use (19 countries).
- The disease or health issue with the second highest number of countries reporting POCT is routine clinical use was HIV/AIDS (17 countries).
- POCT was also reported to be in routine clinical use for the following diseases or health issues in at least five countries: malaria; legionnaires' disease; syphilis; chlamydia infections; hepatitis B; hepatitis C; nosocomial infections; antimicrobial resistance; tuberculosis; invasive pneumococcal disease; dengue; invasive meningococcal disease; gonorrhoea and cryptosporidiosis.

Countries in which POCT is in routine clinical use for the most infectious disease and associated health conditions

- According to the results of the mapping survey, the countries in which the most infectious diseases or associated health issues are covered by POCT are France (55 diseases), Norway (48 diseases), Cyprus (25 diseases) and Spain (25 diseases).
- In the following countries, POCT was reported to be in routine clinical use for at least five infectious diseases or health issues: Denmark; Austria; Germany; Greece; Sweden; Croatia; Malta; Estonia; the Netherlands.

i https://www.ecdc.europa.eu/sites/default/files/documents/Overview-rapid-test-situation-for-COVID-19-diagnosis-EU-EEA.pdf

Guidelines, reimbursement and external quality assessment of POCT

Infectious diseases and associated health issues for which POCT guidelines, reimbursement and external quality assessment are available

- The disease or health issue for which most countries reported that guidelines or similar documentation are available is HIV/AIDS (11 countries), closely followed by influenza (nine countries). Across all diseases and health issues, the mapping exercise results suggested considerable uncertainty about the existence of guidelines.
- The disease or health issue for which most countries reported that POCT is either fully or partially reimbursed is HIV/AIDS (15 countries), closely followed by influenza (13 countries). Overall, the mapping survey responses suggest that POCT is fully or partially reimbursed across most diseases and health issues.
- The disease or health issue for which most countries reported that POCT is externally quality assessed is
 HIV/AIDS (seven countries). The following diseases or health issues were reported to have external quality
 assessment mechanisms in place for POCT in four countries: antimicrobial resistances; influenza;
 legionnaires' disease and tuberculosis. The results suggest that external quality assessment of POCT is less
 common than reimbursement and guidelines.

Countries in which POCT guidelines, reimbursement and external quality assessment are available

- The countries in which the highest number of diseases have POCT guidelines in place, according to the mapping survey, are France (50 diseases) and Norway (47 diseases). The only other country reporting POCT guidelines for more than five diseases or health issues was Spain (seven diseases).
- Overall, the mapping exercise results suggest that POCT for infectious diseases is either fully or partially reimbursed in most countries where it is in routine clinical use. In the following countries, survey responses indicated that POCT was either fully or partially reimbursed across all diseases or health issues for which it was in routine clinical use: France; Cyprus; Austria; Croatia; Malta; Sweden; Romania; Slovenia; the United Kingdom; Ireland and Slovakia.
- Countries in which POCT is externally quality assessed for the most diseases, according to the mapping survey, are Norway (29 diseases) and Cyprus (23 diseases). In several countries, respondents demonstrated a high degree of uncertainty concerning whether or not POCT is quality assessed.

POCT and replacement of other diagnostic testsⁱ

Infectious diseases and associated health issues for which POCT has replaced other diagnostic tests

- Chlamydia infections, HIV/AIDS and legionnaires' disease were the diseases or health issues for which most
 countries reported that POCT has replaced other tests for screening, triaging or diagnosis. In all three cases,
 however, only two countries reported that POCT has replaced other tests.
- Across all diseases and health issues, the results of the mapping exercise suggest a low number of cases in which POCT has replaced other forms of diagnostic test.

Countries in which POCT has replaced other diagnostic tests

- The country in which POCT has had the most significant clinical impact, in terms of replacement of other tests is Spain where it was reported that POCT had replaced other test for 14 infectious diseases or health issues. The only other countries in which respondents reported that POCT had replaced an existing set of tests were Slovenia, Austria, Cyprus, Norway, Belgium, Denmark and Sweden.
- Across all countries, the results of the mapping survey suggest a low number of cases in which POCT has replaced other forms of diagnostic test.

POCT and public health key functions in EU/EEA Member States and the UK

- The public health function which most countries reported POCT-derived results being used for was disease surveillance, reported by seven countries (Belgium, Bulgaria, Cyprus, Finland, Latvia, Slovakia, Slovenia).
- Respondents from six countries surveillance (Belgium, Bulgaria, Finland, France, Slovakia and Slovenia)
 reported that POCT results are used for national reporting of infectious disease, with five countries (Belgium, Bulgaria, Cyprus, Finland, Slovenia) reporting that POCT results are used in national surveillance systems.
- No countries reported that POCT-derived results are used for antibiotic resistance monitoring.
- For all the public health functions addressed in the study, countries were more likely to report that POCT-derived results were not used rather than that they were used.

¹ It is important to note here that the replacement of a test by POCT does not necessarily mean that an infectious disease is diagnosed using POCT in isolation. It is likely that further (non-POCT) testing is conducted to confirm a diagnosis.

In addition to the above findings, this mapping report has also provided a more detailed analysis of the state of POCT in relation to 11 select infectious diseases within the EU/EEA. By looking at which countries make routine clinical use of POCT across these diseases, and by highlighting the different arrangements (guidelines, reimbursement, replacement, quality assessment) surrounding POCT in each case, this analysis has highlighted in more specific terms the ways in which the implementation of POCT differs, both across different diseases and health issues and across different EU/EEA Member States and the UK. Furthermore, this report has also provided summary analyses of the state of POCT implementation within EU/EEA Member States and the UK for each of the 56 infectious diseases or health issues within the scope of the study.

8.1 Questions this analysis has raised

The findings of this mapping review raise several questions and possible areas for future research:

- Why do some infectious diseases and health issues have POCT in routine clinical use in many EU/EEA Member States and the UK, while other diseases and health issues do not?
- Why do some countries have POCT in routine use for more infectious diseases or health issues than others?
- Why are POCT-related guidelines more widely available for some infectious diseases and health issues than for others? Why are guidelines more widely available in some countries than others?
- What reasons might underpin the uncertainty of many mapping survey responses on the question of quidelines for POCT?
- While most countries appear to either fully or partially reimburse POCT through the healthcare system, what are the reasons why reimbursement might not be available for POCT?
- Why is it that external quality assessment of POCT is generally low across all infectious diseases and health issues? Why is POCT for some diseases or health issues externally quality assessed, but POCT for others not? Why do some countries quality assess POCT more consistently than others?
- What factors (e.g. specificity and sensitivity, availability) underpin the low number of cases in which POCT
 has replaced other tests for the screening, triaging or diagnosis of infectious diseases? How have these
 factors been overcome in those instances where POCT has replaced other tests? What are the implications
 of this for ongoing efforts to develop POCT availability in the context of COVID-19?
- What are the reasons why POCT-derived results are not widely used in the public health key functions addressed in this study? What factors underpin the differences between EU/EEA Member States and the UK in this respect?
- Finally, considering the challenges faced in gathering factual data on the use and impact of POCT through this mapping survey, what alternative methodologies might be used to further build the knowledge base in this area?

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¹ Presented in a tabular format in Section 7 of this report, the key findings for each disease and health issue are also presented in the form of heatmaps in Annex 7.

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Annex 1 Survey protocol

This annex includes the survey as it was provided on the EUSurvey platform. The survey form builds on the final mapping protocol which was adapted to align with the technical requirements of the EUSurvey platform.

Annex 2 Scoping interview protocol

This annex provides the protocol used to conduct a scoping interview to assist with the development of the mapping survey, as described in Section 2.1 of this report.

Background and overview of the study

RAND Europe (a not-for-profit research organisation) is conducting an assessment of which infectious diseases and other health-related issues point of care testing (POCT), also termed near patient testing, is available for across EU and EEA countries. We are exploring the extent of use of POCT in clinical practices and how this varies across EU and EEA countries, and the subsequent impacts of using POCT on reporting test results to patients and on public health. This work has been commissioned by the European Centre for Disease Prevention and Control (ECDC).

As part of this study, we are conducting a series of scoping interviews with experts on the availability and use of POCT devices across EU and EEA countries for public health purposes. The purpose of the scoping interviews is to provide the research team with an understanding of the availability and extent of POCT device usage across the EU and EEA countries at a high-level. The interviews will also inform the development of a survey on the current status of POCT across EU and EEA Member States.

Introductory question

Could you briefly describe your role and how it relates to POCT and infectious diseases?

Availability of POCT devices and guidelines

- For the purpose of this study, we have defined a POCT device as a handheld or portable device that can provide a diagnostic result in 90 minutes or less and that is delivered to the end user (i.e. used near the patient rather than in a laboratory setting). Do you feel this definition captures the most important aspects of a POCT device?
 - If yes, as there are differing views on what constitutes a POCT device, or do you think the majority of users and developers of these devices would agree with this definition?
 - If no, what additional characteristics would a POCT device possess that we haven't covered?
- To the best of your knowledge, for which infectious diseases is POCT commonly used for?
 - Is there variation across EU and EEA countries in the types of diseases POCT is used for, e.g. pathogen identification, antibiotic susceptibility testing?
- Are there any specific settings or diseases in which the use of POCT device is widely implemented?
- What specific public health functions is POCT used for in Europe?

Use of POCT in clinical practice

- In general, are guidelines or recommendations available to clinicians for those diseases for which POCT are available for clinical use?
 - Is there variation across EU and EEA countries as to whether guidelines/recommendations are available to clinicians?
- Are POCT devices routinely used in clinical practice for infectious diseases and related health issues?
 - If yes: is the use of POCT for infectious diseases reimbursed?
- Have you seen POCT replace traditional diagnostic techniques for any diseases?
 - If yes, for which diseases?

The impact of POCT devices

- What impact has the use of POCT devices had on patient-level activities, e.g. reporting test results?
- What impact has the use of POCT devices had on public health-level activities, e.g. surveillance, infection/outbreak control?

Annex 3 Follow-up interview protocol

This annex provides the protocol used to conduct follow-up interviews, as described in Section 2.1 of this report.

Introduction

RAND Europe (a not-for-profit research organisation based in Cambridge, UK) has been commissioned by the European Centre for Disease Prevention and Control (ECDC) to conduct an assessment of the use of point of care testing (POCT) devices for infectious disease surveillance, prevention and control within EU/EEA countries. This study is part of a framework contract on the assessment of new technologies for infectious disease surveillance, prevention and control.

Part of this study consists of a mapping exercise that seeks to map the current status of the use of POCT devices and their use for surveillance of infectious diseases and related special health issues in EU/EEA countries for the 56 diseases under EU surveillance. We have also conducted a scoping review on this topic, and plan to have a technical meeting where we bring experts from across Europe to discuss how POCT can be used for infectious disease surveillance, prevention and control.

We conducted a survey across EU/EEA countries as part of this exercise, but unfortunately did not receive responses from some EU/EEA countries. This includes [COUNTRY], which is why you have been contacted. You are being interviewed as an expert in infectious diseases and POCT in [country], although we realise you may not have information about every disease or POCT device.

In this interview I'll ask you about some of the diseases that we've prioritised in our study. We will also cover some general question about how POCT is used in [COUNTRY], and in Europe in general.

Background and role

• Before we begin, could you please let me know your professional role and how long you have been working in the area of infectious diseases or microbiology?

POCT for specific infectious diseases

In this portion of the interview, we'll go through a series of questions about specific infectious diseases which we are prioritising to fill in gaps from our survey data. If you don't know the answer for any particular disease, please just let me know and we can move on to the next disease. We have selected these diseases based on their prevalence in Europe and the likelihood that they have POCT available based on our findings up to this point.

By point of care testing (POCT), we refer to testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient. The test also needs to be turned around in 90 minutes or less. Patient self-testing in a home or community environment is excluded from this definition. This is the ISO definition.

- Are you aware of a POCT device for [DISEASE] that is in routine clinical use in [COUNTRY]?
 - Are there official guidelines, recommendations, patient care pathways or other official documentation for practitioners on POCT for [DISEASE]?
 - How is POCT for [DISEASE] paid for in [COUNTRY]?
 - Has POCT for [DISEASE] replaced a previous test for screening, triaging or diagnosis, and if so, what test was used previously?
 - Has POCT for [DISEASE] been externally quality assessed?
 - Are results obtained through POCT sufficient to make a final diagnosis for [DISEASE]?

[Repeat questions 2a-e for all diseases on priority list]

• Do you know of any other diseases other than the ones we just discussed for which POCT is available in [COUNTRY]? [If yes, go through the questions above for that disease]

Impact of POCT devices

- Can you describe how POCT results are used in [COUNTRY] for public health purposes?
 - Are POCT results used in [COUNTRY] for disease surveillance purposes?
 - Are POCT results fed into the **national surveillance system** in [COUNTRY]?
 - Are POCT results used in [COUNTRY] for outbreak investigation?
 - Are POCT results used in [COUNTRY] for infection control?

¹ ISO. 2016. ISO 22870:2016. Accessible at: https://www.iso.org/obp/ui/#iso:std:iso:22870:ed-2:v1:en

- Are POCT results used for antimicrobial resistance monitoring in [COUNTRY]?
- Are POCT results used in [COUNTRY] for nosocomial infection monitoring?
- Are POCT results used in [COUNTRY] for national reporting?

POCT in EU/EEA countries

Thanks for telling us a little bit about POCT in [COUNTRY]. In the next section, we'll ask a little bit more about POCT across EU/EEA countries, and how POCT use may differ between countries.

- What factors might influence whether or not a country has POCT available for any particular disease?
- What are some of the main advantages of using POCT rather than other methods to diagnose infectious diseases?
- What are some of the main challenges with using POCT rather than other methods to diagnose infectious diseases?
- Do you think POCT will play a role in public health functions such as outbreak detection and disease surveillance in the future?

Closing interview

• Is there anything else you think would be relevant to our study that we haven't had the chance to talk about in this interview?

Thank you for taking the time to speak with us today.

Annex 4 Key search terms used for deskbased research

This annex includes the key Google search terms used during targeted searches undertaken during follow-up desk-based research, as described in Section 2.1 of this report.

Quality assessment:

| [country name] | AND | [disease name OR disease abbreviation] | AND | ("POCT" OR "POC" OR "point of care" OR "point of care | AND | (Quality assessment OR accreditation OR quality control OR quality management) |
|----------------|-----|--|-----|---|-----|--|
| | | | | test") | | |

Reimbursement:

| [country name] | AND | [disease name OR disease abbreviation] | AND | ("POCT" OR "POC" OR "point of care" OR "point of care test") | AND | (reimbursement OR payment OR paid for OR cost OR recovery) |
|----------------|-----|--|-----|--|-----|--|
| _ | | _ | | | | · |

Guidelines:

| [country name] | AND | [disease name OR disease abbreviation] | AND | ("POCT" OR "POC" OR "point of care" OR "point of care | AND | (replacement OR clinical use OR uptake OR implementation OR diagnosis) |
|----------------|-----|--|-----|---|-----|--|
| | | | | test") | | |

Replacement:

| [country | AND | [disease name OR | AND | ("POCT" OR "POC" OR "point of | AND | (guidelines OR recommendations |
|----------|-----|-----------------------|-----|--------------------------------|-----|--------------------------------|
| name] | | disease abbreviation] | | care" OR "point of care test") | | OR patient care pathways) |

Annex 5 Shortlists used to select focus infectious diseases

This annex provides the shortlists developed to select priority infectious disease for detailed analysis. The methodology for developing the shortlists in described in sections 2.1 and 6.1 of this report.

Table 19 lists diseases shortlisted through a basic quantitative analysis of the mapping exercise review. The diseases within this shortlist are those which the most countries reported that POCT was in routine clinical use.

Table 19. Shortlist of diseases based on mapping exercise

| Mapping exercise priority disease shortlist |
|---|
| Influenza – incl. influenza A(H1N1) |
| HIV infection and AIDS |
| Malaria |
| Legionnaires' disease |
| Syphilis |
| Chlamydia infections |
| Hepatitis B |
| Hepatitis C |
| Nosocomial infections |
| Antimicrobial resistance |
| Tuberculosis |
| Invasive pneumococcal disease |

Table 20 lists diseases shortlisted through a basic quantitative analysis of the scoping review. The diseases within this shortlist are those to which POCT was applied most frequently within the literature reviewed in the scoping review.

Table 20. Shortlist of diseases based on scoping review

| coping review priority disease shortlist |
|--|
| fluenza |
| IV |
| epatitis C |
| В |
| yphilis |
| hlamydia trachomatis |
| alaria |
| epatitis B |
| engue |
| roup A Streptococcus |
| onorrhoea |
| rytosporidiosis |

Table 21 lists diseases shortlisted using ECDC Surveillance Atlasⁱⁱ data for the age-standardised rate. The diseases within this shortlist are those with the highest age-standardised rate.ⁱⁱⁱ

Table 21. Shortlist of diseases based on ECDC Surveillance atlas data (age-standardised rate)

| ECDC Surveillance Atlas data shortlist (age-standardised rate) | |
|--|--|
| Campylobacteriosis | |
| Salmnoellosis | |
| Tuberculosis | |

¹ ECDC, Scoping review: Assessment of point of care testing devices for infectious disease surveillance, prevention and control.

ii Available at: https://www.ecdc.europa.eu/en/surveillance-atlas-infectious-diseases

Age-standardised rate data reflected the year 2018, or, where this was not available, 2017. ECDC Surveillance Atlas does not hold age-standardised rate data for the following diseases or health issues: antimicrobial resistance; anthrax; chlamydia infection; lymphogranuloma venereum Creutzfeldt-Jakob disease, variant cryptosporidiosis; diphtheria; gonorrhoea; healthcare associated infections: surgical site infections; influenza; measles; rubella; syphilis (congenital); toxoplasmosis (congenital); zika virus.

| lepatitis C | |
|------------------------------|--|
| Pertussis | |
| Syphilis | |
| nvasive pneumococcal disease | |
| HV Infection | |
| Siardiasis | |
| lepatitis B | |
| lepatitis A | |
| /lumps | |

Table 22 lists diseases shortlisted using ECDC Surveillance Atlasⁱ data for number of cases. The diseases within this shortlist are those with the highest age-standardised rate.ⁱⁱ

Table 22. Shortlist of diseases based on ECDC Surveillance atlas data (number of cases)

| ECDC Surveillance Atlas data shortlist (number of cases) |
|--|
| Campylobacteriosis |
| Gonorrhoea |
| Salmonellosis |
| Tuberculosis |
| Hepatitis C |
| Pertussis |
| Syphilis |
| HIV Infection |
| Invasive pneumococcal disease |
| Giardiasis |
| Hepatitis A |
| Cryptosporidiosis |

ⁱ https://www.ecdc.europa.eu/en/surveillance-atlas-infectious-diseases

ⁱⁱ For 'number of cases', we used data on 'confirmed' reported cases where this was available, and 'all' reported cases where it was not. Number of cases data reflected the year 2018, or, where this was not available, 2017. ECDC Surveillance Atlas does not hold number of cases data for the following diseases or health issues: antimicrobial resistance; chlamydia infection; healthcare associated infections: surgical site infections; hepatitis b; influenza; measles; rubella.

Annex 6

This annex provides a table indicating the infectious diseases or associated health issues for which we have information that POCT is in routine clinical use, shown by each EU/EEA country. The table presents findings from the mapping survey only. The countries are identified using a two-letter country code based on the ISO 3166-1 alpha-2 codes. A separate table providing a mapping of the two-letter country codes and country names is included at the end of Annex 6.

Country mapping table for all infectious diseases

| Disease | ΑT | ВЕ | BG | HR | CY | CZ | DK | EE | FI | FR | DE | GR | HU | IS | ΙE | ΙT | LV | LI | LT | LU | МТ | NL | NO | PL | РΤ | RO | SK | SI | ES | SE | UK |
|-----------------------------|----------|----------|----------|----------|----------|----|----|----------|----|----------|----------|----------|----|----------|----|----|----------|----|----|----|----------|----------|----------|----|----|----------|----|----|----------|----------|----|
| Anthrax | | | | | | | | | | ✓ | | | | | | | | | | | | | √ | | | | | | | | |
| Antimicrobial resistance | | | | | √ | | | | | √ | | √ | | | | | | | | | | ✓ | √ | | | | | | √ | √ | |
| Botulism | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Brucellosis | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | ✓ | | |
| Campylobacteriosis | | | | | | | | | | √ | | | | | | | | | | | | | √ | | | | | | ✓ | | |
| Chikungunya virus disease | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Chlamydia infections | | | √ | | ✓ | | | | | ✓ | | ✓ | | √ | | | | | | | √ | | ✓ | | | | | | ✓ | | |
| Cholera | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | ✓ | | |
| Cryptosporidiosis | | | | | ✓ | | | ✓ | | ✓ | | | | | | | | | | | | | ✓ | | | | | | ✓ | | |
| Dengue | ✓ | | | | | | | | | ✓ | ✓ | | | | | | | | | | | | ✓ | | | | | | ✓ | | |
| Diphtheria | | | | | | | | | | √ | | | | | | | | | | | | | √ | | | | | | | | |
| Echinococcosis | | | | | | | | | | √ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Giardiasis | | | | | √ | | | | | √ | | | | | | | | | | | | | √ | | | | | | ✓ | | |
| Gonorrhoea | | | | | ✓ | | | | | √ | | | | | | | | | | | ✓ | | ✓ | | | | | | ✓ | | |
| Hepatitis A | | | | | ✓ | | | | | √ | | | | | | | | | | | | | √ | | | | | | | | |
| Hepatitis B | | | | √ | ✓ | | | | | √ | | | | | | | | | | | √ | | √ | | | √ | | | ✓ | | |
| Hepatitis C | | | | √ | ✓ | | | | | ✓ | | | | | | | | | | | √ | | √ | | | √ | | | ✓ | | |
| HIV infection and AIDS | | √ | | √ | √ | | ✓ | √ | ✓ | √ | √ | | | | ✓ | | √ | | | | √ | √ | √ | | | √ | | | ✓ | ✓ | 1 |
| Infections with haemophilus | √ | | | | | | | | | ✓ | √ | | | | | | | | | | | | √ | | | | | | | | |

i https://www.iso.org/publication/PUB500001.html

75

| Disease | ΑT | ВЕ | BG | HR | CY | CZ | DK | EE | FI | FR | DE | GR | HU | IS | ΙE | ΙΤ | L۷ | LI | LT | LU | МТ | NL | NO | PL | РΤ | RO | SK | SI | ES | SE | UK |
|---|----------|----------|----------|----------|----------|----|----------|----------|----------|----------|----------|----------|----|----|----|----|----|----|----|----|----|----------|----------|----------|----|----------|----------|----------|----------|----------|----------|
| influenzae group B | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Influenza – including influenza A(H1N1) | 1 | √ | | 1 | √ | | ✓ | √ | √ | √ | √ | √ | | | | | ✓ | | | | | √ | ✓ | | | √ | √ | √ | √ | √ | √ |
| Invasive meningococcal disease | | | | | √ | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | ✓ | √ | | |
| Invasive pneumococcal disease | √ | | | | √ | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | ✓ | √ | √ | | |
| Legionnaires' disease | ✓ | | | | ✓ | | | √ | ✓ | ✓ | ✓ | | | | | | ✓ | | | | | | ✓ | ✓ | | | | ✓ | ✓ | ✓ | ✓ |
| Leptospirosis | | | √ | | | | | | | ✓ | | | | | | | | | | | | | | | | | | | | | |
| Listeriosis | | | | | ✓ | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Lyme neuroborreliosis | | | | | ✓ | | | | | ✓ | | | | | | | | | | | | | √ | | | | | | | | |
| Malaria | √ | √ | | √ | ✓ | | √ | √ | | ✓ | ✓ | √ | | | | | ✓ | | | | | | ✓ | | | | | | ✓ | ✓ | |
| Measles | | | | | √ | | | | | ✓ | | | | | | | | | | | | | √ | | | | | | | | |
| Mumps | | | | | ✓ | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Nosocomial infections | | | | | | | ✓ | | | √ | √ | ✓ | | | | | | | | | | ✓ | ✓ | | | | | | ✓ | | |
| Pertussis | | | | | ✓ | | | | | ✓ | | | | | | | | | | | | | | | | | | | | | |
| Plague | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Poliomyelitis | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Q fever | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Rabies | | | | | | | | | | ✓ | | | | | | | | | | | | | | | | | | | | | |
| Rubella | | | | | ✓ | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Salmonellosis | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | ✓ | | |
| Severe Acute Respiratory Syndrome (SARS) | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Shiga- toxin/verocytotoxin- producing Escherichia coli (STEC/VTEC) infection | √ | | | | | | | | | √ | | | | | | | | | | | | | √ | | | | | | √ | | |
| Shigellosis | | | | | | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | ✓ | | |
| Smallpox | | | | | | | | | | | | | | | | | | | | | | | ✓ | | | | | | | | |

| Disease | AT | ВЕ | ВG | HR | CY | CZ | DK | EE | FI | FR | DE | GR | HU | IS | ΙE | IT | L۷ | LI | LT | LU | MT | NL | NO | PL | PT | RO | SK | SI | ES | SE | UK |
|---|----|----|----|----|----------|----|----|----|----------|----------|----|----|----|----|----|----|----|----|----|----|----|----------|----------|----|----|----|----|----|----------|----|----|
| Syphilis | | | | ✓ | ✓ | | | | | ✓ | | ✓ | | | √ | | | | | | ✓ | | ✓ | | | | | | ✓ | | |
| Tetanus | | ✓ | | | | | | | | ✓ | | | | | | | | | | | | | | | | | | | | | |
| Tick borne encephalitis | | | | | | | | | | √ | | | | | | | | | | | | | √ | | | | | | | | |
| Toxoplasmosis, congenital | | | | | ✓ | | | | | √ | | | | | | | | | | | | | √ | | | | | | | | |
| Transmissible spongiform encephalopathies | | | | | | | | | | √ | | | | | | | | | | | | | | | | | | | | | |
| Trichinellosis | | | | | | | | | | ✓ | | | | | | | | | | | | | | | | | | | | | |
| Tuberculosis | | | | | ✓ | | | | √ | ✓ | | ✓ | | | | | | | | | | √ | ✓ | | | | | | ✓ | | |
| Tularaemia | | | | | | | | | | √ | | | | | | | | | | | | | √ | | | | | | | | |
| Typhoid and paratyphoid | | | | | | | | | | √ | | | | | | | | | | | | | 1 | | | | | | √ | | |
| Variant Creutzfeldt– Jakob's disease | | | | | | | | | | √ | | | | | | | | | | | | | | | | | | | | | |
| Viral haemorrhagic fevers | | | | | √ | | | | | √ | | | | | | | | | | | | | 1 | | | | | | | | |
| West Nile virus infection | | | | | ✓ | | | | | ✓ | | | | | | | | | | | | | ✓ | | | | | | | | |
| Yellow fever | | | | | | | | | | ✓ | | | | | | | | | | | | | | | | | | | | | |
| Yersiniosis | | | | | | | | | | √ | | | | | | | | | | | | | ✓ | | | | | | ✓ | | |
| Zika virus disease | | | | | | | | | | √ | | | | | | | | | | | | | ✓ | | | | | | | | |

The following table provides a mapping of the two-letter country codes and the country names.

| Two-letter country code | Country |
|-------------------------|---------------|
| AT | Austria |
| BE | Belgium |
| BG | Bulgaria |
| HR | Croatia |
| CY | Cyprus |
| CZ | Czechia |
| DK | Denmark |
| EE | Estonia |
| FI | Finland |
| FR | France |
| DE | Germany |
| GR | Greece |
| HU | Hungary |
| IS | Iceland |
| IE | Ireland |
| IT | Italy |
| LV | Latvia |
| LI | Liechtenstein |
| LT | Lithuania |
| LU | Luxembourg |
| MT | Malta |

| Two-letter country code | Country |
|-------------------------|----------------|
| NL | Netherlands |
| NO | Norway |
| PL | Poland |
| PT | Portugal |
| RO | Romania |
| SK | Slovakia |
| SI | Slovenia |
| ES | Spain |
| SE | Sweden |
| UK | United Kingdom |

Annex 7 Survey heatmaps for all infectious diseases

This annex provides heatmaps indicating country-by-country responses to the following questions for each of the 56 infectious diseases or associated health issues:

- Are guidelines or other official documentation covering the use of POCT available?
- Has POCT replaced other tests for screening, triaging or diagnosis?
- Is POCT either fully or partially reimbursed by the healthcare system?
- Is POCT externally quality assessed?

Green cells represent fields where all respondents from the same country provided a positive response. Red cells represent fields where all respondents from the same country provided a negative response. Yellow cells represent fields where survey respondents provided mixed responses. Numbers indicate the number of survey responses received from a country within each field. For example, in the first heatmaps below (for anthrax), a yellow cell under 'Guidelines' for France indicates that survey respondents from that country provided a mixed response regarding the existence of guidelines covering POCT for anthrax. The number '2' in the cell indicates that two respondents answered this question.

The heatmaps present findings from the mapping survey only.

Anthrax

| Austria 0 0 0 | • |
|---------------------|---|
| Additid | 0 |
| Belgium 0 0 | 0 |
| Bulgaria 0 0 | 0 |
| Croatia 0 0 0 | 0 |
| Cyprus 0 0 0 | 0 |
| Denmark 0 0 0 | 0 |
| Estonia 0 0 0 | 0 |
| Finland 0 0 0 | 0 |
| France 2 2 2 | 2 |
| Germany 0 0 0 | 0 |
| Greece 0 0 0 | 0 |
| | 0 |
| | 0 |
| Latvia 0 0 0 | 0 |
| Liechtenstein 0 0 0 | 0 |
| Lithuania 0 0 0 | 0 |
| Malta 0 0 0 | 0 |
| Netherlands 0 0 0 | 0 |
| Norway 1 1 1 | 1 |
| Poland 0 0 0 | 0 |
| Romania 0 0 0 | 0 |
| Slovakia 0 0 0 | 0 |
| Slovenia 0 0 0 | 0 |
| Spain 0 0 0 | 0 |
| Sweden 0 0 0 | 0 |
| United Kingdom 0 0 | 0 |

Antimicrobial resistance

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 1 | 1 | 1 | 1 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 1 | 1 | 1 | 1 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 1 | 1 | 1 | 1 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Reimbursement Replacement Quality assessment Guidelines

Botulism

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Brucellosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | - | - | |

Reimbursement Replacement Quality assessment

Campylobacteriosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Chikungunya virus disease

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Reimbursement Replacement Quality assessment

Chlamydia infections

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 1 | 1 | 1 | 1 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 2 | 2 | 2 | 2 |
| Iceland | 1 | 1 | 1 | 1 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 1 | 1 | 1 | 1 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Cholera

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Reimbursement Replacement Quality assessment Guidelines

Cryptosporidiosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 1 | 1 | 1 | 1 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Dengue

| Austria | 1 | 1 | 1 | 1 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 1 | 1 | 1 | 1 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Reimbursement Replacement Quality assessment Guidelines

Diphtheria

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Echinococcosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Reimbursement Replacement Quality assessment Guidelines

Giardiasis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Gonorrhoea

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 1 | 1 | 1 | 1 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 2 | 2 | 2 | 2 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Hepatitis A

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Hepatitis B

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 1 | 1 | 1 | 1 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 2 | 2 | 2 | 2 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 1 | 1 | 1 | 1 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Reimbursement Replacement Quality assessment

Hepatitis C

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 1 | 1 | 1 | 1 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 1 | 1 | 1 | 1 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 1 | 1 | 1 | 1 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

HIV infection and AIDS

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 1 | 1 | 1 | 1 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 1 | 1 | 1 | 1 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 1 | 1 | 1 | 1 |
| Estonia | 1 | 1 | 1 | 1 |
| Finland | 1 | 1 | 1 | 1 |
| France | 2 | 2 | 2 | 2 |
| Germany | 1 | 1 | 1 | 1 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 1 | 1 | 1 | 1 |
| Latvia | 1 | 1 | 1 | 1 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 2 | 2 | 2 | 2 |
| Netherlands | 1 | 1 | 1 | 1 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 1 | 1 | 1 | 1 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 1 | 1 | 1 | 1 |
| United Kingdom | 2 | 2 | 2 | 2 |

Reimbursement Replacement Quality assessment Guidelines

Infections with haemophilus influenzae group B

| Austria | 1 | 1 | 1 | 1 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 1 | 1 | 1 | 1 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Influenza — including influenza A(H1N1)

| Austria | 1 | 1 | 1 | 1 |
|----------------|---|---|---|---|
| | | | | |
| Belgium | 1 | 1 | 1 | 1 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 1 | 1 | 1 | 1 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 6 | 6 | 6 | 6 |
| Estonia | 2 | 2 | 2 | 2 |
| Finland | 1 | 1 | 1 | 1 |
| France | 2 | 2 | 2 | 2 |
| Germany | 1 | 1 | 1 | 1 |
| Greece | 2 | 2 | 2 | 2 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 1 | 1 | 1 | 1 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 1 | 1 | 1 | 1 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 1 | 1 | 1 | 1 |
| Slovakia | 1 | 1 | 1 | 1 |
| Slovenia | 1 | 1 | 1 | 1 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 3 | 3 | 3 | 3 |
| United Kingdom | 1 | 1 | 1 | 1 |

Invasive meningococcal disease

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 1 | 1 | 1 | 1 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Invasive pneumococcal disease

| Austria | 1 | 1 | 1 | 1 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 1 | 1 | 1 | 1 |
| Slovenia | 1 | 1 | 1 | 1 |
| Spain | 2 | 2 | 2 | 2 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Reimbursement Replacement Quality assessment

Legionnaires' disease

| Austria | 1 | 1 | 1 | 1 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 1 | 1 | 1 | 1 |
| Finland | 1 | 1 | 1 | 1 |
| France | 2 | 2 | 2 | 2 |
| Germany | 1 | 1 | 1 | 1 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 1 | 1 | 1 | 1 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 1 | 1 | 1 | 1 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 1 | 1 | 1 | 1 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 2 | 2 | 2 | 2 |
| United Kingdom | 1 | 1 | 1 | 1 |
| | | | | |

Leptospirosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 1 | 1 | 1 | 1 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Listeriosis

| 0 | 0 | 0 | 0 |
|---|---|---------------------------------------|---|
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 1 | 1 | 1 | 1 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 2 | 2 | 2 | 2 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 1 | 1 | 1 | 1 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| 0 | 0 | 0 | 0 |
| | | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | 0 0 0 0 0 0 0 0 0 1 1 1 0 0 0 |

Lyme neuroborreliosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Malaria

| Austria | 1 | 1 | 1 | 1 |
|---|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Belgium | 1 | 1 | 1 | 1 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 1 | 1 | 1 | 1 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 2 | 2 | 2 | 2 |
| Estonia | 1 | 1 | 1 | 1 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 1 | 1 | 1 | 1 |
| Greece | 2 | 2 | 2 | 2 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| | | | | |
| Latvia | 1 | 1 | 1 | 1 |
| Latvia Liechtenstein | 0 | 0 | 0 | 0 |
| | | | | |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Liechtenstein Lithuania | 0 | 0 | 0 | 0 |
| Liechtenstein Lithuania Malta | 0 0 | 0 0 | 0 0 | 0 0 |
| Liechtenstein Lithuania Malta Netherlands | 0 0 0 | 0 0 0 | 0 0 0 | 0 0 0 |
| Liechtenstein Lithuania Malta Netherlands Norway | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 | 0 0 0 0 |
| Liechtenstein Lithuania Malta Netherlands Norway Poland | 0 0 0 0 1 | 0 0 0 0 1 | 0 0 0 0 1 | 0 0 0 0 1 |
| Liechtenstein Lithuania Malta Netherlands Norway Poland Romania | 0 0 0 0 1 | 0 0 0 0 1 | 0 0 0 0 1 | 0 0 0 0 1 |
| Liechtenstein Lithuania Malta Netherlands Norway Poland Romania Slovakia | 0 0 0 0 1 0 0 | 0 0 0 0 1 0 0 | 0 0 0 0 1 0 0 | 0 0 0 0 1 0 0 |
| Liechtenstein Lithuania Malta Netherlands Norway Poland Romania Slovakia Slovenia | 0 0 0 0 1 0 0 | 0 0 0 0 1 0 0 | 0 0 0 0 1 0 0 | 0 0 0 0 1 0 0 |

Measles

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Mumps

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Nosocomial infections

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 1 | 1 | 1 | 1 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 1 | 1 | 1 | 1 |
| Greece | 1 | 1 | 1 | 1 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 1 | 1 | 1 | 1 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Pertussis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Plague

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Poliomyelitis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Q fever

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Rabies

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Rubella

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Reimbursement Replacement Quality assessment

Salmonellosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Severe Acute Respiratory Syndrome (SARS)

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Shiga-toxin/verocytotoxin-producing Escherichia coli (STEC/VTEC) infection

| Austria | 1 | 1 | 1 | 1 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Shigellosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Smallpox

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 0 | 0 | 0 | 0 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Syphilis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 2 | 2 | 2 | 2 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 1 | 1 | 1 | 1 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 1 | 1 | 1 | 1 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 1 | 1 | 1 | 1 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Tetanus

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 1 | 1 | 1 | 1 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Tick borne encephalitisⁱ

| Austria | 0 | 0 | 0 |
|----------------|---|---|---|
| Belgium | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 |
| France | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 |
| | | | |

Guidelines Replacement Quality assessment

ⁱ Due to an error in the survey, respondents were not asked about arrangements for reimbursement of POCT for tick borne encephalitis.

Toxoplasmosis, congenital

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Transmissible spongiform encephalopathies

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | - | | |

Trichinellosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Tuberculosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 1 | 1 | 1 | 1 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 1 | 1 | 1 | 1 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 1 | 1 | 1 | 1 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 2 | 2 | 2 | 2 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Tularaemia

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Typhoid and paratyphoid

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Variant Creutzfeldt-Jakob's disease

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Viral haemorrhagic fevers

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

West Nile virus infection

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 1 | 1 | 1 | 1 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Yellow fever

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 0 | 0 | 0 | 0 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |

Reimbursement Replacement Quality assessment

Yersiniosis

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 2 | 2 | 2 | 2 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 1 | 1 | 1 | 1 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

Zika virus disease

| Austria | 0 | 0 | 0 | 0 |
|----------------|---|---|---|---|
| Belgium | 0 | 0 | 0 | 0 |
| Bulgaria | 0 | 0 | 0 | 0 |
| Croatia | 0 | 0 | 0 | 0 |
| Cyprus | 0 | 0 | 0 | 0 |
| Denmark | 0 | 0 | 0 | 0 |
| Estonia | 0 | 0 | 0 | 0 |
| Finland | 0 | 0 | 0 | 0 |
| France | 1 | 1 | 1 | 1 |
| Germany | 0 | 0 | 0 | 0 |
| Greece | 0 | 0 | 0 | 0 |
| Iceland | 0 | 0 | 0 | 0 |
| Ireland | 0 | 0 | 0 | 0 |
| Latvia | 0 | 0 | 0 | 0 |
| Liechtenstein | 0 | 0 | 0 | 0 |
| Lithuania | 0 | 0 | 0 | 0 |
| Malta | 0 | 0 | 0 | 0 |
| Netherlands | 0 | 0 | 0 | 0 |
| Norway | 1 | 1 | 1 | 1 |
| Poland | 0 | 0 | 0 | 0 |
| Romania | 0 | 0 | 0 | 0 |
| Slovakia | 0 | 0 | 0 | 0 |
| Slovenia | 0 | 0 | 0 | 0 |
| Spain | 0 | 0 | 0 | 0 |
| Sweden | 0 | 0 | 0 | 0 |
| United Kingdom | 0 | 0 | 0 | 0 |
| | | | | |

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