TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap), 2018

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ECDC TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap)

Report on 2018 survey of EU/EEA country capabilities and capacities

This report of the European Centre for Disease Prevention and Control (ECDC) was prepared by Katrin Leitmeyer and Marc Struelens (ECDC Surveillance Section).

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Abbreviations

AMR	Antimicrobial resistance
ARV	Antiretroviral
CPE	Carbapenemase-producing *Enterobacteriaceae*
EARS-Net	European Antimicrobial Resistance Surveillance Network
EQA	External quality assessment
EU/EEA	European Union/European Economic Area
EULabCap	EU Laboratory Capability Monitoring System
ERLTB-Net	European reference laboratory network for tuberculosis
ESBL	Extended spectrum beta-lactamase-producing *Enterobacteriaceae*
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FWD	Food- and waterborne diseases
HIV	Human immunodeficiency virus
IQR	Interquartile range
MDR TB	Multidrug-resistant tuberculosis
MERS-CoV	Middle East respiratory syndrome coronavirus
MLST	Multilocus sequence typing
NMFP	National microbiology focal points
NAC	National antimicrobial susceptibility committee
NRL	National reference laboratories
OECD	Organisation for Economic Cooperation and Development
PCR	Polymerase chain reaction
SMAP	ECDC's strategic multi-annual programme
VTEC/STEC	Verotoxin- or Shiga toxin-producing *Escherichia coli*
TESSy	The European Surveillance System (ECDC)
TB	Tuberculosis
TB-DST	Tuberculosis drug susceptibility testing
VHF	Viral haemorrhagic fever
WGS	Whole genome sequencing
WHO	World Health Organization

Glossary of terms

Laboratory capability	The ability to perform the following functions: manage laboratory activities; perform sample management; conduct testing and analysis for routine and surge capacity; support public health investigations and report results [1].
Laboratory capacity	Consists of output services completed over a defined time period for each capability [2].
National microbiology focal points	Appointed representatives for public health microbiology in the EU/EEA Member States as part of the Competent Body Structure [3].
National reference laboratories	Public health microbiology laboratories with national responsibility and appropriate tools and skills to be able to support national surveillance and capacity to deal with emergency situations [4,5].
Public health microbiology	A cross-cutting area of microbiology that spans the fields of human, animal, food, water, and environmental microbiology, with a focus on human health and disease. It covers the laboratory's contribution to the detection and diagnosis of infectious microorganisms, and the characterisation and surveillance of microorganisms that have the potential to affect populations [4,5].

Executive summary

Background

ECDC aims to foster and reinforce the public health microbiology system to provide timely and reliable information for infectious threat detection, the assessment of such threats, and their surveillance at the Member State and European Union levels, thereby ensuring the effective prevention and early control of infectious diseases [4]. To ascertain how well this is delivered, ECDC developed, in close collaboration with national microbiology focal points from all European Union/European Economic Area (EU/EEA) countries and the ECDC Advisory Forum, the European Union Laboratory Capability (EULabCap) monitoring programme. The EULabCap bi-annual surveys assess key public health microbiology service capabilities and capacities for EU surveillance and epidemic preparedness. The monitoring results help policymakers at all levels identify possible areas for action and evaluate the functional impact of capacity-strengthening activities and health system reforms.

This fifth consecutive EULabCap report presents EU/EEA laboratory capabilities and capacities in 2018 and the trends of previous survey results over the period 2013–2018 [6-9].

Methods

The EULabCap monitoring tool combines 60 indicators to assess the capability and capacity of microbiology laboratories to provide essential public health functions as defined in EU policies and action plans, international health regulations and European and international technical standards. The EULabCap indicators comprise 28 structural and 32 procedural indicators. They are grouped into 12 targets distributed across three dimensions: primary diagnostic testing, national microbiology reference laboratory services, and laboratory-based surveillance and epidemic response support. Each indicator can be scored at three levels: low, intermediate or high capability/capacity. Aggregated indices were calculated for each target and dimension as the average of component indicator scores; all index values are displayed on a scale of 0–10. In 2018, three indicators were replaced by new ones to reflect new EU standards, and six indicators were slightly modified to update them with state-of-the-art methods and the latest epidemiological trends.

A mixed method was used for data collection and scoring for the 2018 survey, which took place from October to December 2019. To minimise the data reporting burden for the Member States, ECDC retrieved information for 18 indicators from TESSy datasets (The European Surveillance System) and EU disease network reports. For the remaining 42 indicators, the national microbiology focal points (NMFPs) used a questionnaire to collect information from their country. The data collected for 2018 were validated by the NMFPs in December 2019. Individual country EULabCap profile reports and EU benchmarking results were shared the same month with the NMFP to inform the national stakeholders about key results. Maps illustrating the country scores (EULabCap index level overall and per target area) were published on the ECDC Web portal.

Results

All EU/EEA countries participated in the 2018 survey. Data were reported for 98.5% of indicators overall with a reporting rate per country of 93–100% complete data.

Based on change in the mean EULabCap Index over the surveys conducted from 2013 onwards, the European microbiology system performance showed continuous improvement in the participating countries, reaching a mean 7.8/10 EULabCap Index for the EU/EEA in 2018. This represents a 13% increase in the EU/EEA mean score over the past five years.

Substantial capacity gaps between countries remained apparent in 2018, as national EULabCap indices ranged from 6.2 to 9.7. However, these disparities have been decreasing over time, with an inter-country index variation reduced by one third over the 2013–2018 monitoring period. For the first time in 2018, no country displayed a low capacity level for their public health microbiology systems. Between 2013 and 2018, 13 countries upgraded their EULabCap index from low to fair (seven countries) or fair to high level (six countries). Overall, in 2018, 17 countries reported intermediate level of laboratory capacity and capability (score 6.0 to 7.9) and 13 countries high level (score 8.0 or above).

Strong overall EU/EEA laboratory capacities indicated by EU/EEA mean scores of 8.0 or above in 2018 have been consolidating since 2013 in the following areas of practice:

- Use of standardised antimicrobial susceptibility testing methods;
- Inter-laboratory collaboration within national and EU surveillance networks;
- Diagnostic confirmation capability for the 2018 updated list of EU notifiable diseases.

Progress was noted in 2018 in several important technical areas:

- Molecular typing for surveillance further modernised its operations with an EU/EEA mean score of 8.7 for routine use of advanced whole genome sequencing (WGS) methods (compared to 5.5 in 2016);
- The contribution of reference laboratories to outbreak detection and investigation is progressing across countries with an EU/EEA mean score of 8.4 in 2018 (compared to 6.0 in 2013);
- The provision of national diagnostic testing guidelines expanded across countries, with EU/EEA mean score of 8.0 in 2018 (compared to 6.0 in 2013);
- The regulation and support to national reference laboratory services gradually strengthened, as indicated by EU/EEA mean score of 8.5 in 2018 (compared to 8.0 in 2013).

In the area of laboratory preparedness, the EULabCap index score levelled off in 2018 despite updating the challenge list of infectious threats. Most specialised laboratories indicated adequate capability to detect and identify these emerging diseases, as indicated by an EU/EEA mean score of 8.0 in 2018.

The main area of suboptimal performance across the EU/EEA was a persistently inadequate usage or lack of monitoring of diagnostic testing in many countries, with an EU/EEA mean score of 6.3. in 2018. There was a dip in performance in reference laboratory contribution to EU surveillance of antimicrobial resistance for influenza and foodborne pathogens, with a decrease in EU/EEA mean scores from 8.0 in 2016 to 7.3 in 2018.

Not all EU/EEA Member States have reached sufficient levels of laboratory capability and capacity across all targets to conduct effective public health surveillance and provide an adequate level of disease threat response. In 2018, 21 countries fulfilled sufficient (fair to high) capacity levels for at least 10 of 12 EULabCap targets.

Conclusions

The high response rate to the EULabCap surveys highlights the continued commitment of EU/EEA countries to this health system benchmarking process. It also enables a robust assessment of collective EU/EEA and country-level laboratory system capacity. The results of this fifth survey confirm that the EU/EEA, with a mean 7.8/10 EULabCap Index for the EU/EEA in 2018, can rely on microbiology services that are steadily strengthening its collective public health capabilities to detect, identify and characterise infectious disease threats.

Steady increases in EULabCap indices of countries over the five-year monitoring period suggest that public health microbiology shortcomings are being addressed. The narrowing variation in the EULabCap index between countries in recent years indicates technical convergence and progress toward a more equitable balance of laboratory capacities among Member States, thereby contributing to collective health security.

While public health microbiology services in the EU/EEA assessed here in 2018 met most of the key requirements for communicable disease surveillance and response, not all Member States had a balanced laboratory capability and capacity to deliver fully effective public health surveillance and threat response. As assessed by this survey 'Sufficient microbiology capacity' (defined as intermediate or high capacity for at least 10 of 12 EULabCap targets) was reported by 21 Member States in 2018. Likewise, the modernisation of methods has progressed in most EU/EEA countries with upgrading to genomic methods for the detection, surveillance and characterisation of epidemic agents and antimicrobial resistance. Another efficiency gain made in some countries was building digital interoperability between clinical laboratory and public health information systems for disease surveillance and alert at national levels.

The strong reference public health laboratory epidemic preparedness as measured by EULabCap was indicative of the timely deployment across the EU/EEA of SARS-CoV-2 diagnostic confirmation testing at reference laboratory levels early in the COVID-19 pandemic in 2020. However, such indicators did not predict the country ability to rapidly deploy extensive molecular testing in response to the pandemic. The flexibility to mobilise extraordinary surge capacity for decentralised SARS-CoV-2 testing beyond national reference laboratories did not appear linked to the EULabCap emerging disease detection indicators. Therefore, a lesson learned for future EULabCap monitoring is to consider adding national pandemic preparedness indicators for scaling up community diagnostic testing.

Feedback on previous EULabCap country reports indicated that these data were useful for advising national authorities on microbiology capacity strengthening actions. Key gaps and inefficiencies identified by EULabCap in EU and EEA countries include the unmet needs for clinical guidance and audit on the adequate utilisation of diagnostic tests and enhanced digital connections between peripheral laboratory and public health information systems. Both gaps hinder effective disease monitoring and early warning of outbreaks at local, national and EU levels. The EU4Health programme investment plans in digital health interoperability and resilient health services should help address these structural gaps in the coming years.

Introduction

The laboratory detection and characterisation of infectious agents causing human disease provides essential information for clinical management, public health surveillance, and outbreak alert and response. As the COVID-19 pandemic has shown, testing capacity is pivotal for epidemic preparedness and response [10]. Sufficient national laboratory capacity for infectious health threat detection and control is required to fulfil the obligations set forth in EU [11] and international health security legislation [12]. Such capacity relies on the seamless integration of microbiology testing services with public health surveillance systems and on adequate laboratory and information technology infrastructure, skilled professionals and operational resources.

Public health microbiology systems comprise three intertwined components:

- Clinical laboratories performing primary diagnostic testing, antimicrobial drug susceptibility testing and screening, with a focus on patient management and preventive services;
- Public health laboratories serving as reference functions at a national or subnational level, providing specialist diagnostics and characterisation of biological agents;
- Laboratory networks performing harmonisation of methods, quality assessment, and contributing to public health surveillance and alert systems, nationally and internationally.

National health systems in Europe are undergoing continuous administrative and organisational reforms to respond to the challenge of maintaining universal access of aging populations to high-quality care with reduced resources [13]. Following the financial crisis in 2008, health expenditure has either stopped growing or even decreased by various degrees across EU Member States. Public health budget cuts have affected the available resources and investments for laboratory operations.

ECDC's Founding Regulation (EC No. 851/2004) states that 'by encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health' [14]. In this dynamic context, monitoring the collective laboratory capabilities in the EU/EEA is important in order to identify best practices and address potential vulnerabilities. The insufficient health system preparedness encountered when facing the COVID-19 pandemic in early 2020 has been a wake-up call to the public and policy makers worldwide.

Europe has strong assets in this regard. It benefits from a legacy of successful cross-border collaboration among public health and infectious disease experts spanning decades. Microbiologists and epidemiologists have for years participated in dedicated European surveillance networks and other professional initiatives to improve laboratory test methods, promote testing quality, and build capacity. Laboratory mapping exercises in the EU, conducted by ECDC [15] and the European Commission [16], have revealed significant differences in services, infrastructure, technical capacity, public health activities and human resources. Specific areas identified as being of potential EU added-value included the training of laboratory staff, method innovation and harmonisation, and the establishment of specialist technical capacity at the supranational level for rare diseases [15,16].

The ECDC public health microbiology strategies aim to strengthen the capability and capacity of the EU public health microbiology system to provide timely and reliable information that underpins infectious threat detection, assessment and surveillance at the EU level to ensure the effective prevention and control of infectious diseases [4]. [17]. ECDC, in close collaboration with its national microbiology focal points (NMFP) and the ECDC Advisory Forum, developed and piloted in 2013 a system (EULabCap) for monitoring key public health microbiology capabilities and capacity for EU surveillance and epidemic preparedness. After piloting the data collection and indicator scoring instrument, the first survey was launched in 2014 (on 2013 system outputs) [7] and repeated, with minor adjustments, for subsequent surveys on an annual then bi-annual basis [6,8] [9].

The NMFPs are the main contributors to the survey data collection and verification. They are also responsible for disseminating the EULabCap country profile report to their national competent bodies, in accordance with their terms of reference [3]. At the national level, detailed benchmarking information provided as EULabCap country profiles identify structural and operational gaps and present options to strengthen the system where relevant.

This report presents the results of the fifth EULabCap survey as compared with previous surveys and discusses them in the context of responding to the COVID-19 pandemic.

Materials and methods

EULabCap survey

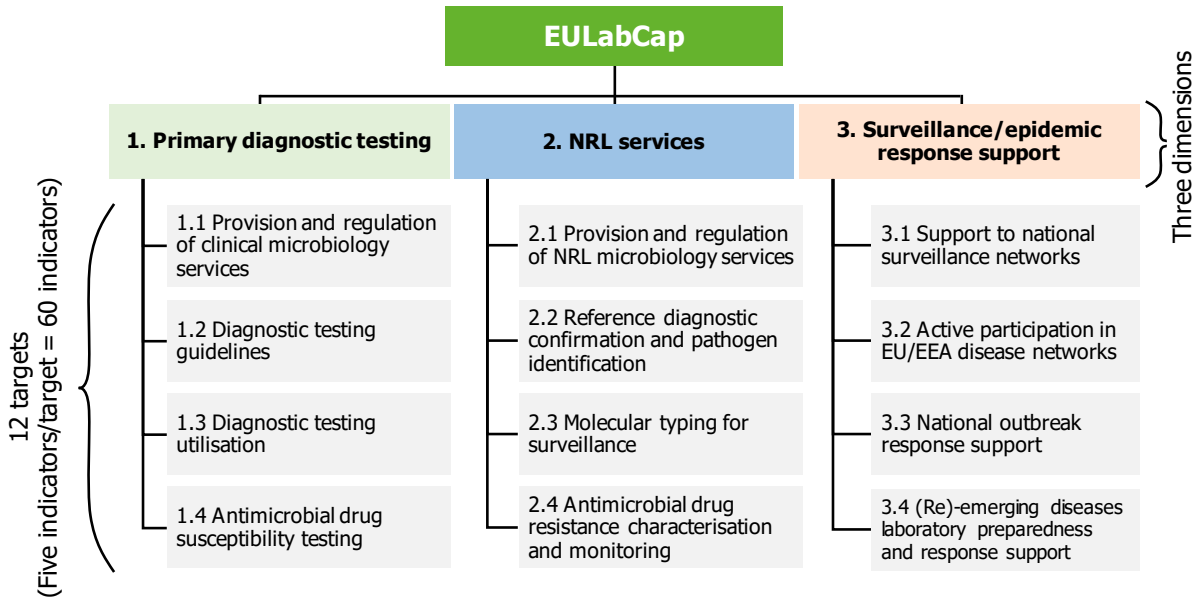
Survey population

The fifth data call for the 2018 EULabCap survey on the laboratory capabilities and capacities of 28 EU Member States and two EEA countries was launched in October 2019. Liechtenstein was not included in the survey due to outsourcing arrangements with laboratories in Switzerland, which is not a member of the EU or EEA.

EULabCap survey tool

An Excel-based data collection tool was developed and piloted in close collaboration with the NMFPs. The EULabCap monitoring tool is composed of 60 performance indicators, grouped into 12 targets (Annex 1) which are equally distributed across the following three public health microbiology system dimensions: primary diagnostic testing, national microbiology reference laboratory (NRL) services, and laboratory-based surveillance and epidemic response support (Figure 1).

Figure 1. Structural overview of EULabCap indicators, by dimension and target



The EULabCap indicators (Annex 1) are of a composite nature in terms of which system elements are measured (structure or process) and how they measure these elements (functional capability or capacity). As of the 2018 survey, they consist of 28 structure and 32 process indicators. They are divided into 44 indicators on laboratory capability and 16 on capacity (Table 1). The policy rationale for the design of the indicators/targets and score levels was based on previously agreed EU policy targets or international technical standards for three quarters of the indicators, while the remainder assess EU surveillance and alert system contributions (Annexes 1 and 2).

Table 1. Distribution of EULabCap indicators by dimension, element and function measured (2018)

Dimension	Number of indicators by element		Number of indicators by function	
	Structure	Process	Capability	Capacity
Primary diagnostic testing	12	8	11	9
National reference laboratory services	6	14	16	4
Surveillance/epidemic response support	10	10	17	3
Total	28	32	44	16

Scoring system

Each indicator was scored at three levels: low (0, 'no or limited capability/capacity'), intermediate (1, 'partial capability/capacity', e.g. below the EU target, or partial compliance) or high (2, 'complete capability/capacity', e.g. EU target reached, or high compliance). Indicators for which data were not available or that were not applicable (NA) to the country were not scored [7].

Indicator modifications

EULabCap indicators and scoring criteria for the fifth survey were reviewed for clarity of wording and applicability by the NMFPs and ECDC disease experts in 2019. Some indicators were modified to conform to current EU standard practice or address emerging issues:

In the context of a technology shift to whole genome sequencing (WGS) three indicators on molecular typing for disease surveillance at national level were replaced by new ones to measure selected WGS-based typing capabilities prioritised in the 'ECDC strategic framework for the integration of molecular and genomic typing into European surveillance and multi-country outbreak investigations' [18].

- Indicator 2.32, 'Proportion of *Salmonella* genotyped', was replaced with 'Use of WGS-based typing of *Listeria monocytogenes* by national public health reference laboratory';
- Indicator 2.33, 'Proportion of MDR- *Mycobacterium tuberculosis* MIRU-VNTR genotyped', was replaced with 'Use of WGS-based typing of MDR-*Mycobacterium tuberculosis* isolates by national public health reference laboratory';
- Indicator 2.34, 'Proportion of *Neisseria meningitidis* genotyped', was replaced with 'Use of WGS-based typing of invasive *Neisseria meningitidis* by national public health reference laboratory'.

The scoring criteria for the following indicators were either slightly modified to improve robustness or updated to address new emerging diseases:

- For indicator 1.32, 'Blood culture test rate', the score was based on the absolute cut-off of 25/1 000 hospital bed-days which equals the median of data reported in the 2016 EULabCap survey;
- For indicator 1.33, '*Clostridium difficile* test rate', the score was based on the absolute cut-off which equals the first quartile of data reported in the 2016 EULabCap survey;
- For indicator 1.35, 'HIV late diagnosis', the score was based on the absolute cut-off which equals the first quartile of data reported in the 2016 EULabCap survey;
- For indicator 3.42, 'Diagnostic and characterisation capability for avian influenza A(H7Nx) and A(H5Nx) viruses available at national level in accordance with ECDC/WHO surveillance guidance', the score was adjusted so as to also include A(H9Nx) viruses;
- For indicator 3.44, 'Diagnostic capability for detection of 5 rare agents', the score was adjusted to not overlap with the diseases/pathogens listed in the 2018-updated EC decision surveillance list of EU notifiable diseases (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945&from=EN), with the introduction of new pathogens Yellow fever virus, Crimean-Congo haemorrhagic fever virus, Usutu virus and *Candida auris;*
- Indicator 2.21 was extended by five pathogens (Chikungunya virus disease, Dengue, Lyme neuroborreliosis, Zika disease and congenital Zika disease) now added to the surveillance list of EU-notifiable diseases (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945&from=EN), updated in 2018.

Data collection and validation

Data collection and validation were performed between October and December 2019. As in previous surveys, a mixed data collection method was used. Information was retrieved for the 60 indicators as follows: 18 indicators were measured by ECDC from datasets accessible in TESSy and EU disease network reports, and 42 indicators were reported by the NMFPs through the questionnaire (Annex 1). Two rounds of validation were performed between November and December 2019. The NMFPs were asked to review and verify the data and correct indicator score calculations.

Data analysis, performance measurement and interpretation

Data completeness was calculated as a percentage of reported data for each indicator across the EU/EEA and for all indicators in each country. Aggregated performance indices were calculated for each target and dimension as the means of component indicator scores per country; all values were displayed on a scale of 0–10.

The EULabCap index scores per country were graded qualitatively by three performance levels, indicating a country's average capability and capacity with regard to its public health microbiology system: low level (index value range: 0 to 5.9), intermediate level (6.0 to 7.9) and high level (8.0 to 10).

The capacity of each national public health microbiology system was further determined by assessing the balance of service provision and performance across the 12 EULabCap targets (Fig.1). 'Sufficient country capacity' was defined as EULabCap target indices at intermediate or high-performance level (score 6 or above) for more than 10 of the 12 targets.

Descriptive data analysis was performed, including measures of central tendency (mean and median) and dispersion (minimum–maximum range, interquartile range) of indicator scores and indices across the EU/EEA countries. Means were used for comparing EU scores average levels by indicator. Medians (and interquartile range) were used for comparing the intercountry distribution of index scores by targets and dimensions over time.

Data reporting

Country reports

In January 2020, ECDC shared 30 individual EULabCap country profile reports in confidence with the respective NMFPs for their perusal and dissemination to national public health stakeholders. Each country report consisted of a customised one-page executive summary for the country's decision makers, presenting the country index scores, the areas of good national system capacity/capability, and those in need of attention. Country results were visualised with: a) a radar graph comparing the country's 2018 EULabCap index median scores for the 12 targets and EU/EEA interquartile score range; b) the 2018 score distribution among all EU/EEA countries and the country's for each indicator; and c) the country's mean score trend per target and indicator over the period 2013–2018. Survey data sources and methods were explained in Annex 1.

EULabCap maps

In December 2019, the EULabCap country capability/capacity levels 2018 were published as EU/EEA online maps. Maps illustrate each country level of EULabCap index scores overall and per system target, categorised as: 'low level' (score 0 to 5.9), 'intermediate level' (score 6.0 to 7.9) and 'high level' (score 8.0 to 10) as in this report.

EULabCap report

This is the present report on the EULabCap 2018 survey data in comparison with 2013–2016 survey data from all participating EU/EEA countries (n=30).

Results

EULabCap 2018 survey

Response rate and data completeness

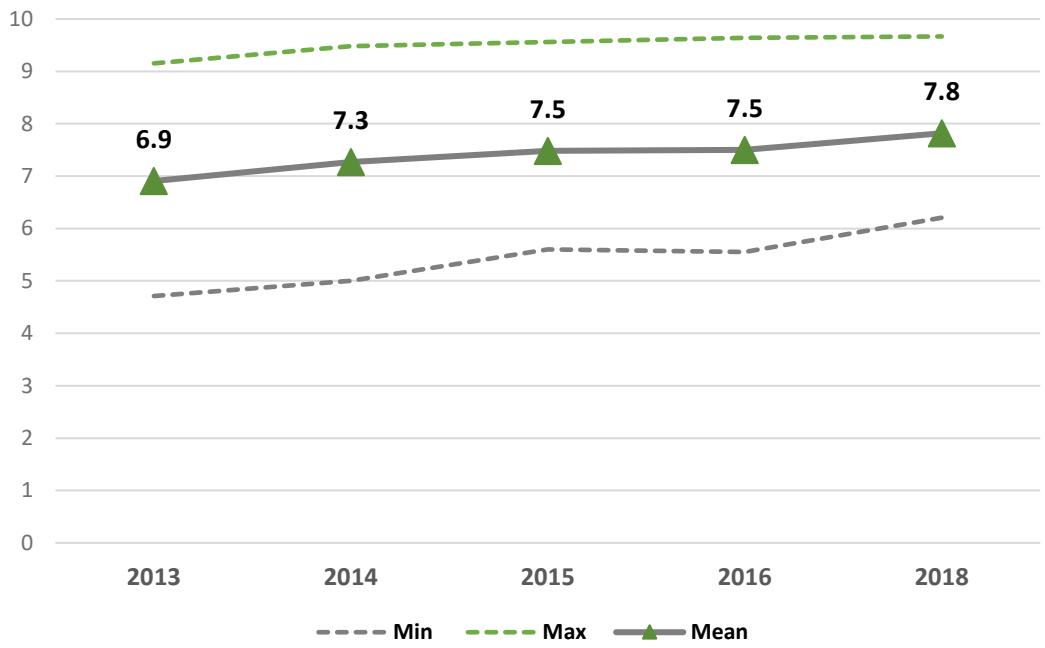
All EU/EEA countries participated in the 2018 survey. Following the trend seen in previous surveys, data completeness continued to improve in 2018. Data were reported for 98.5% of indicators overall, with a range of complete data reporting ratio of 93–100% by country and 87–100% by indicator. Only two indicators (2.35 and 3.35) showed 10% or more missing data in 2018 as compared with four indicators in 2016 and six in 2015.

Laboratory capabilities and capacities at the EU/EEA level

Based on the change in the mean EULabCap Index over the surveys from 2013 onwards, the European microbiology system performance showed continuous improvement in the participating countries, reaching a mean 7.8/10 EULabCap Index for the EU/EEA in 2018, a 13% increase in the EU/EEA mean score over the past five years (Figure 2).

Substantial capacity gaps were still apparent in 2018, as national EULabCap indices ranged from 6.2 to 9.7 between countries. However, these disparities have been decreasing over time, with an inter-country index variation reduced by one third over the 2013-2018 monitoring period (Figure 2). The 2018 survey is the first time that no countries displayed a low capacity level for their public health microbiology systems. Between 2013 and 2018, 13 countries upgraded their EULabCap index: from low (below 6.0) to fair (6.0 to 7.9) in seven countries, and from fair to high level (8.0 or above) in six countries (Annex 4).

Figure 2. Distribution of EULabCap index, EU/EEA countries (n=30), by survey year

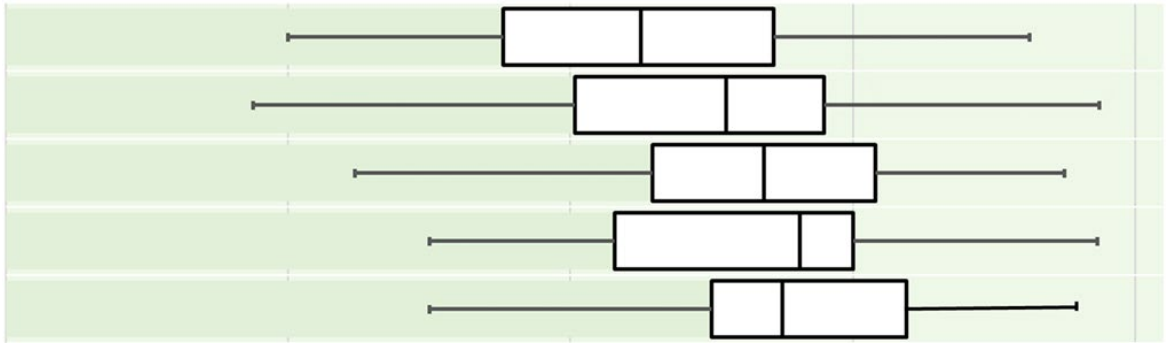


Performance by microbiology system dimension for 2018 showed a median index of 7.5 (IQR 7.0-8.4) for primary diagnostic testing, 7.8 (IQR, 6.1–8.8) for NRL services, and 8.2 (IQR, 7.1–9.0) for laboratory-based surveillance and epidemic response support (Figure 3).

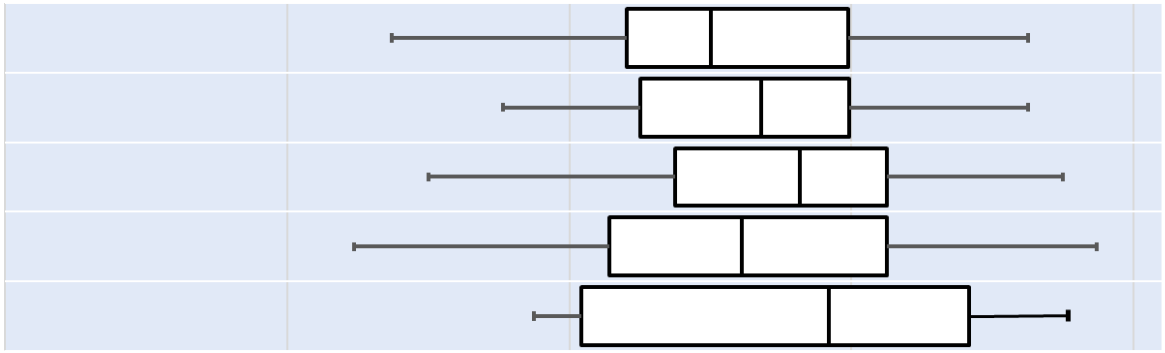
Between 2013 and 2018, the EU/EEA median index scores increased across all three system dimensions (Figure 3). The largest increase was noted for primary diagnostic testing and laboratory-based surveillance and epidemic response support, even though the trend stabilised between 2016 and 2018. At the same time, country disparities within each dimension gradually narrowed over this period.

Figure 3. Box plot (median, interquartile and minimum–maximum ranges) of EULabCap index scores by microbiology system dimension and year, 2013–2018 in descending order (N=30 countries, except N=29 in 2015)

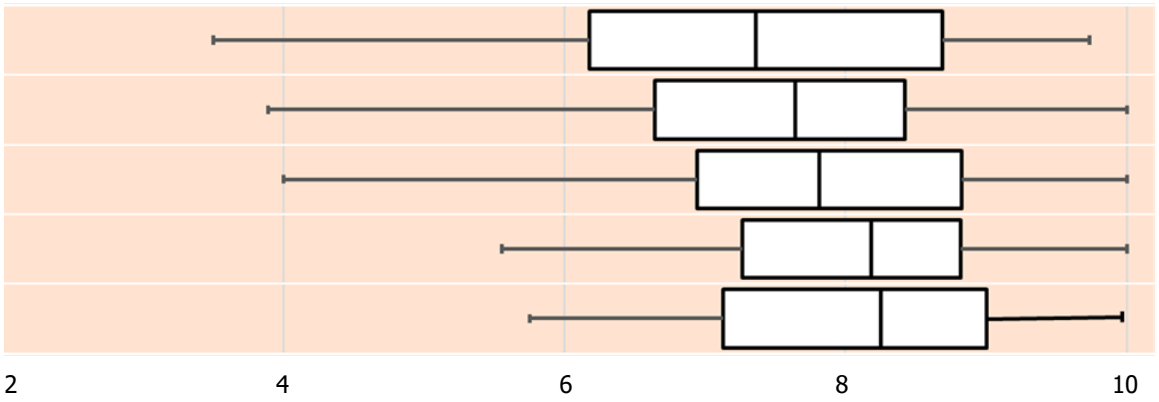
Dimension 1. Primary diagnostic testing



Dimension 2. NRL services

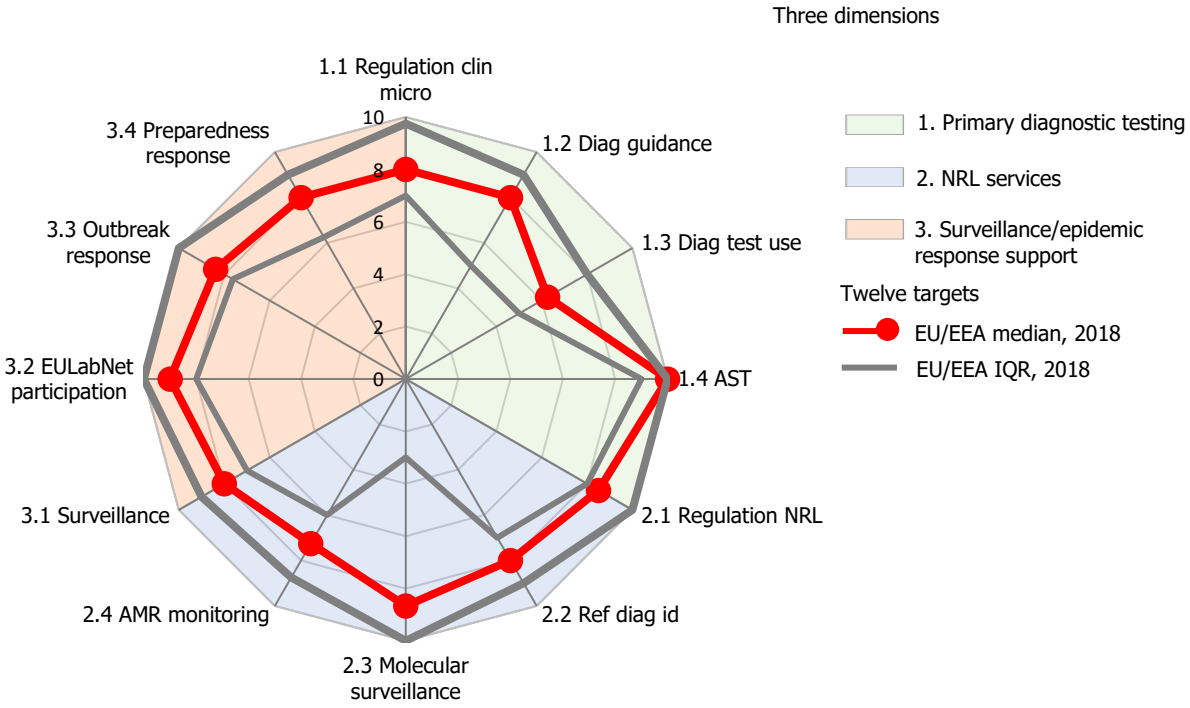


Dimension 3. Surveillance/ epidemic response support



Analysis of performance scores by system target. The 2018 EULabCap target index scores (median and interquartile range) showed a high average performance level (median EU/EEA score 8 and above) for the majority of targets, except for the target on guidance for and use of diagnostic tests and AMR monitoring (Figure 4).

Figure 4. Distribution of EULabCap index scores (EU/EEA median and interquartile range) by target in 2018 (N=30 countries)



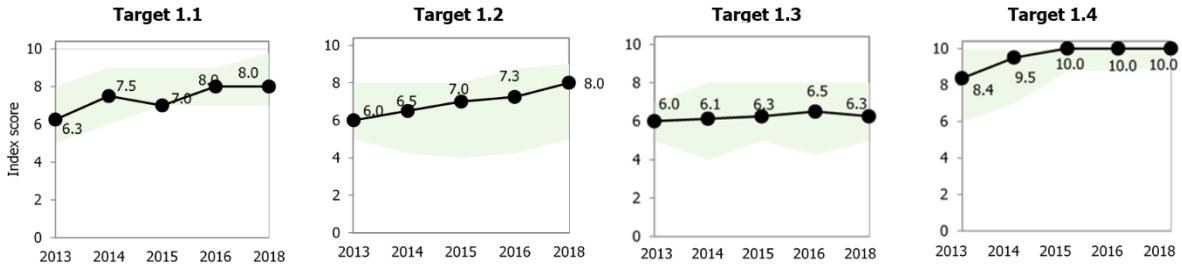
Temporal trends for EU performance by target, 2013–2018

To monitor the evolution of average EU laboratory performance per target and explore the heterogeneity between EU/EEA countries, Figures 5–7 present the yearly median (IQR) EULabCap scores per target and by system dimension over survey years.

Primary diagnostic testing targets

EU/EEA median (IQR) scores (2013–2018) for targets in the dimension of primary diagnostic testing are shown in Figure 5. Between 2013 and 2018, the index showed either an upward trend or a stable performance level for all targets in primary diagnostic testing (Figure 5).

Figure 5. Median and interquartile range of yearly EULabCap target scores in primary diagnostic testing, 2013–2018 (N=30 countries, except N=29 countries in 2015)



Target 1.1. Provision and regulation of clinical microbiology services. This target showed fluctuation in the median score, but there was an overall improvement of performance over time. In 2018, 19 countries had a high level of capacity/capability (score of 8.0 or above) for this target.

Target 1.2. Diagnostic testing guidelines. Although a continuous positive trend in performance was observed over time (mean score 8.0 in 2018 compared to 6.0 in 2013), the wide interquartile ranges still reflect disparity between countries with regard to the availability of national diagnostic and screening guidelines. In 2018, 16 countries had a high level of capacity/capability (score of 8.0 or above) for this target.

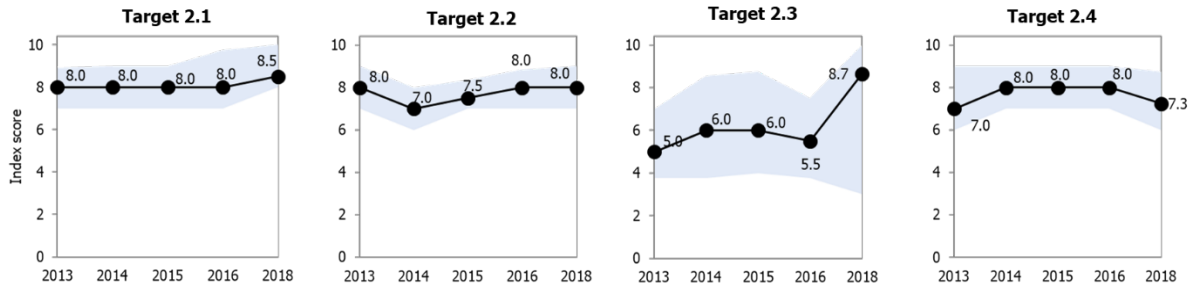
Target 1.3. Diagnostic testing utilisation. This is a weaker target within the primary diagnostic testing dimension, with no improvement over time. In 2018, only 11 countries had a high level of capacity/capability (score of 8.0 or above) for this target.

Target 1.4. Antimicrobial drug susceptibility testing. This target showed rapid and continuous improvement in the use of standard methods and breakpoints over the years, with 26 countries ranking as 'high capacity/capability' performance for harmonised testing in 2018.

National reference laboratory services

EU/EEA median (IQR) scores (2013–2018) for targets in the area of national reference laboratory services are shown in Figure 6.

Figure 6. Median and interquartile range of yearly EULabCap target scores for national reference laboratory services, 2013–2018 (N=30 countries, except N=29 countries in 2015)



Target 2.1. Provision and regulation of NRL microbiology services. High performance scores were found across surveys with regard to organisation, regulation, and funding of their NRL infrastructure and delivery of public health functions. There was a further mean score increase in 2018 for this target and 23 countries showed high level of capacity/capability.

Target 2.2. **Reference diagnostic confirmation and pathogen identification.** Good performance results were sustained across countries with an EU/EEA mean score of 8.0 in recent surveys. Of note, in 2018, 19 countries achieved high level of performance for the diagnostic confirmation of EU notifiable diseases, the list of which was expanded in 2018 [19].

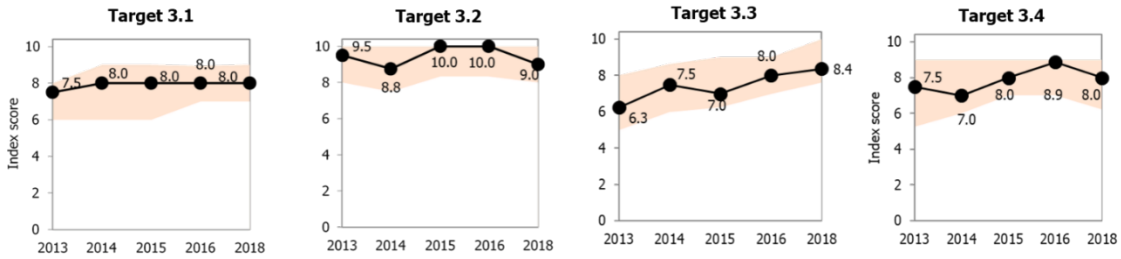
Target 2.3. Molecular typing for surveillance. With a rapidly shifting state of art, indicators for this target were adapted several times over the years. This challenging operational target was characterised by a low baseline level of capability/capacity in half of the countries over the previous surveys. For this survey, three indicators were updated to score the use of whole-genome-based typing in line with the latest ECDC strategic framework for the integration of genomic typing into European surveillance. There is persistent heterogeneity among EU/EEA Member States indicated by a wide index dispersion by country. In 2018, 17 countries showed overall high level of capacity/capability for this target. Progress was noted overall with an EU/EEA mean score of 8.7 in 2018 for routine use of WGS methods. This score compares well to the EU/EEA molecular surveillance score of 5.5 in 2016 when technical capability was measured through indicators of mixed practice combining DNA fingerprinting and WGS-based typing methods. Of note, numerical scores are not directly comparable between surveys as those indicators have changed from quantitative output capacity in 2013-2016 to qualitative capability criteria in 2018.

Target 2.4. Antimicrobial drug resistance characterisation and monitoring. Good results were found across surveys. In 2018, 14 countries showed a high level of capacity/capability to accurately characterise and monitor antimicrobial resistance determinants for national/EU-wide surveillance. Decreasing performance in 2018 as compared to 2016 was associated with limited reference laboratory contribution in some countries to EU surveillance of drug-resistant influenza and One-Health cross-sectoral harmonised methods for surveillance of AMR in foodborne pathogens.

Laboratory-based surveillance and epidemic response support

EU/EEA median (IQR) scores by target in the dimension of laboratory-based surveillance and epidemic response support from 2013 to 2018 are shown in Figure 7.

Figure 7. Median and interquartile range of yearly EULabCap target scores for laboratory-based surveillance and epidemic response support, 2013–2018 (N=30 countries, except N=29 countries in 2015)



Target 3.1. Support to national surveillance networks. The EU/EEA mean index for this target increased from intermediate (2013) to high (2018) while gaps between countries became smaller. In 2018, 19 countries showed a high-performance level of laboratory data reporting to surveillance systems, including automated digital reporting in 16 countries.

Target 3.2. Active participation in EU/EEA disease networks. Very high-performance levels of NRL participation in EU network activities were seen over surveys, with mean indices between 9.0 and 10.0. In 2018, NRL from 29 countries were actively participating in the EU/EEA networks. Fluctuation for this target suffered from business discontinuity in ECDC-supported laboratory networks, resulting in EU network indicators that could not be scored in 2014- 2016.

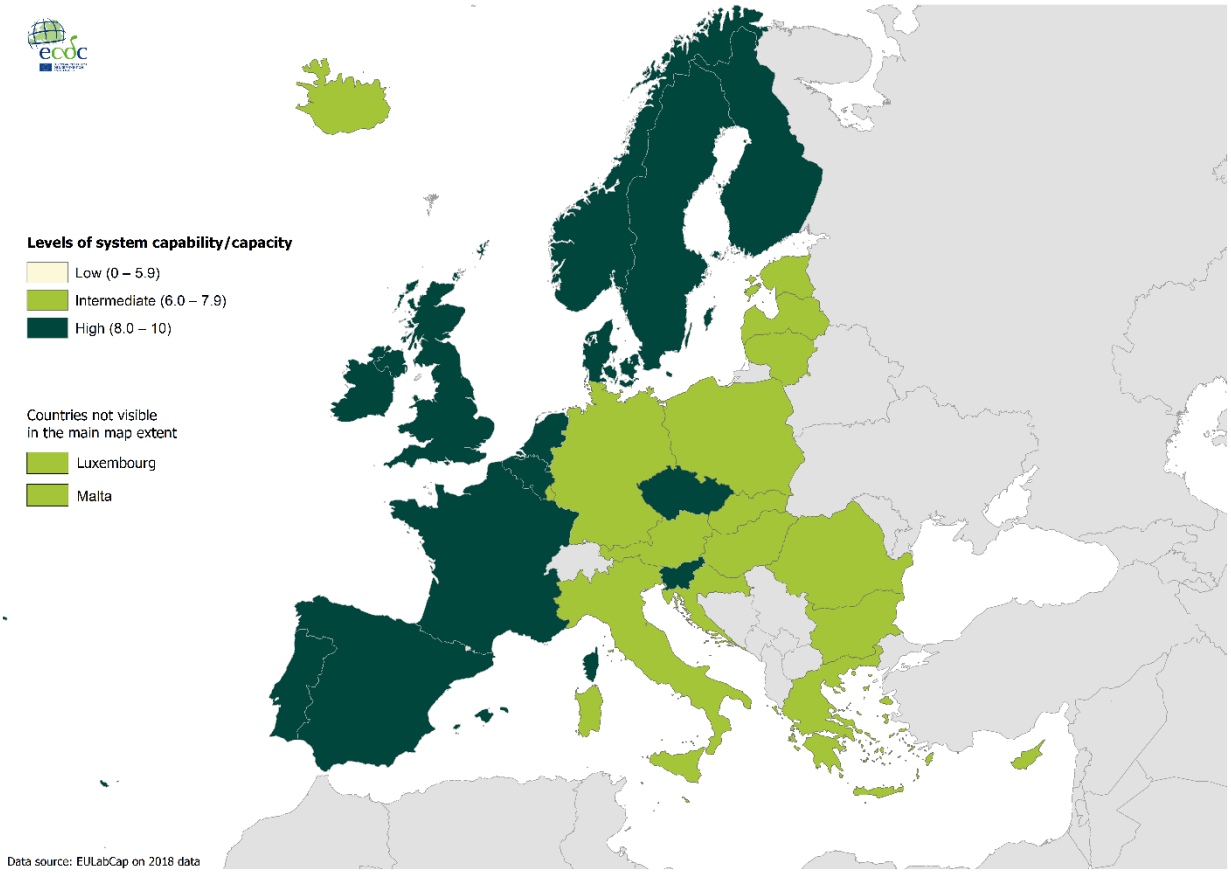
Target 3.3. National outbreak response support. The contribution of reference laboratories to outbreak detection and investigation has been progressing steadily across countries, with an EU/EEA mean score rise from of 6.0 in 2013 to 8.4 in 2018, when NRL from 22 countries showed a high-performance level for this core public health function.

Target 3.4. (Re-)emerging disease laboratory preparedness and response support. Over the years, the up-to-date diagnostic capability for rare and (re-)emerging diseases improved in the EU/EEA increased and country disparities decreased. Despite updating the challenge list of infectious threats as indicators for the latest survey conducted in 2019, specialised laboratories in 17 countries indicated adequate capability to detect and identify these emerging diseases with maintaining a good EU/EEA mean score of 8.0 in 2018.

Laboratory capabilities and capacities at country level

As in previous surveys, the country EULabCap index showed substantial variation between EU/EEA countries yet this gap has been narrowing over the years. Figure 8 shows the mapping of system capability and capacity performance level (low, intermediate or high) by country in the EU/EEA in 2018.

Figure 8. Level of public health microbiology system capability/capacity, by EULabCap index in 2018, EU/EEA (N=30 countries)



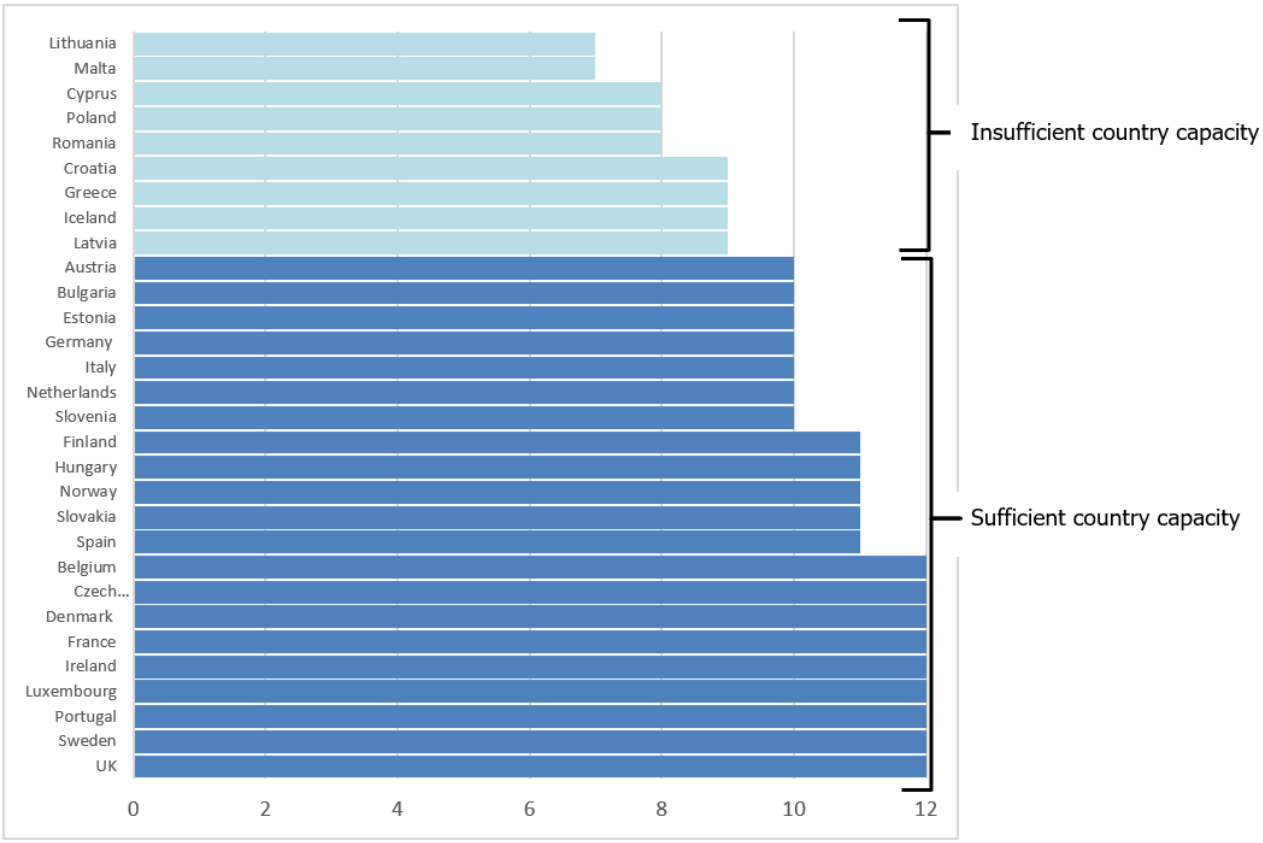
Overall, in 2018, 17 countries reported an intermediate level of laboratory capacity and capability (Index score 6.0 to 7.9) and 13 countries high level (8.0 or above) (Figure 8).

Between the 2016 and 2018 surveys, four countries (Cyprus, Finland, Poland and Slovenia) progressed to a higher level of national system capability and capacity, one country (Slovakia) decreased in level, and the others remained at the same level (Annex 4).

As with the EULabCap country index scores, target index scores varied substantially between countries. The EU/EEA country performance level for each target is available in a map format (Annex 5). Country-specific radar graphs display the geometric profile of target index scores for each EU/EEA country (2016 and 2018) visualising the structural imbalance in the performance across targets in several countries (Annex 6).

In 2018, 21 countries reached 'sufficient capacity' for at least 10 out of 12 microbiology system targets, which indicates a fairly well-balanced array of capacities across targets within their national system (Figure 9).

Figure 9. Distribution of EU/EEA countries ranked by the increasing number of EULabCap targets with target index ≥6.0/10, 2018 (n=30 countries)



** 'Sufficient country capacity' is defined as reaching a EULabCap target index at an intermediate or high performance level (score 6 or above) for at least 10 out of the 12 targets (■) while 'insufficient country capacity' is defined as a EULabCap index score of 6 or above for 9 or fewer targets (■).*

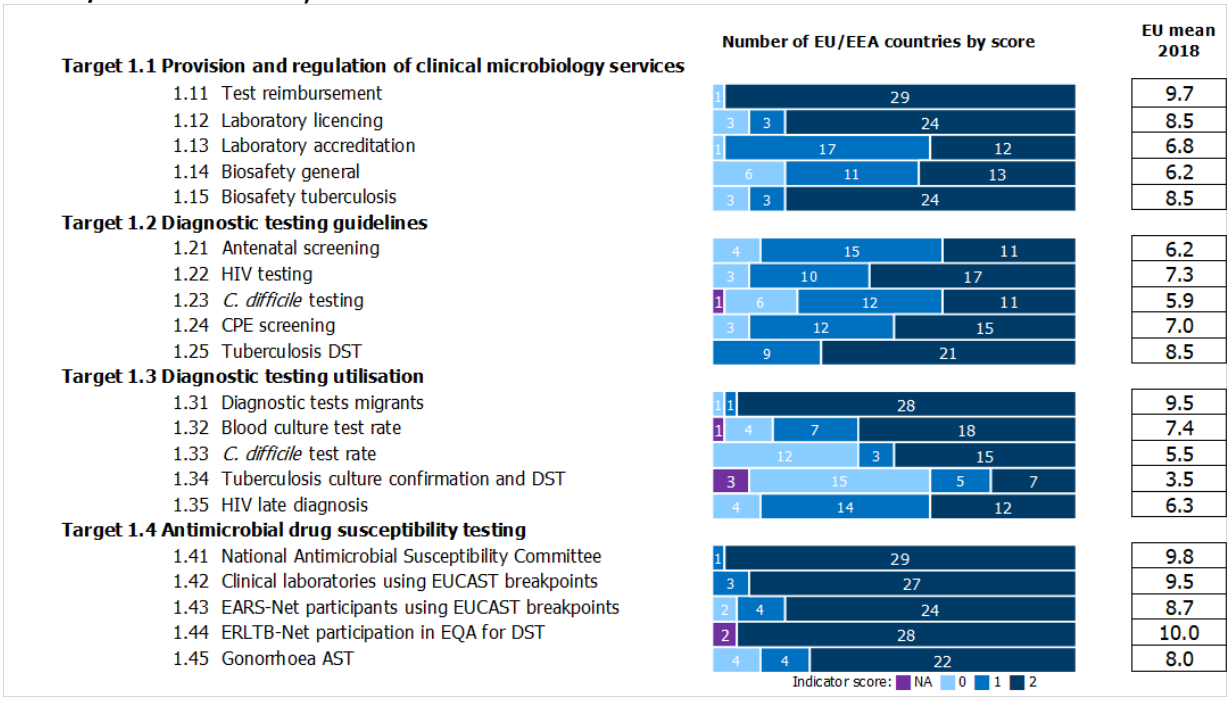
Indicator 2018 score distribution by country

Figures 10, 11 and 12 present a detailed analysis of the 2018 distribution of national scores and the EU mean index by indicator within each system dimension (primary diagnostic testing, NRL, and laboratory-based surveillance and epidemic response support). Results indicate the strengths and weaknesses in specific technical areas across the EU/EEA.

Primary diagnostic testing

Figure 10 shows the distribution of country scores for the 20 indicators on primary diagnostic testing and the EU/EEA mean scores per indicator for 2018. In 2018, several indicators scored low across the EU/EEA (quality accreditation of laboratories, biosafety general regulations, diagnostic testing guidelines or test utilisation rates, tuberculosis drug susceptibility testing).

Figure 10. Distribution of scores for EULabCap indicators of primary diagnostic testing by country and EU/EEA mean scores, 2018



In 2018, EU/EEA primary diagnostic testing showed good capacity in several technical areas (Figure 10): all but a few countries publicly funded or reimbursed clinical microbiology tests and offered testing for HIV infection and tuberculosis to undocumented migrants.

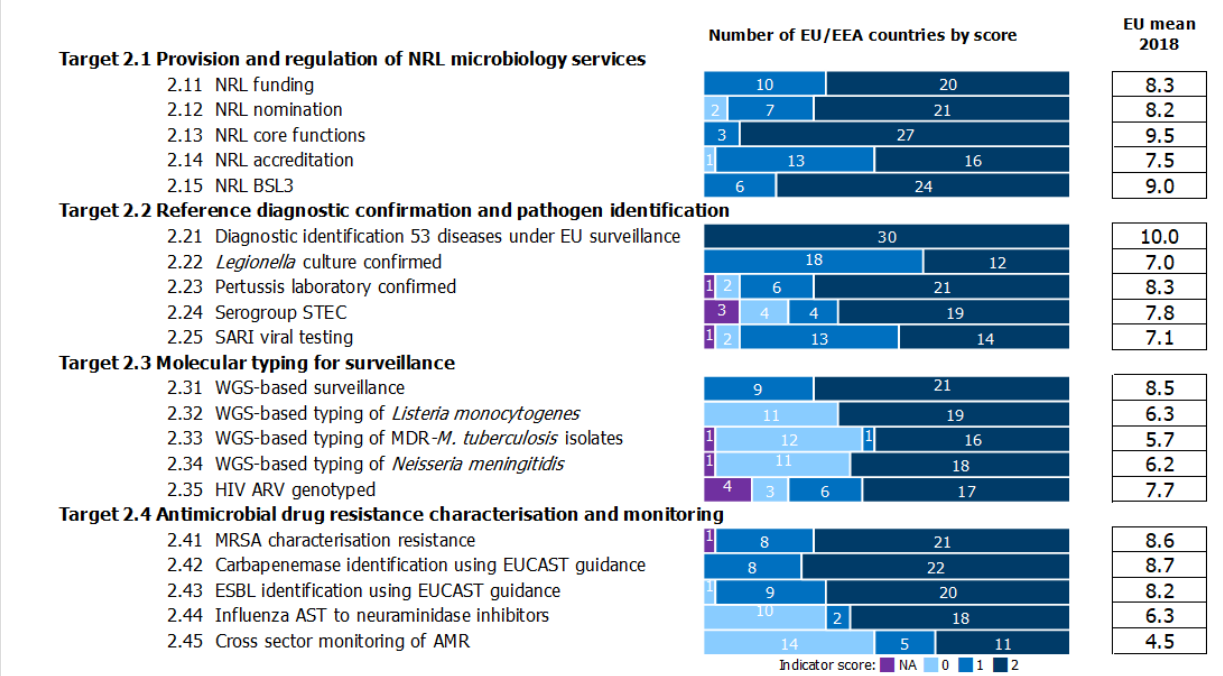
Antimicrobial susceptibility testing maintained a high level of capability/capacity in most EU/EEA countries. Standardisation of antibiotic susceptibility testing continued to advance, with 29 countries having established a national antimicrobial susceptibility committee (NAC) or equivalent function. European Committee on Antimicrobial Susceptibility Testing (EUCAST) breakpoints were used for interpretive reporting of antibacterial drug susceptibility testing results in the vast majority of the clinical laboratories and countries. Clinical laboratories participating in EARS-Net used EUCAST breakpoints in 24 countries in 2018.

Gaps remained with diagnostic and drug susceptibility testing access. For instance, fewer than half of the countries reached the target of 80% of culture-confirmed tuberculosis cases in 2018. The EU/EEA median percentage of new HIV cases older than 14 years with initial CD4 counts <350 (late diagnosis) is still around 50%.

National reference laboratory services

Figure 11 shows the national scores for the 20 indicators for measuring national reference laboratory services and the EU/EEA mean scores for these indicators in 2018. Indicators on provision and regulation of national reference services, capabilities for diagnostic confirmation, and capacity for national AMR characterisation generally scored intermediate or high performance across a wide majority of countries. In contrast, several NRL indicators on molecular typing capabilities and EU-level AMR surveillance capacity scored lower in a substantial minority of countries (Figure 11).

Figure 11. Distribution of scores for EULabCap indicators of national reference laboratory services and EU/EEA mean scores, 2018



In 2018, nomination and funding of NRLs to deliver public health functions progressed in EU/EEA countries. However, six countries still lacked full-NRL access to Biosafety Level 3 facilities, and quality accreditation of reference tests was required in only half of the countries.

All countries had reference diagnostic capabilities for case confirmation of at least 36 of the 57 EU-notifiable communicable diseases as per EU case definitions updated in 2018 (Figure 11 and Table 2) [19]. All countries notified in-house confirmation capability for 28 high-priority and/or epidemic-prone diseases (Table 2). For rare diseases (e.g. rabies, yellow fever, or smallpox), which require specialised testing facilities, materials and know-how, identification by NRL was available either domestically or by bilateral agreements with NRLs in other countries. In 2018, two countries lacked domestic capability for diagnostic confirmation of poliovirus, Zika virus and diphtheria, and seven countries lacked capability for yellow fever diagnostics (Table 2).

Table 2. Number of EU/EEA countries capable of diagnostic confirmation testing for 57 EU notifiable diseases listed in Decision (EU) 2018/945 in 2018

Diseases/ health issue	Number of countries (N=30)
ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION	30
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	
BRUCELLOSIS (*Brucella* spp.)	
CAMPYLOBACTERIOSIS (*Campylobacter* spp.)	
CHOLERA (*Vibrio cholerae*)	
CRYPTOSPORIDIOSIS (*Cryptosporidium* spp.)	
GIARDIASIS (*Giardia lamblia*)	
GONORRHOEA (*Neisseria gonorrhoeae*)	
HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (*Haemophilus influenzae*)	
HEPATITIS A (Hepatitis A virus)	
HEPATITIS B (Hepatitis B virus)	
HEPATITIS C (Hepatitis C virus)	
INFLUENZA (Influenza virus)	
INFLUENZA A(H1N1)	
LISTERIOSIS (*Listeria monocytogenes*)	
MALARIA (*Plasmodium* spp.)	
MEASLES (Measles virus)	
MENINGOCCOCAL DISEASE, INVASIVE (*Neisseria meningitidis*)	
MUMPS (Mumps virus)	
PERTUSSIS (*Bordetella pertussis*)	
PNEUMOCOCCAL INVASIVE DISEASE(S) (*Streptococcus pneumoniae*)	
RUBELLA (Rubella virus)	
RUBELLA, CONGENITAL (including Congenital Rubella Syndrome)	
SALMONELLOSIS (*Salmonella* spp. other than *Salmonella* Typhi and *Salmonella* Paratyphi)	
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	
SHIGELLOSIS (*Shigella* spp.)	
SYPHILIS (*Treponema pallidum*)	
SYPHILIS, CONGENITAL AND NEONATAL (*Treponema pallidum*)	
TOXOPLASMOSIS, CONGENITAL (*Toxoplasma gondii*)	
TUBERCULOSIS (*Mycobacterium tuberculosis* complex)	
TYPHOID/PARATYPHOID FEVER (*Salmonella* Typhi/Paratyphi)	
CHLAMYDIAL INFECTION (*Chlamydia trachomatis*), INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	29
DENGUE (Dengue virus)	
ECHINOCOCCOSIS (*Echinococcus* spp.)	
LEGIONNAIRES' DISEASE (*Legionella* spp.)	
YERSINIOSIS (*Yersinia enterocolitica* , *Yersinia pseudotuberculosis*)	
DIPHTHERIA (*Corynebacterium diphtheriae, C. ulcerans* and *C. pseudotuberculosis*)	28
LEPTOSPIROSIS (*Leptospira* spp.)	
PLAGUE (*Yersinia pestis*)	
POLIOMYELITIS (Polio virus)	
TULARAEMIA (*Francisella tularensis*)	
ZIKA VIRUS DISEASE (Zika virus)	
ANTHRAX (*Bacillus anthracis*)	27
CHIKUNGUNYA VIRUS DISEASE (Chikungunya virus)	
Q FEVER (*Coxiella burnetii*)	
SEVERE ACUTE RESPIRATORY SYNDROME — SARS (SARS-coronavirus, SARS-CoV)	
TETANUS (*Clostridium tetani*)	
TICK-BORNE ENCEPHALITIS (TBE virus)	
TRICHINELLOSIS (*Trichinella* spp.)	
VIRAL HAEMORRHAGIC FEVERS (VHF)	
WEST NILE FEVER (West Nile virus infection, WNV)	
ZIKA VIRUS DISEASE, CONGENITAL (Zika virus)	
LYME NEUROBORRELIOSIS *(Borrelia burgdorferi)*	26
YELLOW FEVER (Yellow fever virus)	25
BOTULISM (*Clostridium botulinum*)	24
RABIES (Lyssa virus)	
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	21
SMALLPOX (Variola virus)	19

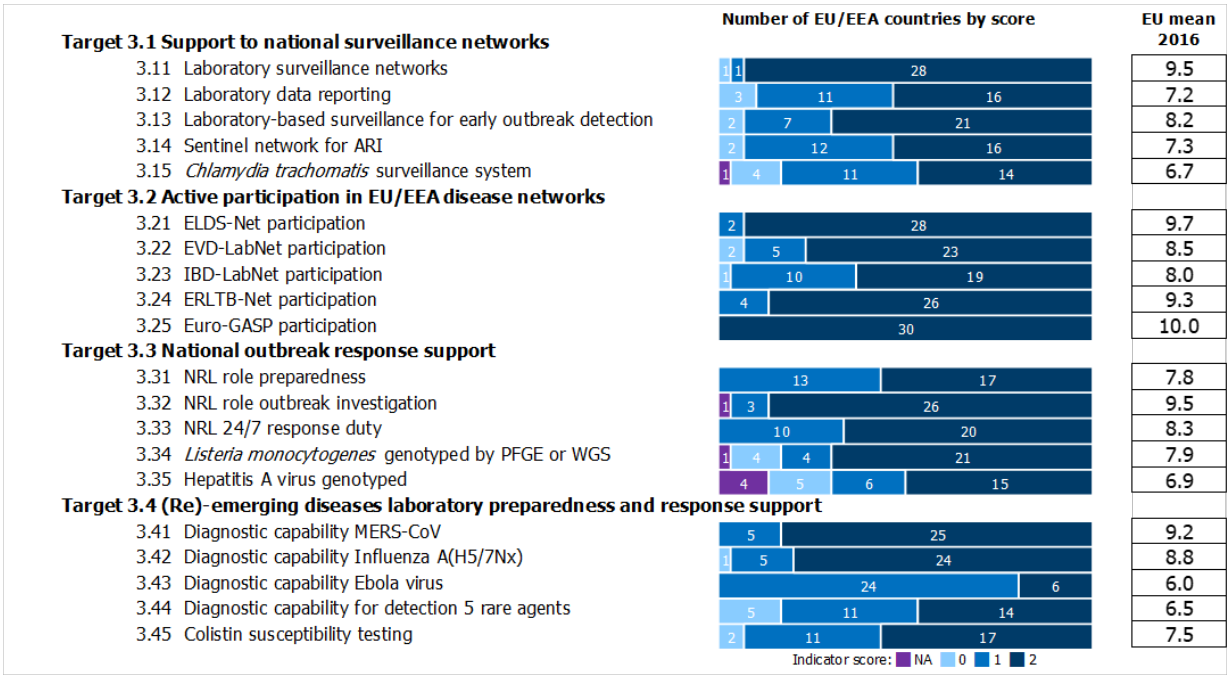
Since the last survey, technical capacity and the use of advanced methods by NRL progressed further, as evidenced by the EU mean score increase for indicators on *Bordetella pertussis* diagnostics and STEC serogrouping. The major progress was seen with practice shift from molecular to genomic surveillance. Between 2016 and 2018, WGS-based typing use for routine national surveillance extended from 15 to 21 countries, as compared with none in 2013. In 2018, the technology was used in 16 to 21 countries for surveillance and/or outbreak investigation of four indicator pathogens (Figure 11).

Regarding NRL contribution to AMR monitoring, indicators remained stable over recent surveys for national identification of AMR mechanisms in indicator pathogens. Reporting capacity indicators for EU AMR surveillance of influenza virus and foodborne bacteria showed uneven performance across countries. The quantitative indicator for ECDC-reported susceptibility data on *Salmonella enterica* and *Campylobacter jejuni/C. coli* in accordance with EU cross-sectoral harmonised methodology was fully complied with in only 11 countries in 2018.

Laboratory-based surveillance and epidemic response support

Figure 12 shows the distribution of national scores for the 20 indicators on laboratory-based surveillance and NRL epidemic preparedness and response support with EU mean score 2018 per indicator. These indicators showed intermediate to high levels of capability/capacity with continued progress in performance across countries for most indicators as compared with the previous years.

Figure 12. Distribution of scores for EULabCap indicators of laboratory-based surveillance and response support and EU/EEA mean scores, 2018



In this survey, as in previous years, nearly all countries received top performance scores for the operation o national sentinel laboratory surveillance networks for six or more diseases or AMR pathogens. Half the countries reported that they had automated electronic system for reporting clinical microbiology data to national surveillance databases in 2018 (Figure 12). The disease coverage and operational capabilities of these digital reporting systems were further assessed in 2019.

Laboratory-based surveillance capacities notably increased across countries in 2018 in the areas of acute respiratory infections (ARI) virological surveillance, colistin susceptibility testing as well as genotyping hepatitis A viruses. NRLs widely participated in EU disease networks in 2018 with EU scores ranging from 8.0 to 10.0 between networks (Figure 12).

Laboratory contribution to epidemic preparedness and response continued to progress in 2018. This include NRL support to outbreak detection, participation in national outbreak investigations and provision of 24/7 emergency duty. Regular analysis of microbiology data for national outbreak detection was implemented in 28 countries and performed on a weekly basis in 21 countries in 2018. All countries involved NRL experts in outbreak investigations at the national level. In 26 countries, they contributed to the investigation of more than 25% of the outbreaks. NRL response support duty teams from all countries had defined roles and responsibilities in national preparedness plans for health treats due to epidemic prone or high-consequence pathogens. These were tested by conducting simulation exercises in 17 countries in 2018 (Figure 12).

Although stable overall for re-emerging disease diagnostic capabilities, some indicator score changes were likely the result of updating them in the last survey. The decreasing score for the detection of five rare agents was related to the replacement of indicator diseases to new or difficult-to-detect pathogens including Crimean-Congo haemorrhagic fever virus, Hantavirus, Toscana virus, Usutu virus and *Candida auris* (Figure 12).

Discussion

Monitoring process

The EULabCap is the first EU-wide initiative to measure and monitor the capabilities and capacities of EU/EEA microbiology laboratories underpinning effective communicable disease surveillance and epidemic preparedness. The indicator framework jointly developed for this purpose by expert consensus, with its common terminology and taxonomy of public health microbiology services, was essential to its success. The sustained response rate and completeness of data illustrate the continued commitment of national experts to a robust and transparent European monitoring process.

EULabCap survey methods have several limitations. Firstly, some indicators vary with respect to country relevance. For example, the indicator 'information sharing within a national network' is less relevant in a small country. Similarly, some capacity indicators on laboratory-confirmed cases may not apply to smaller countries due to low disease incidence.

Secondly, about two-thirds of the indicators are based on self-reporting and thus prone to a certain degree of subjective interpretation by the national experts who collect the information. An external validation of capabilities, for example through external quality assessments and simulation exercises, would be helpful to address this limitation [20-24].

Thirdly, indicator data access was not universal, and some NMFPs were unable to provide data for all indicators. This could be related to the lack of an active data collection instrument, a lack of designated NRLs for specific diseases, outsourcing of some of the reference services to other countries, and NMFP time constraints. The assessment of laboratory capacity is probably accurate for small countries or countries with centralised services but less so for countries with decentralised services. Quantitative capacity indicators of primary diagnostic testing utilisation were particularly challenging and onerous to measure, leaving room for variation in data accuracy and representativeness between countries.

Finally, data comparability over time was slightly limited by minor modifications of a number of indicators/scoring criteria. These revisions have ensured that indicators/scoring criteria are in line with new standards of practice and the evolving epidemiological context but have also hampered the year-to-year comparability of a few indicators, as discussed in the result section.

EU public health microbiology capacities

The results of this fifth survey confirm that the EU/EEA can rely on microbiology services that are steadily strengthening its collective capabilities to detect, identify and characterise infectious disease threats. The aggregate EULabCap index score of 7.8 (on a scale of 0–10) confirms that, on the whole, the EU/EEA has a strong public health microbiology system, with substantial capacity for communicable disease detection, disease surveillance, risk assessment, and outbreak response.

The observed increase in the mean EULabCap index – from 6.9 in 2013 to 7.8 in 2018 – probably reflects genuine improvement in technical and organisational capacities of the laboratory systems in the Member States over the five-year monitoring period. Only a small part of the score increase may be related to minor changes in the indicators or scoring methodology. Steady increases in EULabCap indices over the five-year monitoring period suggest that public health microbiology shortcomings are being addressed. Narrowing variation in the EULabCap index between countries over the past years indicates technical convergence and progress toward a more equitable balance of laboratory capacities among Member States.

Since the first EULabCap survey, the primary diagnostic testing dimension scored lowest in performance, reflecting gaps in clinical laboratory service provision and regulations. Performance scores have substantially increased over the last five years. Several of these improvements were guided by guidance on diagnostic testing, harmonised protocols on laboratory-based surveillance, technology transfer, and quality assurance activities carried out by EU laboratory networks [25]. However, recent EULabCap results indicate that primary diagnostic testing remains the weakest area of public health microbiology system in the EU and EEA and suffers from great disparity among countries. These structural gaps were reflected during the COVID-19 pandemic response, when diagnostic testing policies, methodologies and capacities have differed across countries. Testing capacities were constrained by limited molecular testing infrastructure and trained laboratory personnel as well as shortages of supplies.

Since 2014, all EU/EEA countries declared having access to a range of diagnostics for specific agents, which is required to meet obligations for EU surveillance reporting. There were only a handful of rare diseases or high-consequence pathogens requiring specialised containment facilities for which countries rely on third party arrangements. Most EU/EEA countries also reported extended capabilities for the diagnosis and characterisation of emerging agents, such as novel types of avian influenza viruses, and rare and/or imported viruses such as MERS-

CoV and Ebola virus. This observation is consistent with the results of investigations in the field of laboratory preparedness and response in Europe, including those conducted with the support of ECDC and the EU Health Programme [25,26].

Success in confronting the AMR long-term threat to global health depends on adequate testing to detect and trace the transmission of drug resistance that drives this "silent pandemic". It is reassuring that the capacity for harmonised antimicrobial drug susceptibility testing has been steadily improving in Europe along the lines of the standards set by EUCAST. In 2018 national antimicrobial susceptibility committees (NACs) were established in nearly all Member States to sustain this testing guidance. Clinical laboratories are using EUCAST breakpoints for the interpretation of susceptibility testing results, enabling robust EU surveillance data reporting on AMR trends to EARS-Net, in accordance with the EU case definitions. These achievements are in line with the EU and global-policy focus on combating antimicrobial resistance and a testimony to quality improvement of clinical laboratory practice across Europe through professional leadership [27,28]. Despite the overall high level of capacity for antimicrobial drug resistance surveillance, compliance with the EU protocol for harmonised monitoring of antimicrobial resistance in human *Salmonella enterica* and *Campylobacter jejuni/C. coli* isolates [29] is limited.

Laboratories face new challenges to detect the emergence of multidrug-resistant pathogens [30-32]. Advanced molecular and genome sequence-based detection and characterisation methods are needed for the timely and accurate surveillance of antimicrobial resistance [30-32]. EULabCap results indicate wide capability to identify mechanism of resistance in bacteria and perform national monitoring surveys across countries. This is complemented by ongoing genomic surveys on carbapenemase-producing bacteria in Europe [33-35] and national application of WGS for typing of drug resistant pathogens [36].

A key innovation highlighted by the EULabCap results is the integration of whole genome sequencing in enhanced surveillance of communicable diseases and antimicrobial resistance [37]. In 2018, 21 EU/EEA countries reported the use of WGS in routine surveillance, as compared with 15 in 2016 [36]. This massive method shift is consistent with the ECDC Expert Opinion and Strategic framework [18,24]. Genomic data collection and analysis requires common approaches and collaboration at the EU level to investigate multi-country epidemics [24,38-41].

Regarding laboratory-based surveillance and epidemic response support, the EU/EEA index increased in 2016, with a further convergence of scores among countries. The majority of countries scored high on indicators of national sentinel laboratory-based surveillance. However, despite gradual improvements over the years, many countries still received intermediate scores for their reporting of microbiology data. Cluster detection capability improved in several countries but not all countries perform a weekly analysis to ensure early warning capabilities. Implementing automated e-reporting of laboratory data is a critical step to real-time laboratory-based surveillance, which is still not standard procedure in about half of the countries due to financial and technical hurdles [42]. These countries should consider IT solutions that speed up data transfer and analysis to improve the efficiency and timeliness of laboratory-based surveillance and enhance their alert systems. New partnerships for integrated clinical and public health service provision are being developed in Europe [43].

The EULabCap surveys have revealed both strengths and vulnerabilities of EU laboratory networking activities. Whereas NRL participation in ECDC disease-specific laboratory networks was consistently at a high level, reflecting longstanding EU collaboration between laboratory scientists and public health specialists, funding discontinuities occurred during renewal of short-term outsourcing contracts. A cost–benefit analysis of the EU reference laboratory networks concluded that the benefits of maintaining an overarching system of EU reference laboratory networks are likely to outweigh the costs, both from a Member State and from an EU perspective [16]. Building on trusted collaboration in EU surveillance and reference laboratory networks for influenza and emerging viral diseases, ECDC convened within weeks a COVID-19 Network. The new network is bringing together epidemiology and virology experts as operational contact points to share good practice, validate new test methods and develop surveillance strategies in support of pandemic response [44,45]. Ad hoc surveys of EU networks should be used to rapidly appraise detection capacities in Europe when a public health event is caused by a newly discovered agent such as MERS-CoV in 2014 [22]. A rapid survey conducted in response to the COVID-19 emergency demonstrated the reactivity of NRLs across EU/EEA countries to develop, validate and deploy SARS-CoV-2 specific RT-PCR assays for diagnostic confirmation only weeks after discovery of the virus [46].

While public health microbiology services in the EU/EEA meet most key requirements for communicable disease surveillance and response, not all Member States showed fully balanced laboratory capability and capacity. As assessed by this survey 'Sufficient microbiology capacity' (defined as intermediate or high capacity for at least 10 of 12 EULabCap targets) was reported by 21 Member States in 2018. Likewise, modernisation has progressed with upgrading to genomic methods for the detection, surveillance and characterisation of epidemic agents and antimicrobial resistance. Another area for efficiency gain is the adoption of digital interoperability between clinical laboratory and public health information systems for disease surveillance and early warning at national levels and beyond.

Conclusions

The results of the fifth EULabCap survey confirmed that Europe is steadily building more robust defences against health threats such as antimicrobial resistance and epidemics by improving laboratory diagnostics and characterisation of infectious agents. Inequalities in laboratory capabilities are slowly overcome indicating progress toward a stronger and more cohesive Europe for disease detection, surveillance and control.

Strengths of the EU/EEA public health microbiology system were largely consistent across surveys. High performance assets include quality diagnostics, harmonised antimicrobial drug susceptibility testing, quality and responsive reference laboratory services, collaboration between laboratories and surveillance networks, and deployment of advanced WGS methods for pathogen tracing at the Member State level and in the EU as a whole.

ECDC, in collaboration with the EU/EEA countries, the European Commission and other EU agencies and partners, will continue monitoring the European laboratory capacity as a basis for future country support activities. The usefulness of the EULabCap monitoring system will be further evaluated by systematically collecting NMFP feedback on the use of reports for action at the national level. ECDC will continue to appraise technological advances in microbiology, foster innovation, support the integration of genomic data into European surveillance systems, and share best practices across the European microbiology community.

The resilience and responsiveness of national health systems were severely tested in 2020 by the COVID-19 pandemic. The laboratory epidemic preparedness as measured by EULabCap until 2018 did not appear to predict the country response capacity to rapidly deploy extensive molecular testing for COVID-19. The flexibility to mobilise extraordinary SARS-CoV-2 testing surge capacity was not captured by the EULabCap "routine" emerging disease detection indicators. Therefore, a lesson learned from this reality check is to consider adding national capacity indicators for scaling up pandemic diagnostic testing for future EULabCap monitoring surveys.

Stakeholder feedback on EULabCap country reports indicates that these have been useful for advising national authorities on capacity-strengthening actions in many countries [47]. Vulnerabilities persist in diagnostic testing capacities and information system interoperability. Priority actions for real-time disease monitoring at local, national and EU levels should focus on developing wider clinical guidance on the utilisation of diagnostic tests, strengthening diagnostic testing capacity, building closer professional partnerships across health sectors and accelerating digital connections between laboratory and public health information systems. Drawing the lessons from the COVID-19 crisis, the EU4Health Programme investments in digital health and resilient health services should help address these microbiology system gaps in the coming years. Cooperation and modernisation of practices will enable the EU/EEA to better prevent and manage future epidemics.

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Annex 1. EULabCap survey list of targets, indicators and scoring options

Dimension 1. Primary diagnostic testing

Targets/indicators	Source (NMFP/ECDC) and scoring options
Target 1.1 Regulation clin micro Provision and regulation of clinical microbiology services.	
Indicator 1.11 Test reimbursement Clinical microbiology laboratory tests were funded/reimbursed in total, or in part, either by a national insurance scheme or by a governmental budget.	NMFP NA = information not reported by the NMFP, 0 = no tests are reimbursed, 1 = for hospital in-patient testing, 2 = for in- and outpatient testing.
Indicator 1.12 Laboratory licencing Clinical microbiology laboratories obtained a licencing authorisation/registration from health authorities (or professional organisations) according to legal/regulatory requirements.	NMFP NA = information not reported by the NMFP, 0 = not required by law/regulation, 1 = required for some laboratories, 2 = required for all laboratories.
Indicator 1.13 Laboratory accreditation Clinical microbiology laboratories accredited their diagnostic tests according to either ISO 17025, ISO 15189, or equivalent national standards.	NMFP NA = information not reported by the NMFP, 0 = no laboratories, 1 = some laboratories, 2 = all laboratories.
Indicator 1.14 Biosafety general Clinical microbiology laboratories must receive a biosafety authorisation/permit for performing operations at Biosafety Level (BSL)2 and BSL3.	NMFP NA = information not reported by the NMFP, 0 = not required by law/regulation, 1 = for BSL3 facilities, 2 = for both BSL2 and BSL3 facilities.
Indicator 1.15 Biosafety tuberculosis Culture-based tuberculosis diagnostic and drug susceptibility tests were restricted to laboratories compliant with performing BSL3 operations in line with the WHO tuberculosis laboratory biosafety manual.	NMFP NA = information not reported by the NMFP, 0 = not required by law/regulation, 1 = for DSTs, 2 = for all TB culture tests and TB DSTs.
Target 1.2 Diag guidance Diagnostic testing guidelines	
Indicator 1.21 Antenatal screening National guidelines are available for antenatal screening of congenital infection and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines information not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.22 HIV testing National guidelines are available for HIV diagnostic testing and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines information not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.23 *C. difficile* testing National guidelines are available for *Clostridium difficile* diagnostic testing in healthcare associated diarrhoea and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines information not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.24 CPE screening National guidelines are available for screening of hospitalised patients for carbapenem-resistant/carbapenemase-producing *Enterobacteriaceae* and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.25 Tuberculosis DST National guidelines are available for tuberculosis laboratory diagnostic and drug susceptibility testing and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Target 1.3 Diag test use Diagnostic testing utilisation	
Indicator 1.31 Diagnostic tests migrants Accessible diagnostic testing for HIV infection and/or tuberculosis was available to undocumented migrants in your country.	NMFP NA = information not reported by the NMFP, 0 = testing is not available, 1 = testing available for HIV infection, 2 = testing available for HIV infection and tuberculosis.

Indicator 1.32 Blood culture test rate Number of blood culture sets tested/1 000 hospital bed-days by EARS-Net participating hospitals from your country.	ECDC 0 = information not reported to EARS-Net, or not reported in the country, 1 = < 25/1 000 hospital bed-days, 2 = 25/1 000 hospital bed-days and more.
Indicator 1.33 *C. difficile* test rate Total number of *Clostridium difficile* diagnostic tests* performed/1000 hospital-bed-days, based on national estimate**. * A test = a stool sample tested by one or more diagnostic *Clostridium difficile* assays including toxin immunoassay, toxin cytotoxic cell-culture assay, PCR, or culture ** Estimate can be determined using a (representative) sample of a survey	NMFP 0 = not measured in the country, 1 = < 4/1 000 hospital bed-days, 2 = 4 /1 000 hospital bed-days or more.
Indicator 1.34 Tuberculosis culture confirmation and DST Percentage of new pulmonary tuberculosis cases confirmed by culture and tested for susceptibility to first-line drugs.	ECDC 0 = <80% culture confirmed, 1 = ≥80% culture confirmed BUT <95% DST of cultures, 2 = ≥80% culture confirmed AND ≥95% DST of cultures.
Indicator 1.35 HIV late diagnosis Percentage of new HIV cases older than 14 years reported with initial CD4 counts (<350 cells/µl - late diagnosis).	ECDC 0 = CD4 cell count not reported to ECDC, 1 = > 48 percent, 2 = ≤ 48 percent
Target 1.4 AST Antimicrobial drug susceptibility testing	
Indicator 1.41 National Antimicrobial Susceptibility Committee (NAC) A National Antimicrobial Susceptibility Committee (NAC) is established and its representative attended of EUCAST General Committee meeting.	ECDC 0 = NAC not established or inactive in 2016, 1 = NAC formation in process in 2016, 2 = NAC established and active in 2016.
Indicator 1.42 Clinical laboratories using EUCAST breakpoints Percentage of clinical laboratories in the country that used EUCAST clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians.	ECDC 0 = <10% of clinical laboratories, 1 = 10-50% of clinical laboratories, 2 = >50% of clinical laboratories.
Indicator 1.43 EARS-Net participants using EUCAST breakpoints Percentage of clinical laboratories participating in EARS-Net that have used EUCAST clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians	ECDC NA = information not reported to ECDC, 0 = <25% of clinical laboratories, 1 = 25-75% of clinical laboratories, 2 = >75% of clinical laboratories.
Indicator 1.44 ERLTB-Net participation in EQA for DST Tuberculosis Reference Laboratories that participated in ECDC-funded ERLTB-Net external quality assessment scheme in 2018 achieved 80% performance level for culture and susceptibility testing for first- and second-line drugs.	NMFP NA = information not reported by the NMFP, 0 = no participation, 1 = participation with performance <80%, 2 = participation with performance ≥80%.
Indicator 1.45 Gonorrhoea AST National surveillance of gonococcal antimicrobial resistance is providing susceptibility data on 10% or more of reported gonorrhoea cases.	NMFP NA = information not reported by the NMFP, 0 = no surveillance of AMR at national level, 1 = susceptibility data were provided for <10% of reported cases, 2 = susceptibility data were provided for ≥10% of reported cases.

Dimension 2. National reference laboratory services (NRL)

Targets/indicators	Source (NMFP/ECDC) and scoring options
Target 2.1 Regulation NRL Provision and regulation of national reference microbiology services	
Indicator 2.11 NRL funding National reference laboratory (NRL) for public health microbiology services were financially supported at least in part by health authorities or other competent bodies.	NMFP NA = information not reported by the NMFP, 0 = no funding, 1 = funding to some NRLs, 2 = funding to all NRLs.
Indicator 2.12 NRL nomination NRLs were officially nominated by health authorities or other competent bodies.	NMFP NA = information not reported by the NMFP, 0 = no NRL was officially nominated, 1 = some NRLs were officially nominated, 2 = all NRLs were officially nominated.

Targets/indicators	Source (NMFP/ECDC) and scoring options
Indicator 2.13 NRL core functions The majority of NRLs delivered the following functions: (ECDC will use the answers provided for each function (indicators 2.13a to 2.13e) to calculate the indicator score) 2.13(a) Reference diagnostics. 2.13(b) Reference material resources. 2.13(c) Scientific advice and diagnostic guidance. 2.13(d) Collaboration and research development. 2.13(e) Monitoring, alert and response.	NMFP For 2.13a-2.13e 0 = no, 1 = yes. **NOTE: ECDC will use the scores provided for each function to calculate the overall score.** NA = information not reported by the NMFP, 0 = 1-2 functions, 1 = 3-4 functions, 2 = all 5 functions.
Indicator 2.14 NRL accreditation NRLs accredited at least some of their diagnostic tests according to either ISO 17025, ISO 15189, or equivalent national standard.	NMFP NA = information not reported by the NMFP, 0 = no NRL accredited their tests, 1 = some NRLs accredited their tests, 2 = all NRLs accredited their tests.
Indicator 2.15 NRL BSL3 NRLs have access to biocontainment facilities with biosafety authorisation for performing Biosafety Level 3 operations.	NMFP NA = information not reported by the NMFP, 0 = no BSL3 facility available for NRLs, 1 = partial access for some BSL3 operations, 2 = full access for all BSL3 operations.

Target 2.2 Ref diag id **Reference diagnostic confirmation and pathogen identification**	
Indicator 2.21 Diagnostic identification 53 diseases under EU surveillance Case confirmation* with pathogen identification for EU surveillance was available within your country by primary and/or reference laboratory for the 53 communicable diseases. *according to the laboratory criteria described in the Case definitions of the Decision 2018/945 of 22 June 2018 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D0945&from=EN)	NMFP NA = information not reported by the NMFP, 0 = <20 pathogens/issues, 1 = 20-35 pathogens/issues, 2 = >35 pathogens/issues.
Indicator 2.22 *Legionella* culture confirmed Culture confirmation of Legionnaires' disease was performed for EU reported cases in accordance with EU case definition/ELDS-Net guidance.	ECDC 0 = not reported to ECDC, 1 = <10% of reported cases were culture confirmed, 2 = ≥10% of reported cases were culture confirmed.
Indicator 2.23 Pertussis laboratory confirmed Laboratory confirmation of *Bordetella pertussis* (by culture or PCR) was performed for EU reported cases in accordance with EU case definition/EUPertLabNet guidance.	ECDC NA = not applicable because of zero cases reported, 0 = no case-based reporting to ECDC, 1 = <10% of reported cases were culture or PCR confirmed, 2 = ≥10% of reported cases were culture or PCR confirmed.
Indicator 2.24 Serogroup STEC O-serogrouping was performed and reported to ECDC for cases of STEC/VTEC in accordance with EU case definition (percentage of isolates with serogroup reported out of total number of cases reported, excluding non-typeable isolates).	NMFP NA = information not reported by the NMFP, 0 = serogroup was reported for <80% of reported cases, 1 = serogroup was reported for 80-99% of reported cases, 2 = serogroup was reported for 100% of reported cases.
Indicator 2.25 SARI viral testing National guidelines and reference virological diagnostic testing were available for investigation of Severe Acute Respiratory Infection (SARI) cluster in accordance with WHO guidance.	NMFP NA = not available/not applicable, 0 = not available at the national level, 1 = implemented without monitoring, 2 = implemented with monitoring.
Target 2.3 Molecular surveillance Molecular typing for surveillance	
Indicator 2.31 WGS surveillance Whole genome sequencing (WGS) -based typing of human pathogens was used in national reference laboratories for routine surveillance of one or more disease/health issue.	NMFP NA = information not reported by the NMFP, 0 = no activity and no national plan in place, 1 = no activity but a plan in place/in progress for at least 1 human pathogen, 2 = WGS is used routinely for typing in national surveillance - of at least 1 human pathogen.
Indicator 2.32 *Listeria monocytogenes* genotyped Use of WGS-based typing of *Listeria monocytogenes* by national public health reference laboratory	NMFP NA = information not reported by the NMFP or not applicable because zero cases reported, 0 = WGS-based typing not used by NRL, 1 = WGS-based typing used by NRL only for outbreak investigations, 2 = WGS-based typing used by NRL for both routine national surveillance and outbreak investigations.

Indicator 2.33 MDR-TB MIRU-VNTR genotyped Use of WGS-based typing of MDR-*M. tuberculosis* isolates by national public health reference laboratory	NMFP NA = information not reported by the NMFP or not applicable because zero cases reported, 0 = WGS-based typing not used by NRL, 1 = WGS-based typing used by NRL only for outbreak investigations, 2 = WGS-based typing used by NRL for both routine national surveillance and outbreak investigations.
Indicator 2.34 *N. meningitidis* typed Use of WGS-based typing of invasive *Neisseria meningitidis* isolates by national public health reference laboratory	NMFP NA = information not reported by the NMFP or not applicable because zero cases reported, 0 = WGS-based typing not used by NRL, 1 = WGS-based typing used by NRL only for outbreak investigations, 2 = WGS-based typing used by NRL for both routine national surveillance and outbreak investigations.
Indicator 2.35 HIV ARV genotyped Total number of HIV isolates genotyped by antiretroviral target sequence analysis divided by the total number of new HIV cases with sufficient HIV viral load reported to national surveillance.	NMFP **Number of initial HIV isolates genotyped =** **Number of new HIV cases reported=** **NOTE: ECDC will use the numbers provided to calculate the percentage and score accordingly.** NA = information not reported by the NMFP, 0 = type reported for <20% of reported cases, 1 = type reported for 20-50% of reported cases, 2 = type reported for >50% of reported cases.
Target 2.4 AMR monitoring Antimicrobial drug resistance characterisation and monitoring	
Indicator 2.41 MRSA characterisation resistance Identification of antimicrobial resistance mechanisms and/or genotyping was performed for methicillin-resistant *Staphylococcus aureus* (MRSA) isolates in accordance with EUCAST/*Staphylococcus aureus* reference laboratory network guidance.	NMFP NA = information no reported by the NMFP, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.42 Carbapenemase identification using EUCAST guidance Identification of type of carbapenemase was performed for carbapenemase producing Gram-negative bacilli isolates in accordance with EUCAST guidance.	NMFP NA = information no reported by the NMFP, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.43 ESBL identification using EUCAST guidance Identification of type of extended spectrum beta-lactamase was performed for ESBL-producing Gram negative bacilli isolates in accordance with EUCAST guidance.	NMFP NA = information no reported by the NMFP, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.44 Influenza AST to neuraminidase inhibitors Human influenza virus susceptibility monitoring to neuraminidase inhibitors by phenotypic/genotypic methods was performed and results were reported by National Influenza Centres/influenza reference laboratories to ECDC.	ECDC 0 = Neuraminidase inhibitors susceptibility not monitored, 1 = Neuraminidase inhibitors susceptibility monitoring was performed but results not reported to ECDC, 2 = Neuraminidase inhibitors susceptibility monitoring was performed and results were reported to ECDC.
Indicator 2.45 Cross sector monitoring of AMR in human and animal bacterial isolates Antimicrobial susceptibility data on *Salmonella* and *Campylobacter* were reported to ECDC in accordance with the EU protocol for harmonized monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates.	ECDC NA = not available/not applicable, 0 = not established, 1 = occasional joint surveys, 2 = integrated annual reporting. 0 = Annual *Salmonella* and *Campylobacter* AST data were not reported to ECDC OR data reported were not compliant with EU harmonised protocol (either not-base-based or not quantitative); 1 = *Salmonella* AST data obtained by a EUCAST recommended method were reported quantitatively to ECDC as per EU protocol at least for (cefotaxime OR ceftazidime) AND (ciprofloxacin OR pefloxacin) AND meropenem; 2 = Fulfilling score 1 AND *Campylobacter* AST data obtained by a EUCAST recommended method were reported quantitatively to ECDC as per EU protocol at least for: erythromycin AND ciprofloxacin.

Dimension 3. Laboratory-based surveillance and epidemic response support

Targets/indicators	Source (NMFP/ECDC) and scoring options
Target 3.1 Surveillance Support to national surveillance networks	
Indicator 3.11 Laboratory surveillance networks Reference laboratories and/or public health bodies were collaborating with national networks of clinical laboratories contributing data on surveillance of communicable diseases.	NMFP NA = information not reported by the NMFP, 0 = no national network of laboratories, 1 = national networks collaborating for 1-5 diseases/AMR issues, 2 = national networks collaborating for more than five diseases/AMR issues.
Indicator 3.12 Laboratory data reporting Surveillance networks of clinical laboratories reported microbiological data to a central national public health surveillance database.	NMFP NA = information not reported by the NMFP, 0 = no surveillance report OR only paper-based reporting, 1 = for at least one disease by online forms/email files, 2 = for at least one disease by machine to machine upload from a laboratory information management system.
Indicator 3.13 Laboratory-based surveillance data for early outbreak detection Microbiology data from laboratory-based national surveillance systems were centrally analysed and reported to stakeholders for incidence trends and early warning of excess rates/clusters of epidemic prone disease above baseline rates for diseases under EU surveillance.	NMFP NA = information not reported by the NMFP, 0 = not performed at national level, 1 = for at least one disease performed at least monthly, 2 = for at least one disease performed at least weekly.
Indicator 3.14 Sentinel network for ARI National Influenza Centres/influenza reference laboratories performed a systematic sentinel sampling of influenza and respiratory syncytial viruses.	ECDC 0 = systematic sentinel sampling by the National Influenza Centres/influenza reference laboratory, 1 = sentinel sampling only for influenza, 2 = sentinel sampling for influenza AND respiratory syncytial virus.
Indicator 3.15 *Chlamydia trachomatis* surveillance system National system for collecting and reporting surveillance data on *Chlamydia trachomatis* infection was in place AND reported laboratory-based information in accordance with the guidance for *Chlamydia* control in Europe.	NMFP NA = information not reported by the NMFP, 0 = no reporting at national level, 1 = partial system, 2 = full system.
Target 3.2 EULabNet participation Active participation in EU disease networks	
Indicator 3.21 ERLI-Net participation Country was an active participant in the European Reference Laboratory Network for Human Influenza (ERLI-Net) /European Influenza Surveillance Network (EISN) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e.g. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.
Indicator 3.22 EVD-LabNet participation Country was an active participant in the European expert laboratory network for emerging viral diseases (EVD-LabNet) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.
Indicator 3.23 EUPert-LabNet participation Country was actively participating in the European Pertussis Laboratory Network (EUPert-LabNet) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.
Indicator 3.24 ERLTB-Net participation Country was an active participant in European reference laboratory Network for TB (ERLTB-Net) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.

Indicator 3.25 EARS participation Country was an active participant in the European Antimicrobial Resistance Surveillance Network (EARS-Net) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.
Target 3.3 Outbreak response National outbreak response support	
Indicator 3.31 NRL role preparedness NRLs had defined roles and responsibilities described and tested in exercises as part of the national preparedness and response plan for health threats due to epidemic prone/high consequence pathogens.	NMFP NA = information not reported by the NMFP, 0 = no, 1 = yes but without simulation exercises, 2 = yes with simulation exercises.
Indicator 3.32 NRL role outbreak investigation Percentage of outbreaks investigated at the national level for which NRL personnel participated as a member of the outbreak investigation team.	NMFP NA = information not reported by the NMFP, 0 = no participation in outbreak investigation team, 1 = participate in <25% of outbreaks, 2 = participate in ≥25% of outbreaks.
Indicator 3.33 NRL 24/7 response duty NRLs for epidemic prone/high consequence pathogens have trained personnel available for assistance in outbreak teams at national level.	NMFP NA = information not reported by the NMFP, 0 = no personnel available, 1 = personnel available during working hours, 2 = personnel available in 24/7 duty roster.
Indicator 3.34 *Listeria monocytogenes* genotyped by PFGE or WGS Percentage of the total number of *Listeria monocytogenes* isolates genotyped by pulsed-field gel electrophoresis (PFGE), or by whole genome sequencing (WGS), out of the total number of reported listeriosis cases at national level.	NMFP NA = information not reported by the NMFP/not applicable (e.g. less than 10 cases per year), 0 = genotyping was not done, 1 = type reported for <80% of reported cases, 2 = type reported for 80-100% of reported cases.
Indicator 3.35 Hepatitis A virus genotyped Percentage of hepatitis A virus clinical samples genotyped by sequence analysis out of all hepatitis A cases reported at national level.	NMFP NA = information not reported by the NMFP, 0 = genotyping was not done, 1 = type reported for <20% of reported cases, 2 = type reported for ≥20% of reported cases.
Target 3.4 Preparedness response (Re)-emerging diseases laboratory preparedness and response support	
Indicator 3.41 Diagnostic capability MERS-CoV Diagnostic capability for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infection available at national level in accordance with WHO surveillance guidance.	NMFP NA = information not reported by the NMFP, 0 = no diagnostic capability, 1 = screening test only, 2 = screening AND confirmation/identification.
Indicator 3.42 Diagnostic capability Influenza A(H5Nx), A(H7Nx) and A(H9Nx) Diagnostic and characterisation capability for avian influenza A(H5Nx), A(H7Nx) and A(H9Nx) viruses available at national level in accordance with ECDC/WHO surveillance guidance.	NMFP NA = information not reported by the NMFP, 0 = no specific diagnostic capability, 1 = HA identification available, 2 = HA and NA identification available.
Indicator 3.43 Diagnostic capability Ebola virus Diagnostic and characterisation capability (within country AND/OR through formal agreement with laboratories in other countries) for Ebola virus infection.	NMFP NA = information not reported by the NMFP, 0 = no national capacity nor formal agreement with other laboratories, 1 = molecular detection at BSL3 level or formal agreement with BSL3 laboratory in another country, 2 = further characterisation at BSL4 level within the country.
Indicator 3.44 Diagnostic capability for detection of five rare agents One or more reference virology laboratories in your country have detection capability for human infection with the following 5 (re)-emerging pathogens: Crimean-Congo haemorrhagic fever virus/Hantavirus/Toscana virus/Usutu virus/*Candida auris.* **Based on EVD-LabNet directory and a 2018 survey on Candida auris detection.*	ECDC* 0 = for less than 2 pathogens , 1 = for at least 2 out of 5 pathogens, 2 = for all 5 pathogens
Indicator 3.45 Guidance for colistin susceptibility testing /confirmation and identification of resistance mechanism by NAC or NRL National guidance was available for colistin susceptibility testing and detection of acquired colistin resistance in carbapenem-resistant *Enterobacteriaceae* and confirmation and identification of colistin resistance mechanisms was provided by NRL to clinical laboratories.	ECDC NA = information not reported by the NMFP, 0 = neither guidance nor reference confirmation were available at national level, 1 = technical guidance for colistin susceptibility testing has been issued by the National Antimicrobial Susceptibility Committee (NAC) and/or National Reference Laboratory OR confirmation of acquired colistin resistance and identification of resistance mechanism in clinical isolates are provided by the National Reference Laboratory to clinical laboratories, 2 = Both of the above were provided to clinical laboratories.

Annex 2. Policy rationale for EULabCap targets: key capabilities/capacities

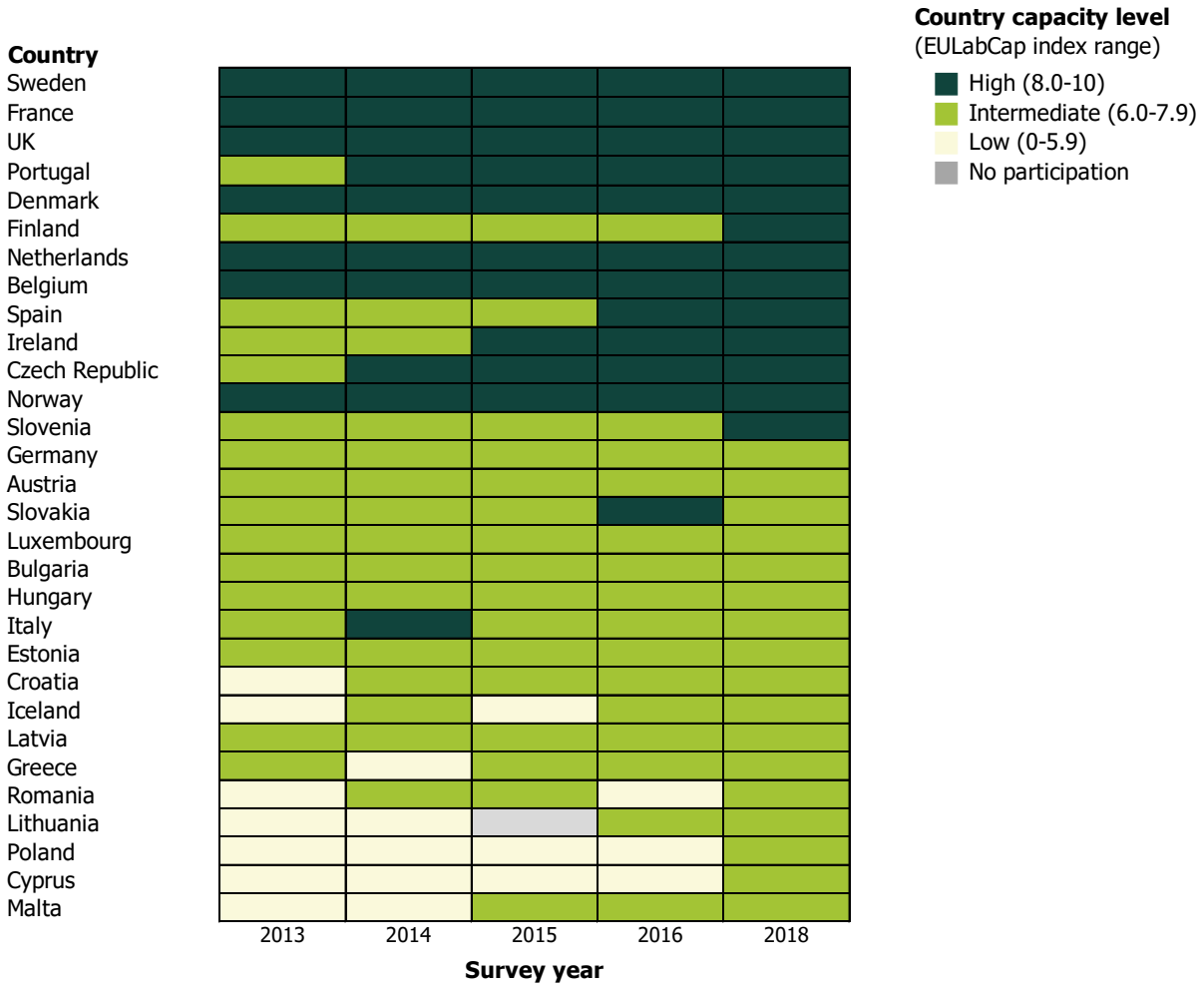
Target	Rationale for key capability/capacity
1.1. Provision and regulation of clinical microbiology services	Provision of reliable, quality-assured, safe and fully accessible clinical diagnostic microbiology services is a prerequisite for adequate case ascertainment and surveillance/threat notification systems.
1.2 Diagnostic testing guidelines	Availability of national primary diagnostic and screening testing guidelines (e.g. who to test, how to test, and when to test) is a prerequisite to guarantee sufficient sensitivity for case ascertainment and surveillance/threat notification systems.
1.3 Diagnostic testing utilisation	Awareness of national testing practices provides a basis for monitoring sensitivity of case ascertainment and surveillance/notification systems.
1.4 Antimicrobial drug susceptibility testing	Implementation and monitoring of compliance with EU standards for antimicrobial drug susceptibility testing is a prerequisite for accurate and comparable EU surveillance of antimicrobial resistance, in accordance with EU strategy on AMR.
2.1 Provision and regulation of national reference microbiology services	Organisation, regulation, and funding of national reference laboratory infrastructure and core public health functions are key elements for informing surveillance and epidemic preparedness at national and EU levels, in accordance with NMFP consensus.
2.2 Reference diagnostic confirmation and pathogen identification	Availability of national reference laboratory testing capability and capacity and a robust sample referral and reporting system to the national authorities is a prerequisite for effective surveillance and epidemic preparedness at national and EU levels in accordance with NMFP consensus.
2.3 Molecular typing for surveillance	Development and implementation of harmonised methodologies to integrate molecular typing data into surveillance for priority diseases form a prerequisite for informing public health action based on EU-wide risk assessment of disease transmission.
2.4 Antimicrobial drug resistance characterisation and monitoring	Accurate characterisation and monitoring of antimicrobial resistance determinants across human and animal populations for national/EU-wide surveillance informs public health action to contain cross-border and cross-species transmission of multidrug-resistant pathogens.
3.1 Support to national surveillance networks	National surveillance networks connecting clinical/public health laboratories for reporting diagnostic information to surveillance databases and linking microbiological and epidemiological information are essential for efficient communicable disease and drug resistance surveillance and early infectious threat detection.
3.2 Active participation in EU disease networks	Active participation and collaboration between experts in EU disease networks promote exchange of best practice and capacity-building, which foster sufficient collective capacity in the EU for threat detection, investigation, disease surveillance and epidemic preparedness.
3.3 National outbreak response support	Preparation and involvement of the national reference laboratory capacities and staff in outbreak monitoring and response activities in collaboration with clinicians, epidemiologists, and microbiologists ensure the effective contribution of laboratory testing to support epidemic detection and control.
3.4 (Re)-emerging diseases laboratory preparedness and response support	Up-to-date diagnostic capability for rare and (re)-emerging diseases and effective channels for collaboration are critical for laboratory preparedness and the deployment of timely and reliable emergency response to national and cross-border events.

Annex 3. Data completeness by indicator, EULabCap surveys 2013–2018

			2013		2014		2015		2016		2018	
	Target	Indicator	Total number NA	Countries	Total number NA	Countries	Total number NA	Countries	Total number NA	Countries	Total number NA	Countries
Dimension 1	1.1	1.11	2	CY, IE	1	CY	1	CY	0		0	
		1.14	1	GR	0		0	-	0		0	
	1.2	1.22	0	-	1	NL	1	NL	0		0	
		1.23	1	LV	2	HR, NL	2	HR, NL	1	HR	0	
		1.24	1	LV	1	LV	0		0		0	
	1.3	1.31	3	NL, PO, PT	0		1	NL	0		0	
		1.32	0		0		0		0		1	UK
		1.33	6	GR, HR, NL, PO, PT, RO	8	BE, DE, LU, NO, PO, RO, SI, SV	9	BE, DE, ES, FR, GR, IE, NO, PT, RO	0		0	
		1.34	0		3	FR, IT, LU	1	FR	1	FR	3	FR, LT, LU
	1.4	1.41	1	MT	1	CY	1	CY	0		0	
		1.42	2	CY, MT	1	CY	1	CY	0		0	
		1.44	2	DE, IS	2	DE, IS	1	IS	1	IS	2	IS, LT
		1.45	0		2	CZ, DE	1	DE	1	DE	0	
Dimension 2	2.1	2.11	1	PO	1	PO	1	PO	0		0	
		2.12	1	PO	1	PO	0		0		0	
		2.13	1	PO	0		0		0		0	
		2.14	1	MT	3	IT, MT, PO	1	MT	0		0	
		2.15	0		1	PO	0		0		0	
	2.2	2.23	0		7	BE, BG, CY, IS, IT, SI, PO	5	BE, BG, LU, MT, PO	1	MT	1	CY
		2.24	6	BG, CY, HR, LV, MT, PT	6	BG, CY, HR, LV, MT, PT	8	CY, HR, GR, MT, PO, PT, RO, SV	4	CY, EL, HR, NL	3	CY, HR, NL
		2.25	1	MT	3	CY, IS, MT	3	CY, IT, MT	2	CY, MT	1	CY
	2.3	2.31	1	MT	3	HR, MT, SV	2	HR, SV	2	HR, MT	0	
		2.32	5	CZ, LT, MT, PT, SV	0		0		3	DE,FR, PT	0	
		2.33	11	CZ, EE, FR, HU, IS, LT, LV, PT, RO, SI, UK	4	CY, IS, MT, SI	4	CY, IS, LU, SI	4	HR, IS, MT, SI	1	IS
		2.34	4	HR, IS, PO, SV	2	BG, HR	0		1	IS	1	IS
		2.35	2	MT, PT	9	ES, GR, IT, NL, PO, PT, RO, SV, UK	9	ES, GR, IT, NL, PO, PT, RO, SV, UK	8	EL, ES, IT, NL PL, RO, SV ,UK	4	ES, IT, SL, UK
	2.4	2.41	1	CY	1	CY	0		1	CY	1	UK
		2.42	2	CY, MT	0		0		0		0	
		2.43	2	CY, MT	1	CY	0		0		0	
		2.44	2	CY, MT	0		0		0		0	
		2.45	1	MT	1	MT	0		0		0	
Dimensio	3.1	3.11	1	MT	1	MT	0	-	0		0	
		3.12	0		0		1	MT	0		0	
		3.13	4	HU, IS, LT, MT	2	IS, MT	2	CY, IS	1	CY	0	

*Legend: AT (Austria), BE (Belgium), BG (Bulgaria), CY (Cyprus), CZ (Czechia), DE (Germany), DK (Denmark), EE (Estonia), EL (Greece), ES (Spain), FI (Finland), FR (France), HR (Croatia), HU (Hungary), IE (Ireland), IS (Iceland), IT (Italy), LT (Lithuania), LV (Latvia), LU (Luxembourg), MT (Malta), NL (Netherlands), NO (Norway), PL (Poland), PT (Portugal), RO (Romania), SE (Sweden), SI (Slovenia), SV (Slovakia), UK (United Kingdom). * Indicators were not applicable*

Annex 4. EU/EEA country capacity level by year based on EULabCap index, 2013–2018

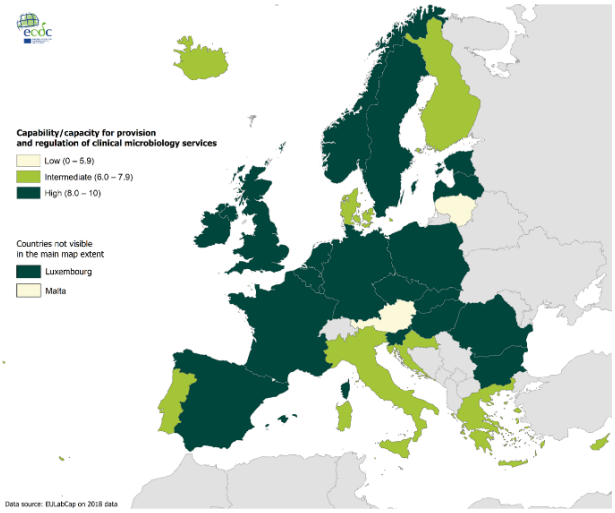


** N=30 countries, except N=29 countries in 2015; countries sorted by decreasing score in 2018*

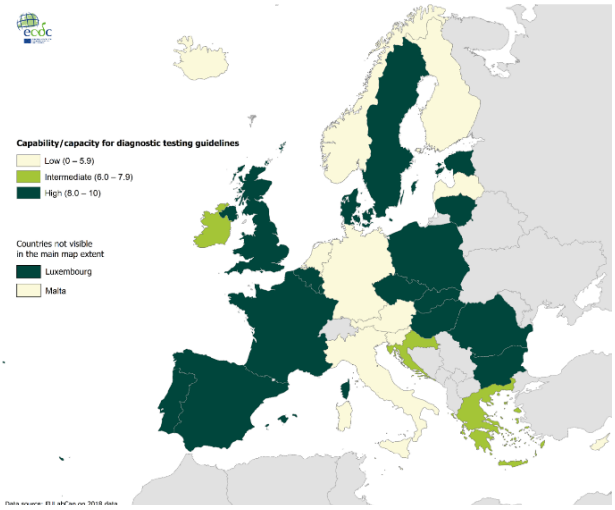
Annex 5. Maps of EULabCap target performance by country, 2018

Dimension 1: primary diagnostic testing, targets 1.1–1.4, 2018

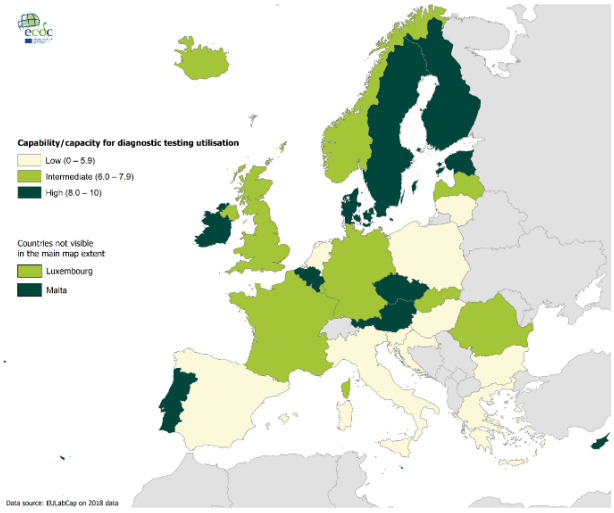
Target 1.1 Provision and regulation of clinical microbiology services



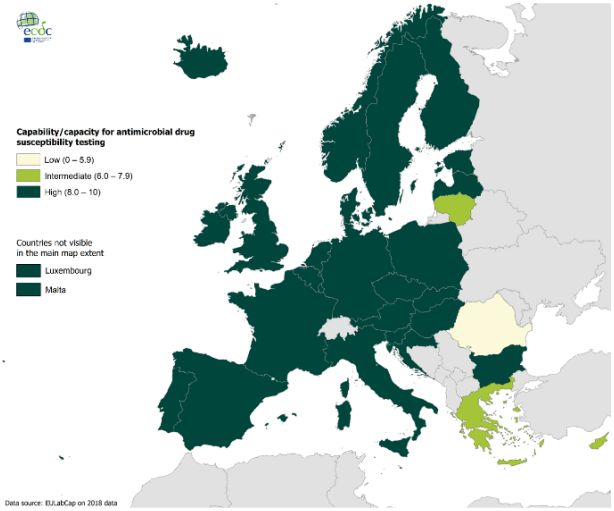
Target 1.2 Diagnostic testing guidelines



Target 1.3 Diagnostic testing utilisation

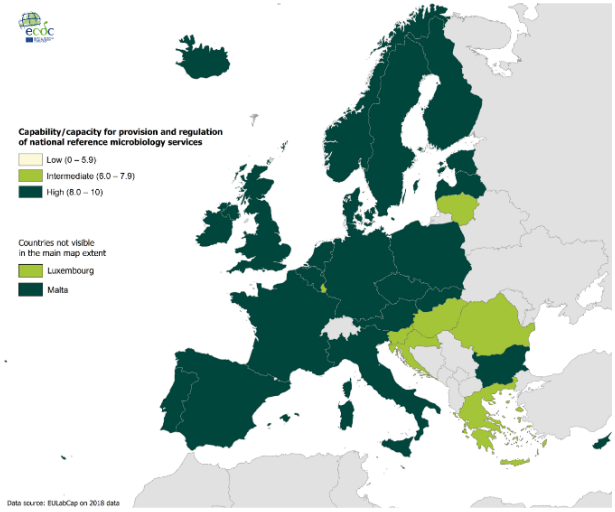


Target 1.4 Antimicrobial drug susceptibility testing

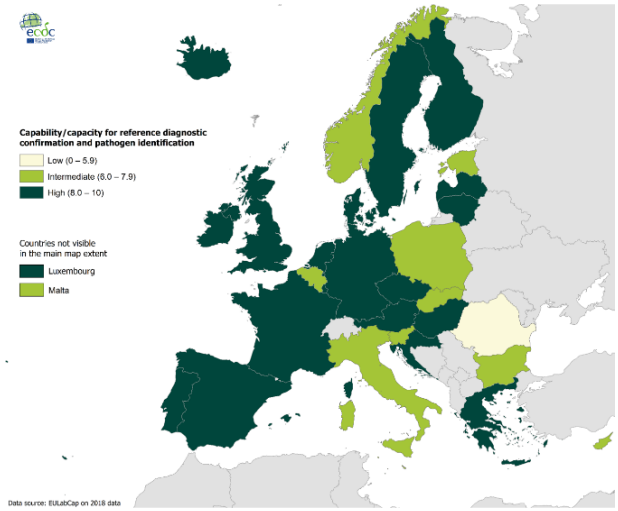


Dimension 2: national reference laboratory services, targets 2.1–2.4, 2018

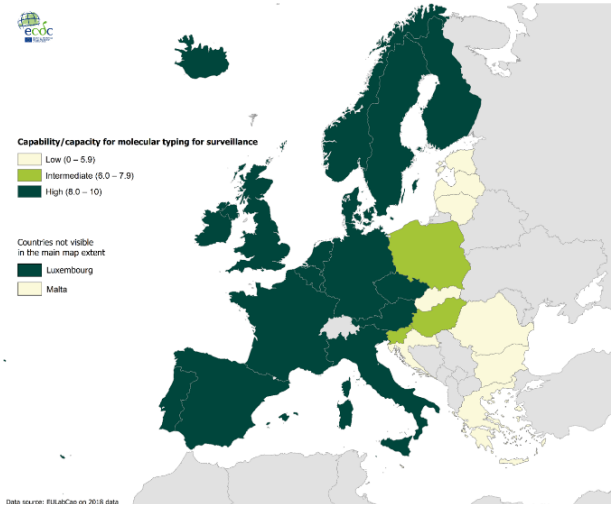
Target 2.1 Provision and regulation of national reference microbiology services



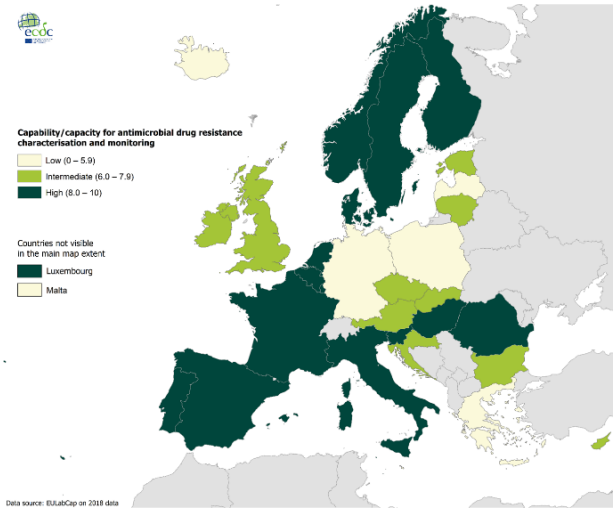
Target 2.2 Reference diagnostic confirmation and pathogen identification



Target 2.3 Molecular typing for surveillance

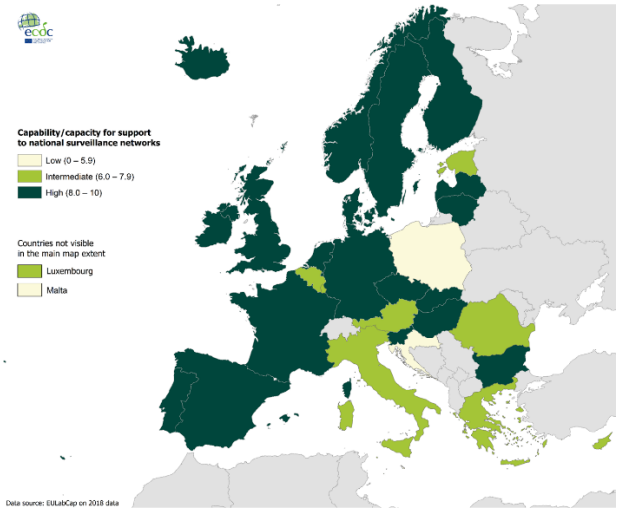


Target 2.4 Antimicrobial drug resistance characterisation and monitoring

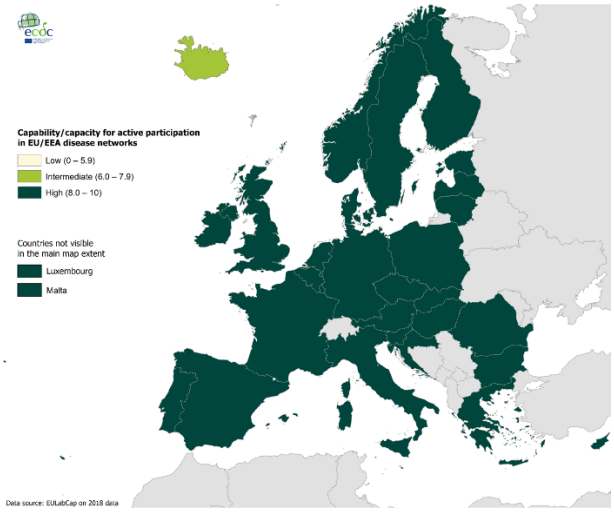


Dimension 3: laboratory-based surveillance and epidemic response support, targets 3.1–3.4, 2018

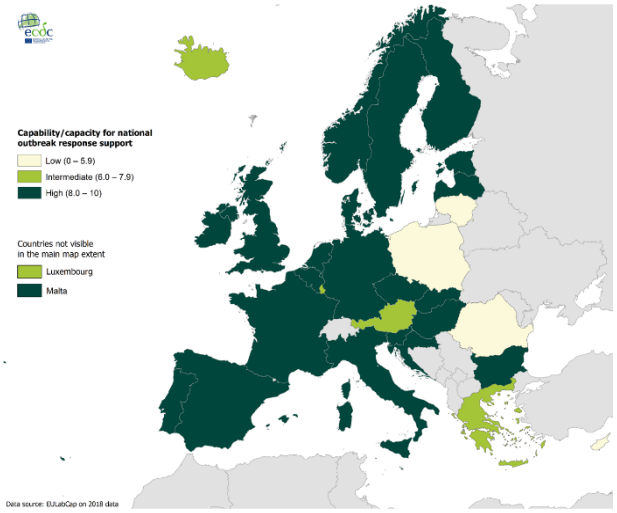
Target 3.1 Support to national surveillance networks



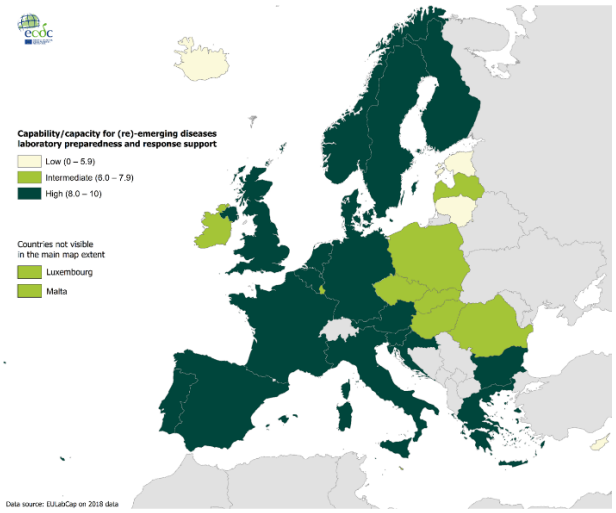
Target 3.2 Active participation in EU/EEA disease networks



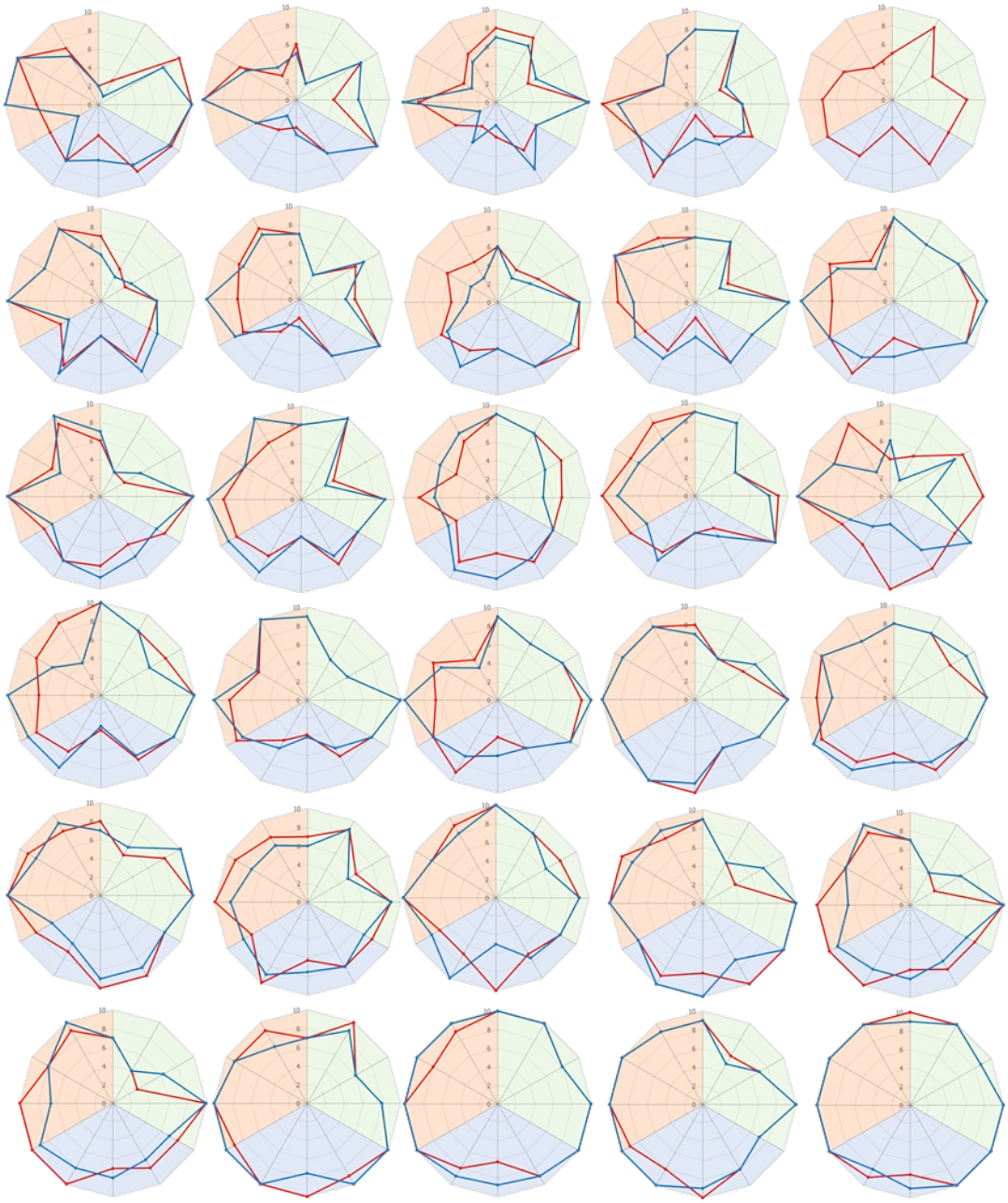
Target 3.3 National outbreak response support



Target 3.4 (Re)-emerging diseases laboratory preparedness and response support



Annex 6. Radar graphs of EULabCap target index scores for each country, 2016 and 2018



Note: The radar charts compare the EULabCap target index scores of 30 countries and two survey years: 2018 (red line, N=30 EU/EEA countries) and 2016 (blue line, N=30 EU/EEA countries) scores
The charts are displayed in ascending order of total index country score (2016) and arranged from top left to bottom right (lowest to highest score)

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