



**TECHNICAL** DOCUMENT

# Strategy for the external quality assessment of public health microbiology laboratories

**ECDC TECHNICAL DOCUMENT**

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2017–2020



This report of the European Centre for Disease Prevention and Control (ECDC) was prepared by Barbara Albiger and Marc Struelens, with support from Eeva Broberg, Neil LeBlanc, Katrin Leitmeyer, and Joana Revez.

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## Abbreviations

ARHAI	Antimicrobial resistance and healthcare-associated infections programme (ECDC)
AST	Antimicrobial susceptibility testing
Compendium	Laboratory external quality assessment compendium for ECDC contract managers
DP	Disease programme
ECDC	The European Centre for Disease Prevention and Control
EEA	European Economic Area
EQA	External quality assessment
EU	European Union
EULabCap	EU laboratory capability monitoring system
EVD	Emerging and vector-borne diseases programme (ECDC)
FWD	Food- and waterborne diseases and zoonoses programme (ECDC)
IRV	Influenza and other respiratory virus programme (ECDC)
HSI	HIV, sexually transmitted infections and viral hepatitis programme (ECDC)
MAR	Microbiology activities report
MoU	Memorandum of understanding
TESSy	The European Surveillance System (ECDC)
TB	Tuberculosis programme (ECDC)
VPD	Vaccine-preventable diseases programme (ECDC)
WGS	Whole genome sequencing

## Executive summary

Over the last seven years, the European Centre for Disease Prevention and Control (ECDC) supported over 100 external quality assessment (EQA) exercises. These EQAs were managed by ECDC's disease networks to strengthen the contributions of laboratories to public health disease surveillance and threat detection.

ECDC EQAs are much valued by participants and stakeholders as a capacity support activity. However, the EQA schemes face strong competition over limited resources because of new laboratory technologies, most notably whole genome sequencing. But this also offers new opportunities. A review of past EQA exercise processes and publication outputs has already identified areas for further improvement.

In keeping with the ECDC Public Health Microbiology Vision and Strategy 2018–2022 [1] and the strategic microbiology support objectives of the Single Programming Document 2017–2020 [2], ECDC's Microbiology Coordination Section developed a multi-disease ECDC's strategy for cost-efficient design and management of ECDC EQAs. This strategy was developed in consultation with the National Microbiology Focal Points, ECDC EQA contract managers and the Joint Microbiology and Surveillance Steering Committee. The strategy outlines the priority areas to be considered to fulfil the following vision:

By 2020, ECDC-supported EQAs will help improve and maintain high quality and comparability of key laboratory surveillance data reported at the European level and foster capabilities to detect emerging and epidemic diseases or drug resistance threats across EU Member States.

To translate the EQA vision into action, the strategy focuses on four priorities:

- Consolidated EQA schemes with better quality and higher efficiency
- Enhanced availability and impact of EQA data
- EQAs oriented towards higher laboratory capacity
- Monitoring the usefulness to participants.

These priorities are supported by ten objectives and their respective indicators and targets.

In addition, criteria for prioritising the scope of future EQAs were defined to address new technical developments in the field of molecular diagnostics and genomic surveillance within ECDC's budget limitations, while safeguarding the EU public health value of ECDC EQAs.

In 2017, the Microbiology Coordination Section tested the implementation of this strategy based on a review of 2016 EQA schemes/reports to determine the baseline for cost-efficient management of ECDC EQAs. From 2018 onwards, the Microbiology Coordination Section will collect all data relevant of EQA schemes conducted in the previous year and monitor progress towards the strategic targets of each scheme. This information will be reported back to the EQA contract managers in the disease programmes. A performance analysis of EQA exercises and of specific EQA schemes will be shared with the National Focal Points for Microbiology in the annual ECDC Microbiology Activities Report. Starting in 2019, an ECDC microbiology support performance indicator summarising the participants' feedback on the practical benefits of their EQA participation will be published in the Director's Annual Report.

## Context

Regulation (EC) No 851/2004 for establishing a European centre for disease prevention and control (ECDC) [3] and Decision No. 1082/2013/EU on serious cross-border threats to health give ECDC a mandate to engage in the detection, surveillance, and risk assessment of threats to human health from communicable diseases at the EU level [3,4].

In the European Union (EU), there are 56 notifiable communicable diseases and related health issues. Disease surveillance and disease reporting is carried out by the Member States and based on a set of agreed EU case definitions [5]. These EU case definitions lay down the clinical, laboratory and epidemiological criteria used to identify and classify cases and the involved disease agents. Because laboratory criteria and services are essential to identify the agents involved in communicable diseases, it is fundamental that ECDC provides Member States with services, tools and expertise to strengthen the capacity, quality and capability of laboratories. In this context – Article 5 of the Founding Regulation about the operation of dedicated surveillance networks and networking activities – the Centre has the mandate to assure quality and to foster collaborations [3]:

### Article 5.2

'The Centre shall ensure the integrated operation of dedicated surveillance networks of authorities and structures designated under Decision No 2119/98/EC, where necessary with the assistance of one or more of the surveillance networks. It shall in particular: (a) provide quality assurance by monitoring and evaluating surveillance activities of such dedicated surveillance networks to ensure optimal operation;

(b) maintain the database(s) for such epidemiological surveillance; (c) communicate the results of the analysis of data to the Community network; and (d) harmonise and rationalise the operating methodologies.'

#### Article 5.3

'By encouraging cooperation between expert and reference laboratories, to foster the development of sufficient capacity within the EU for diagnosis, detection, identification and characterisation of infectious agents which may threaten public health. The Centre shall maintain and extend such cooperation and support the implementation of quality assurance schemes<sup>1</sup>.'

According to the ECDC Strategic Multi-Annual Programme 2014–2020, supporting the implementation of quality assurance schemes constitutes one of the priorities of the ECDC microbiology support team [6].

One of the main tools set up to fulfil this mandate is the provision of laboratory proficiency testing (PT) otherwise known as external quality assessment (EQA), a term that refers to testing the capacity of participating laboratories. Covered areas include: detection and identification of pathogens, typing of isolates, screening of virulence/resistance determinants, interpretation of results, data analysis, determining the accuracy of test results reported by individual laboratories, and comparing tests results across laboratories and countries.

ECDC does not operate its own laboratories; instead, the Centre opted for a network approach and relies upon the microbiological capacity and capability in EU/EEA Member States. The majority of ECDC initiatives on microbiology capability and capacity strengthening, including the provision of EQA schemes, are therefore outsourced.

ECDC commissions and supports EQA schemes across public health microbiology laboratories in the EU/EEA countries to:

- verify the quality and comparability of surveillance data reported at EU/EEA level; and to
- support threat detection capabilities for emerging and epidemic diseases or antimicrobial resistance.

ECDC EQAs go back to several disease networks that were integrated into ECDC between 2006 and 2010. During this integration process, the objectives and rationale for ECDC EQAs were reviewed regularly to enhance the consistency of EQA schemes, improve scientific quality, and ensure that EQAs are fit for purpose for EU surveillance. Even so, there is room for improvement: management should be more cost-efficient and information should be used collaboratively. As part of its 2018–2022 strategy to improve EQA coordination, the Microbiology Coordination Section issued a so-called compendium for ECDC EQA contract managers to support the procurement of EQAs. The compendium also harmonises the structure and content of EQA reports and provides standardised certificates of EQA participation [7].

The EU public health added-value of ECDC EQAs was also assessed by external stakeholders' evaluations. In 2014, the second independent evaluation of ECDC (2008–2012) [8] indicated that laboratory EQAs were one of the most valued capacity-building activities and confirmed that the provision of ECDC EQAs benefited the harmonisation of methods and helped improve data quality, thus allowing more cross-country comparability. The feedback from Member States confirmed that ECDC EQAs fill a gap and often play a unique role in the accreditation of reference laboratories at the national level. This is especially true for the diagnostics of rare/imported diseases and rare identification/characterisation tests that are limited to specialist public health laboratories. However, Member State feedback also highlighted persistent capability gaps in some Member States due to limited progress in achieving sufficient proficiency over the years. Ineffective capacity building efforts or lack of resources might be the reason behind these deficiencies [8].

Since 2010, ECDC has supported 121 EQA schemes for over 30 pathogens and one health issue (antimicrobial resistance) (Table 1) at an annual cost of between EUR 15 000 to 140 000 per EQA scheme.

Between 2014–2016 the Microbiology Coordination Section has been conducting internal strategic reviews of EQAs. This work was part of the strategic multi-annual work planning and the ECDC disease networks activities. Despite substantial budget restrictions, the strategic reviews achieved two goals:

- Strengthening the public health relevance of EQA content and the consistency of design, by offering constructive peer support and review of draft documents at concept stage (i.e. specifications of the EQA scheme) as well as reporting and interpretation (i.e. EQA reports and recommendations).
- The provision of strategic direction and technical support to ensure the consistency and scientific quality of EQA schemes.

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<sup>1</sup> Quality assurance schemes refers to, and includes, external quality assessments (EQA) as a key activity as part of wider laboratory quality management systems.

One result of these reviews was the update of the 2013 'Laboratory external quality management (EQA) compendium for ECDC contract managers', a practical handbook for good procurement practices for ECDC-supported EQA schemes to increase cost-efficient EQA management.

In recent years, public health microbiology and surveillance have seen the rapid development of molecular typing methods and the increasing use of whole genome sequencing (WGS). These developments pose new challenges, but also offer new opportunities when planning and conducting EQA schemes.

To take into account EU budget limitations with regard to health and new technical developments in the field of molecular and genomic-based surveillance, the ECDC Chief Scientist asked the ECDC Chief Microbiologist and the Microbiology Coordination Section to produce an ECDC strategy for laboratory EQAs to safeguard the EU public health value of ECDC EQAs and guarantee their fitness for the purpose of conducting public health surveillance and responding to outbreaks and epidemics.

**Table 1. Overview of numbers of ECDC-supported EQA schemes by Disease Programme (DP), pathogen, testing area and year, 2010–2016**

DP <sup>a</sup>	Pathogens	Testing area <sup>c</sup>					Number of EQA schemes/year <sup>d</sup>						
		D	T	V	A	I	2010	2011	2012	2013	2014	2015	2016
ARHAI	<i>Enterococcus faecalis</i> , <i>E. faecium</i> , <i>E. coli</i> , <i>K. pneumoniae</i> , <i>P. aeruginosa</i> , <i>S. pneumoniae</i> , <i>S. aureus</i> , <i>Acinetobacter</i> spp. <sup>b</sup>	x			x		1	1	1	1	1	1	1
	Meticillin-resistant <i>Staphylococcus aureus</i>		x				1						
	<i>Clostridium difficile</i>		x					1		1	1		
	Carbapenemase-producing <i>Enterobacteriaceae</i>			x						1			
EVD	Hantavirus	x					1						
	Yellow fever virus*	x					2						
	Crimean–Congo Haemorrhagic Fever Virus	x						1					
	Tick-borne encephalitis virus	x						1					
	West Nile fever virus*	x						2	1				
	Rift Valley fever virus	x							1				
	Dengue virus	x								1			
	Lassa virus	x								1			
	Middle-East respiratory syndrome coronavirus	x									1		
	Chikungunya virus*	x									2	1	
	Zika virus	x											1
IRV	Human influenza virus**	x			x		2			2		2	
FWD	<i>Salmonella enterica</i>		x		x		2		1	1	2	1	1
	Verocytotoxin-producing <i>E. coli</i>		x	x			2		1		2	1	1
	<i>Listeria monocytogenes</i>		x							2	1	1	1
	<i>Campylobacter jejuni</i> and <i>C. coli</i>					x					1		1
	Variant Creutzfeldt–Jakob	x				x	1		1	1			1
	<i>Legionella pneumophila</i>	x	x				4	4	4	4		4	
HSH	<i>Neisseria gonorrhoeae</i>				x		1	1	1	1	1	1	1
VPD	<i>Corynebacterium diphtheriae</i>	x	x				1		2	1			
	<i>Neisseria meningitidis</i>	x	x		x			1	1		1		1
	<i>Haemophilus influenzae</i>	x	x	x				1	1		1		1
	<i>Streptococcus pneumoniae</i>	x	x		x		1		1		1		1
	<i>Bordetella pertussis</i>	x	x				1		2	1			1
	TB	<i>Mycobacterium tuberculosis</i> ***	x	x		x		2	2	1	2	2	2
							22	15	19	20	17	14	14

<sup>a</sup> DP: Disease Programmes; ARHAI: Antimicrobial Resistance and Healthcare-Associated Infections Programme; EVD: Emerging and Vector-borne Diseases Programme; IRV: Influenza and other Respiratory Viruses Programme; FWD: Food- and Waterborne Diseases and Zoonoses Programme; HSH: HIV, Sexually Transmitted Infections and Viral Hepatitis Programme; VPD: Vaccine Preventable Diseases Programme; TB: Tuberculosis Programme.

<sup>b</sup> The annual EQA covers at least six of the eight bacterial species under surveillance by EARS-Net and some of the possible bacterial-antimicrobial combinations, reflecting the current epidemiology of resistance in the EU/EEA.



<sup>c</sup> D: detection (by culture, molecular or serological methods) and/or identification; T: typing; V: virulence/resistance determinants screening; A: antimicrobial susceptibility testing; I: interpretation and analysis.

<sup>d</sup> For each pathogen, the number of schemes depends on the panel of strains and the test method.

\* For yellow fever virus, West Nile fever virus and chikungunya virus, EQA 1 focused on direct detection by PCR and EQA 2 was based on serology.

\*\* For human influenza virus, EQA 1 focused on rapid detection by PCR and virus culture with antigenic and genetic characterisation, EQA 2 focused on antiviral susceptibility detection by phenotypic and genotypic testing. In addition to ECDC EQAs, WHO HQ provided yearly EQAs on PCR detection. ECDC EQAs and WHO EQA followed a biennial cycle due to feasibility and funding.

\*\*\* For Mycobacterium tuberculosis, EQA 1 focused on conventional diagnostic tests and EQA 2 focused on molecular typing.

## Vision

By 2020, ECDC-supported external quality assessments will help improve and maintain high quality and comparability of key laboratory surveillance data reported at the European level and foster capabilities to detect emerging and epidemic diseases or drug resistance threats across EU Member States.

## Areas covered by the ECDC strategy for laboratory EQAs

The ECDC strategy for laboratory EQAs defines the guiding principles of the EQAs of the Centre and aims to consolidate EQAs by increasing efficiency and output. This should be done in strategic alignment with the Centre's mandate. The entire process should be based on a common vision of human pathogen laboratories, shared by the European Commission and ECDC [9,10], and described in the ECDC public health microbiology strategy [1], ECDC's single work programming document 2018–2020 [2], and ECDC's long-term surveillance strategy 2014–2020 [11]. In addition, ECDC's country support [12] and training strategies [13] should be taken into account.

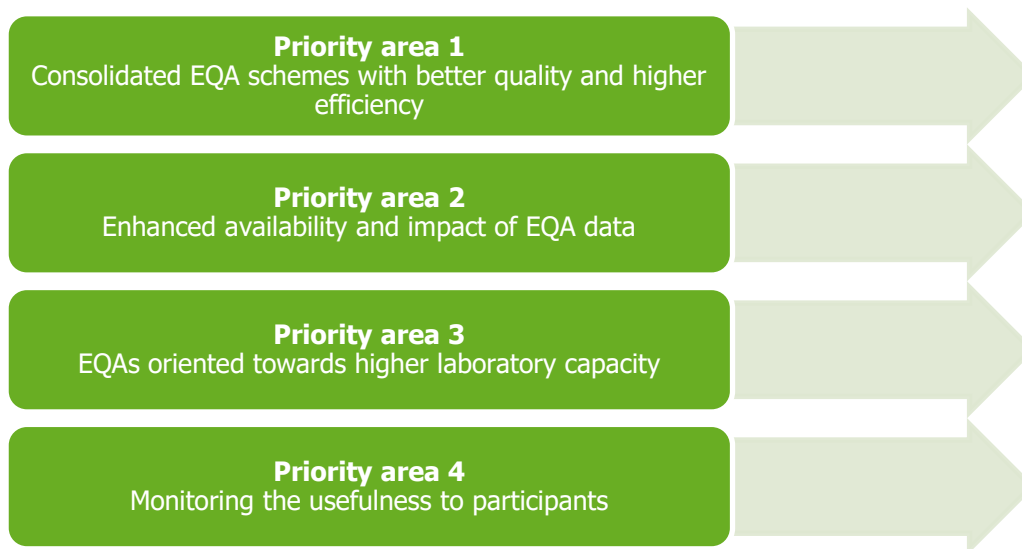
This strategy paper supports 'strategic objective 3' of the ECDC single work programming document 2018–2020, which aims to 'strengthen public health infrastructure and processes' through 'well administered and effective external quality assessments (EQA) schemes [that] complement the efforts performed by Member States, WHO and the European Commission and [are] accompanied by technical guidance and expert training' [2].

This strategy was developed in close consultation with the National Focal Points for Microbiology (NMFPs), ECDC EQA contract managers and the Joint Microbiology and Surveillance Steering Committee. It mainly focuses on the four priority areas (Figure 1) for which indicators and targets have been developed. One of the outcomes of the consultation with the National Focal Points for Microbiology is the list of criteria that ECDC should consider when prioritising future EQAs.

## Audience for the ECDC strategy for laboratory EQAs

The ECDC EQA strategy is aimed at the following intended audiences:

- ECDC external stakeholders, i.e. the European Commission, the ECDC Management Board, the National Focal Points for Microbiology, as well as ECDC disease networks, the national public health reference laboratories, and EQA providers.
- ECDC Senior Management Team, Heads of Disease Programmes, and ECDC EQA contract managers.

**Figure 1. Priority areas of the strategy for laboratory EQAs**

## Definition, goals, benefits and objectives of ECDC EQAs

### General definition of EQAs

External quality assessment (EQA) is a system designed to objectively assess the quality of test results obtained by a laboratory by means of an external agency (i.e. EQA provider). It allows for comparison of the performance of a laboratory's testing to an outside source of a peer group of laboratories or to the performance of a reference laboratory. Participation in EQAs is a fundamental aspect of laboratory quality management. The term EQA is often used synonymously with the term proficiency testing. EQAs are usually performed in the context of EQA schemes designed to offer a cycle of services that test specific analytical methods and matrix samples. An EQA scheme can consist of several EQA rounds or distributions per year. EQAs should always lead to corrective actions if needed.

### Definition and description of ECDC EQAs

ECDC EQAs are an integral part of a quality improvement cycle and capability strengthening process that is collectively developed across the EU within ECDC's disease networks. EQAs include technical training and capacity building activities (Figure 2).

Often, ECDC-run EQA schemes complement other national or international EQA schemes to ensure diagnostic quality or support accreditation of clinical diagnostic laboratory testing under ISO15189 and/or ISO17025. Even though ECDC EQAs are not primarily designed to support accreditation efforts, EQA results can help laboratories meet some of the requirements needed for national accreditation.

ECDC EQA schemes do not assess the performance of clinical laboratory tests that are primarily used for clinical diagnosis and case management, with the exception of EQAs for antimicrobial susceptibility testing methods offered to clinical laboratories reporting on a voluntary basis to the EARS-Net surveillance programme.

### EU public health added-value and other benefits

The second independent external evaluation of the ECDC (2008–2012) and feedback from ECDC disease networks through surveys and informal consultations emphasised the EU added-value of ECDC EQAs [8]. EQA schemes were considered among the most effective capacity-building activities promoted by ECDC. Overall, 75% of the external evaluation respondents answered that the primary effect of EQAs was to help laboratories obtain (inter)national accreditation. More than half of respondents replied that they detected capacity gaps they had not been aware of before and that they had since adopted measures to strengthen capacity in these areas.

The benefits of ECDC EQAs are summarised below.

Benefits for ECDC disease networks and European laboratory-based surveillance:

- Improvement of surveillance data quality and accuracy (e.g. pulsed-field gel electrophoresis data for *Listeria monocytogenes*)
- Improvement of the EU-level laboratory capacities for the surveillance, prevention and control of infectious diseases (e.g. antiviral susceptibility testing for influenza)
- Increased adherence to EU case definitions when reporting to TESSy (e.g. ARS-Net data on antimicrobial susceptibility testing using EUCAST breakpoints) leading to better data comparability
- Harmonisation of microbiological testing methods (e.g. serology for *Bordetella pertussis*)
- Establishment and maintenance of capacity for emerging and/or rare diseases (e.g. for Ebola virus, MERS-CoV, Zika virus)
- Increasing the good reputation of and interest in the ECDC disease networks outside the EU/EEA (e.g. EU Enlargement countries and European Neighbourhood Policy partner countries).

Benefits for public health microbiology laboratories in EU/EEA Member States:

- Identification of technical issues and improvement of the laboratory quality through corrective actions
- Documentation of proficiency testing to offer additional credentials for the national accreditation of microbiology laboratories
- Access to services (where no alternative scheme exists or participation in a commercial EQA is too expensive)
- Additional income for laboratories in Member States that provide EQA services to network members (e.g. Statens Serum Institut, Denmark, which carries out EQAs for food- and waterborne diseases, or Public Health England, which carried out influenza EQAs earlier.)
- Improvement and harmonisation of methods, allowing inter- and intra-laboratory comparability.
- Support for the introduction of new technologies and methods
- Development of skills and expertise for staff members
- Improved collaboration and information flow between laboratories and between Member States
- Improved Member State preparedness and surge capacity for coordinated outbreak response
- Strengthened laboratory capacities at the country level to improve surveillance, prevention and control of infectious diseases.

## Prioritisation criteria for EQA scope

The National Focal Points for Microbiology were consulted to select and rank possible criteria for the prioritisation of EQAs in order to safeguard the EU public health value of ECDC EQAs and contribute to sustained laboratory quality assurance while addressing new needs arising from technical developments in the field of molecular diagnostics and genomic-based surveillance. Spending should be kept within the limits of the budget. The Focal Points agreed on the following ranking (from most to least important):

- Support of new technologies, methods and interpretation standards
- Support of identification capability for emerging diseases, rare diseases, and drug resistance
- Support of molecular typing, with results reported to EU surveillance
- Support of EU technical harmonisation
- Accreditation requirements and quality assurance.

Commercial availability and costs for Member States were not considered relevant criteria in prioritising future ECDC EQAs.

ECDC EQAs should favour the participation of EU/EEA laboratories, yet there could be instances where the participation of laboratories from non-EU/EEA countries had a strong public health added value or was of vital interest to the non-EU country in question. The decision to involve non-EU/EEA countries shall take into account the following:

- Non-EU/EEA countries can be given priority for collaboration with ECDC if covered by ECDC's International Relations Policy and existing cooperation frameworks (such as a memorandum of understanding, an administrative agreement, or a cooperation project for technical assistance)
- EU added value for public health, ECDC strategies for participation of EU candidate/potential candidate countries in ECDC disease networks and surveillance activities
- Availability of resources.

These criteria should help the heads of ECDC's disease programmes and ECDC's senior management prioritise resources and budget lines during the planning process for the annual and multi-annual work plan. For the participation of non-EU countries, the heads of the disease programmes and the senior management should consult the International Relations Section to confirm which non-EU/EEA countries qualify for priority collaboration. As per its terms of reference, the Microbiology Coordination Section will continue to provide strategic advice to

Senior Management on public health microbiology activities of the Centre (including EQAs) and coordinate and enhance consistency and public health added value of the Centre's microbiology activities across Disease Programmes and shared resource units.

## Goals of ECDC EQAs

The goal of ECDC EQAs is to appraise the proficiency of public health microbiology laboratories in using microbiological test methods that underpin capabilities in the following areas:

- Diagnostic confirmation of disease for reporting to The European Surveillance System (TESSy), in accordance with EU case definitions for 52 notifiable diseases and antimicrobial resistance [5]
- Outbreak detection, investigation and response
- Control of communicable diseases (e.g. tuberculosis isolation and treatment)
- Preparedness (e.g. avian influenza strains)

## Operational objectives of ECDC EQAs

The following operational public health objectives of ECDC EQAs were identified:

- Assessment of the quality and comparability of surveillance data reported by EU/EEA Member States
- Support of threat detection capabilities for emerging diseases, epidemic diseases, and drug resistance.

These objectives are coherent with the laboratory and public health objectives of EQAs outlined in the WHO laboratory quality management system handbook developed under the International Health Regulations (IHR) [14]

**Figure 2. ECDC EQA quality improvement cycle**



## Guiding principles of ECDC EQAs

ECDC EQAs should adhere to the following principles:

- Be an integral part of the EQA's quality improvement cycle
- Be an integral part of the capability strengthening process for ECDC disease networks
- Have clear objectives defined in relation to ECDC's disease-specific surveillance objectives
- Strive for inclusive laboratory participation, covering all EU/EEA Member States
- Adhere to international quality standards (e.g. ISO standards)
- Adhere to EU or international gold standard methods
- Monitor compliance with international interpretation criteria, units of measurement, and result reporting formats, i.e. EU case definitions and laboratory guidance for surveillance at the EU/EEA; adapt EQAs accordingly
- Provide annual and multi-annual laboratory/Member State proficiency assessments following a pre-defined pass/fail threshold of proficiency
- Report results of all EQA schemes to participants and publish main findings anonymously at the EU level in a timely manner
- Assess the participants' use of the results for quality improvement or accreditation purposes
- Offer follow-up training and capacity building activities to participating laboratories
- Indicate corrective measures if an EQA detects non-proficiency or harmonisation gaps
- Measure the effect of corrective measures and capacity building activities over consecutive EQA rounds.

## Priority areas, strategic objectives, indicators and targets

To translate the vision into actions, the strategy will focus on four priority areas (Figure 1).

Achieved levels in the execution of strategic EQA requirements are colour-coded as follows: green (compliant), amber (partially compliant), red (non-compliant); all indicators will be marked individually.

### Priority area 1: Consolidated EQA schemes with better quality and higher efficiency

Strategic objective 1.1: Enforce the guiding principles and compliance with the ECDC compendium for laboratory EQA that has been developed as a manual for ECDC EQA contract managers.

Indicators 1.1.1–1.1.5: Compliance with the ECDC compendium for laboratory EQAs, Version 5

Target: By 2020, each EQA scheme will be at least 80% compliant with the guiding principles laid out in the ECDC compendium for laboratory EQAs.

Implementation: ECDC EQA contract managers, with the support of the Microbiology Coordination Section and EQA providers, should keep up to date with ECDC surveillance objectives, revised EU case definitions, laboratory methods, and quality standard developments to guarantee compliance throughout all EQA cycles, including the design phase.

Monitoring: The Microbiology Coordination Section completes the checklist (Table 2) based on the latest EQA tenders and reports compliance for each scheme; an exact percentage of compliance will be calculated.

Data source: EQA call for tender specifications and EQA reports.

**Table 2. Indicators and criteria for compliance of specific EQA scheme with ECDC compendium**

EQA compliance criterion	Indicator
The EQA scheme has clear objectives defined in relation to ECDC's disease-specific surveillance objectives.	1.1.1
Methodology is clearly outlined, including adhering to EU or international gold-standard methods and interpretation criteria, if available and appropriate. If no gold standard is available or used, reasons for using alternative methods are explained.	1.1.2
In EQA schemes, proficiency is rated pass/fail; this is based on the separation of the core and educational sample panels, where applicable.	1.1.3
The EQA scheme provides performance assessments for individual laboratories and Member States.	1.1.4
If applicable, the EQA scheme takes into account previous EQA results at the EU level; the annual report compares performance trends over time.	1.1.5

Strategic objective 1.2: Promote the inclusive laboratory participation of all EU/EEA countries

Participation in EQAs is a fundamental aspect of laboratory quality management.

Indicator 1.2.1: Inclusive Member States participation in ECDC EQAs

Target: By 2020, each EQA scheme will have a coverage of at least 80% of EU/EEA Member States. If a particular test is not available in some of the participating countries, coverage should be 80% or more of the total number of countries with the technical expertise to participate. If the EQA target group includes non-EU/EEA countries, this should be explained in the tender specifications and in the final report.

Implementation: The ECDC EQA contract managers, with the support of the EQA providers, promote maximum laboratory participation of EU/EEA Member States by guaranteeing equal access to EQA panels. The ECDC EQA contract managers, with the support of the EQA providers, record the reasons for non-participation of EU/EEA Member States. In relevant cases, the EQA report should present and analyse the reasons why some Member States did not participate.

Monitoring: The Microbiology Coordination Section records the number of participating EU/EEA Member States and the number of participating laboratories as given in EQA reports and monitors the progress towards full participation (Table 3).

Data source: EQA call for tender technical specifications and EQA reports.

**Table 3. Indicator criteria for rating EU/EEA Member State coverage**

Number of EU/EEA Member States participating in an EQA exercise	Colour code
0 ≤14	Red
15 – ≤23	Amber
24 – 31	Green

## Priority area 2: Enhanced availability and impact of EQA data

Strategy objective 2.1: Enhance the availability and quality of EQA reports to ECDC stakeholders.

To comply with Article 12 of ECDC Founding Regulation, ECDC 'shall ensure that the public and any interested parties are rapidly given objectives, reliable and easily accessible information with regard to the results of its work' [3]. To ensure distribution to ECDC disease network members and other ECDC stakeholders, results of EQA schemes should be made available on the ECDC website in a timely manner. Supported formats are ECDC technical report, ECDC surveillance report (with EQA data), or peer-reviewed publication in scientific journals.

Equally important are the quality of the reported data and an analysis of overall performance because EQA results also have a bearing on other activities of the disease networks and support ECDC's core function of surveillance and outbreak investigation and response.

Indicator 2.1.1: Systematic reporting of EQA data to ECDC stakeholders

Target: By 2020, each EQA scheme will publish a report summarising the aggregated EU-level results from each EQA exercise. Possible formats are ECDC surveillance report including EQA data, standalone ECDC EQA technical report or peer-reviewed publication in scientific journal. Reports will be published in the calendar year after the EQA round was completed.

Implementation: EQA providers produce an EQA report in accordance with the ECDC EQA report template and compendium. ECDC EQA contract managers, with the support of the Microbiology Coordination Section, peer-review the EQA draft report, provide feedback and improve its scientific quality, and evaluate its content.

Monitoring: The Microbiology Coordination Section records the published report and determines a timeframe for publication (Table 4).

Data source: EQA call for tender technical specifications and published EQA reports.

**Table 4. Indicator criteria for quality and timeliness of EQA reporting**

EQA reporting criteria	Colour code
Contractor delivers EU-level report in a format that deviates substantially from the official ECDC report template.	Red
Contractor delivers EU-level report aligned with ECDC template; report is peer-reviewed* by ECDC EQA contract managers and the Microbiology Coordination Section, but not published in the calendar year after the year the EQA round was completed.	Amber
Report which meets all criteria as above ('amber'), but is published in the calendar year after the year the EQA round was completed.	Green

\* As defined by the Internal Procedure on handling external and internal requests for scientific advice and other ECDC outputs with scientific content – ECDC/IP/56 – Rev. 2 (currently with the ECDC senior management team for approval)

Strategy objective 2.2: Link EQA data to EU surveillance data

EQA findings that point at limitations in the methods routinely used for laboratory-based surveillance or event confirmation (e.g. technical inconsistencies, harmonisation gaps) should be mentioned in other EU surveillance reports as these technical problems can compromise the accuracy and comparability of surveillance data. EU surveillance reports should also take note of low EQA participation and EQA performance ratings.

Indicator 2.2.1: Reference to the latest EQA results and reports in the Surveillance Atlas of Infectious Diseases

Target: By 2020, each disease in the Surveillance Atlas of Infectious Diseases which is also covered by one or several EQAs will have links to the latest EQA results and the respective reports.

Implementation: ECDC EQA contract managers update the 'remarks and interpretation' tab in the Surveillance Atlas each year with the latest EQA results and links to the respective reports.

Monitoring: The Microbiology Coordination Section records all updates (Table 5).

Data source: Surveillance Atlas of Infectious Diseases.

**Table 5. Indicator criteria for references to EQA results in the Surveillance Atlas of Infectious Disease**

EQA scheme linkage to surveillance results	Colour code
The EQA reports cited as quality background information on the disease-specific pages of the Surveillance Atlas of Infectious Diseases are outdated or missing.	Red
The disease specific-pages of the Surveillance Atlas of Infectious Diseases list the latest EQA reports on EQA results as quality background information.	Green

### Priority area 3: EQAs oriented toward higher laboratory capacity

Strategy objective 3.1: Conduct country support and training activities at the generic and the disease-specific levels based on the needs identified by the EQAs.

It is important for ECDC to address capacity and capability gaps identified through EQAs by proposing remedial support and training activities; all such activities should be verified by follow-up.

Indicator 3.1.1: Provision of laboratory support and training activities

Target: By 2020, all ECDC EQAs will be linked to country support and training activities.

Implementation: ECDC EQA contract managers request specific country support and training activities services in the tender specification for EQA framework contracts. It also should be highlighted in the EQA reports.

Monitoring: The Microbiology Coordination Section records the country support and training activities conducted after each EQA round (Table 6).

Data source: EQA tender and report, Management Information System: work programme actions year n+1. This may also be captured in the Participant Feedback Survey.

**Table 6. Indicator and scoring criteria for EQA follow-up by laboratory support and training activities**

EQA scheme follow-up with capacity building support	Colour code
No disease-specific or generic laboratory support/training courses planned, despite a number of identified issues, for the calendar year after the year the EQA round was completed.	Red
Disease-specific or generic laboratory support/training courses addressing identified issues are planned for the calendar year after the year the EQA round was completed.	Green



## Priority area 4: Monitoring the usefulness to participants

Strategy objective 4.1: Monitor the added-value for public health of ECDC EQAs

ECDC will systematically collect feedback on the practical application of EQA results by participating EU/EEA laboratories. This user benefit indicator will be recorded after each EQA round.

Indicator 4.1.1: Monitoring of corrective measures and accreditation input

Target: By 2020, all ECDC EQA documents will be included in the Member States' laboratory accreditation dossiers, provided that corrective measures were taken at the laboratory level.

Implementation: ECDC EQA contract managers include a service request for a post-EQA feedback evaluation survey in the call for tender, framework or specific contracts, in accordance with the ECDC EQA compendium (template for participant feedback survey).

Monitoring: The Microbiology Coordination Section monitors the use and results of systematic EQA participant surveys on corrective measures; ECDC EQA certificates are added to the laboratory accreditation dossier (Table 7).

Data source: EQA tender (if administered by contractor) and report, results of EQA participant feedback survey.

**Table 7. Indicator and scoring criteria on practical usefulness of EQA based on participant survey**

EQA exercise inclusion of participant feedback survey	Colour code
No EQA feedback survey performed after an EQA	Red
Participant feedback survey conducted, in accordance with the EQA compendium template	Green



## Implementation of the EQA strategy

The implementation of this strategy will be based on the mutual trust and collaboration of the Member States and the ECDC disease networks that participate in ECDC EQAs.

The implementation of the strategy relies mostly on ECDC EQA contract managers, support by the heads of ECDC's disease programmes and the respective heads of units. ECDC EQA contract managers have the tasks to procure and monitor all EQAs services and therefore have a critical role in ensuring the cost-efficient management of these EQAs. Head of units and Heads of Disease Programmes should guarantee sustainable EQA funding to ensure continuity, sustainability and quality as well as the optimised use of the EQA results.

The ECDC Chief Scientist as authorising officer also plays a central role in ensuring the cost-efficient management of all EQAs.

ECDC EQA contract managers should encourage EQA providers to ensure the cost-efficient management of the ECDC EQAs. EQA providers should commit to providing the highest standards of quality.

The Chief Microbiologist and the Microbiology Coordination Section will foster, advise and oversee the implementation of the strategy and, together with the contract managers, monitor the EQA scheme's performance and outputs. They also have a strategic role advising the ECDC EQA contract managers, the Heads of Disease Programmes and the authorising officer and peer-review the EQAs, thus ensuring a consistent methodology from concept design to final reporting.

## Monitoring of the implementation of the strategy

The implementation of the strategy will be monitored annually by the Microbiology Coordination Section with the support of ECDC EQA contract managers.

In 2017, the Microbiology Coordination Section piloted the strategy implementation and tested/revised the performance indicators based on 2015–16 EQA schemes/reports to determine the baseline performance level of management for ECDC EQAs.

Starting in 2018, the Microbiology Coordination Section will collect data for every indicator for each of the EQA schemes executed in the previous year and monitor the progression towards the targets.

From 2019 onwards, an ECDC microbiology support and outcome performance indicator summarising the participants' feedback on the practical benefits accrued by their EQA participation will be published in the Director's Annual Report.

## Reporting of the implementation of the strategy

The overall performance analysis of ECDC EQAs and the performance analysis of each EQA scheme against the targets will be reported annually to the National Focal Points for Microbiology in the annual ECDC Microbiology Activity Report.

# References

1. European Centre for Disease Prevention and Control. ECDC public health microbiology strategy 2018–2022. Stockholm: ECDC; 2018. Available from: <https://ecdc.europa.eu/sites/portal/files/documents/ECDC-public-health-microbiology-strategy-2018-2022.pdf>.
2. European Centre for Disease Prevention and Control. Single Programming Document – 2018–2020. Stockholm: ECDC; 2018. Available from: <https://ecdc.europa.eu/sites/portal/files/documents/ECDC-Single-Programming-Documents-2018.pdf>.
3. European Commission. Regulation (EC) No 851/2004 of the European Parliament and of the council of 21 April 2004 establishing a European centre for disease prevention and control. Strasbourg: Official Journal of the European Union; 2004. Available from: <https://publications.europa.eu/en/publication-detail/-/publication/77d98344-249e-486a-a9a9-88931b01aa7c/language-en>.
4. European Commission. Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC. Strasbourg: Official Journal of the European Union; 2013. Available from: [http://ec.europa.eu/health/sites/health/files/preparedness\\_response/docs/decision\\_serious\\_crossborder\\_threats\\_22102013\\_en.pdf](http://ec.europa.eu/health/sites/health/files/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf).
5. Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions. Available from: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L\\_.2018.170.01.0001.01.ENG](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2018.170.01.0001.01.ENG).
6. European Centre for Disease Prevention and Control. ECDC strategic multi-annual programme 2014–2020. Stockholm: ECDC; 2014. Available from: <http://ecdc.europa.eu/en/aboutus/Key%20Documents/Strategic-multiannual-programme-2014-2020.pdf>.
7. European Centre for Disease Prevention and Control. Updated public health microbiology strategy and work plan 2012–2016. Stockholm: ECDC; 2011. Available from: [http://ecdc.europa.eu/en/healthtopics/microbiology/Documents/1203\\_updated-ECDC-public-health-microbiology-strategy-work-plan-2012-2016.pdf](http://ecdc.europa.eu/en/healthtopics/microbiology/Documents/1203_updated-ECDC-public-health-microbiology-strategy-work-plan-2012-2016.pdf).
8. Economisti Associati srl, Coffey International Development Ltd., Libero Istituto Universitario Carlo Cattaneo – CREMS, CEMKA-EVAL, and IBF International Consulting. The second independent evaluation of the ECDC in accordance with its Founding Regulation (European Parliament and Council Regulation (EC) no. 851/2004); Bologna: Economisti Associati; 2014. Available from: <https://ecdc.europa.eu/sites/portal/files/media/en/aboutus/Key%20Documents/ECDC-external-evaluation-2014.pdf>.
9. European Centre for Disease Prevention and Control, Management Board. Update of the position statement of the Commission and ECDC on human pathogen laboratories: a joint vision and strategy for the future. Stockholm: ECDC; 2011. Available from: [http://ecdc.europa.eu/en/healthtopics/microbiology/Documents/111214\\_microbiology\\_laboratory.pdf](http://ecdc.europa.eu/en/healthtopics/microbiology/Documents/111214_microbiology_laboratory.pdf).
10. European Commission – Consumers, Health, Agriculture and Food Executive Agency; Health Unit. Study on cost-benefit analysis of reference laboratories for human pathogens. Brussels: European Commission; 2016. Available from: [https://ec.europa.eu/health/sites/health/files/preparedness\\_response/docs/2016\\_laboratorieshumanpathogens\\_frep\\_en.pdf](https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/2016_laboratorieshumanpathogens_frep_en.pdf).
11. European Centre for Disease Prevention and Control. Long-term surveillance strategy 2014–2020. Stockholm: ECDC; 2013. Available from: <http://ecdc.europa.eu/en/aboutus/key%20documents/long-term-surveillance-strategy-2014-2020.pdf>.
12. European Centre for Disease Prevention and Control. ECDC Management Board, thirty-seventh meeting, Stockholm, 14–15 June 2016. ECDC country support strategy. Stockholm: ECDC; 2016. Available from: <https://ecdc.europa.eu/sites/portal/files/media/en/aboutus/Documents/MB37-05-ECDC-Country-Support-Strategy.pdf>.
13. European Centre for Disease Prevention and Control. ECDC Management Board, thirty-fourth meeting, Stockholm, 16–17 June 2015. ECDC public health training strategy. Stockholm: ECDC; 2015. Available from: [https://ecdc.europa.eu/sites/portal/files/media/en/aboutus/what-we-do/training\\_activities/Documents/MB34-16%20Public%20Health%20Training%20Strategy.pdf](https://ecdc.europa.eu/sites/portal/files/media/en/aboutus/what-we-do/training_activities/Documents/MB34-16%20Public%20Health%20Training%20Strategy.pdf).
14. World Health Organization. Laboratory quality management system handbook. Geneva: WHO; 2011. Available from: [http://apps.who.int/iris/bitstream/10665/44665/1/9789241548274\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44665/1/9789241548274_eng.pdf).

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