EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

ECDC GUIDE

# Guide for EU-level external quality assessments (EQAs) for public health microbiology laboratories

**ECDC** GUIDES AND TOOLS

# Guide for EU-level external quality assessments (EQAs) for public health microbiology laboratories

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# Contents

# Abbreviations

| | |
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| AMR | Antimicrobial resistance |
| ECDC | The European Centre for Disease Prevention and Control |
| EEA | European Economic Area |
| ENP | European neighbourhood policy |
| EQA | External quality assessment |
| EU | European Union |
| EURL | EU reference laboratory |
| PT | Proficiency testing |
| SRM | Stakeholder relationship management |
| WHO | World Health Organization |

# Context

Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 provides an amended mandate for ECDC, and Regulation (EU) 2022/2371 of 23 November 2022 on serious cross-border threats to health reinforces ECDC's responsibilities for detection, surveillance, and risk assessment of threats to human health from communicable diseases at the EU level [1,2]. Under these mandates, ECDC is tasked with ensuring the coordination and operation of EU surveillance networks, encouraging cooperation between expert laboratories, and fostering the development of sufficient capacity and capability within the community for the diagnosis, detection, identification and characterisation of infectious agents which may pose a threat to public health [1].

Within the integrated networks for epidemiological surveillance, ECDC has undertaken activities to enhance capabilities and strengthen capacity for pathogen detection, characterisation and uniform surveillance of specific diseases and antimicrobial resistance (AMR). One of the key activities to support the network laboratories has been the provision of external quality assessment (EQA) schemes. These EU-level EQA schemes aim to strengthen capability and use of reliable laboratory methodologies to ensure comparability of data for EU-level surveillance purposes.

Since 2010, ECDC has coordinated more than 180 EQA schemes covering over 30 pathogens and special health issues, including AMR. According to external evaluation and feedback from the ECDC disease networks, the EQA schemes have been assessed to be the most effective laboratory capability building activity supported by ECDC [3]. EQA activities have generally been provided to the network laboratories as part of more comprehensive laboratory support contracts, established through open procurement procedures or framework partnership agreements.

In November 2022, Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health was adopted [2]. This Regulation provides the legal mandate for the European Commission to designate and fund EU reference laboratories (EURLs) in the area of public health. The network of EURLs for public health will be operated and coordinated by ECDC. It will provide support to the disease networks to promote good practice and alignment among Member States on diagnostics, testing methods, use of certain tests for harmonised surveillance, notification, and harmonised data reporting by Member States, with the provision of EQAs specifically mentioned as one area of responsibility of the EURLs for public health. Therefore, the laboratory support that has been provided through ECDC will gradually be transitioned to the EURL model. This document aims to outline the main principles for EQA as part of ECDC's role to coordinate and harmonise EURL activities across disease areas.

# Audience

The guide is intended for EURLs for public health that will provide EQAs to public health microbiology laboratories.

# Objectives of this guide

- This guide is intended to provide a set of principles for EURLs for public health on how to plan, coordinate, and implement EU-level EQAs for public health microbiology laboratories.
- This document is not intended to offer comprehensive technical guidance on the general implementation of EQAs. For detailed guidance, please see WHO's manual for organising a national EQA programme for health laboratories and other testing sites [4], and/or relevant national guidelines.

# Definition and description of EU-level public health microbiology laboratory EQAs

External quality assessment (EQA) is a system designed to objectively assess the quality of test results reported by a laboratory through an external actor (i.e. EQA provider) and provide feedback to improve performance. It allows for a performance comparison of a laboratory's diagnostic workflows with that of a peer group of laboratories and/or a reference laboratory [5]. Participation in EQAs is a fundamental aspect of laboratory quality management.

For the purpose of this guide, EQA is defined as the process whereby an external provider (in this case, a EURL for public health) sends samples or sequence data for testing and/or analysis to the set of laboratories participating in the EQA. The results from all laboratories are then compared and analysed by the EQA provider before being reported back to the participating laboratories. An EQA scheme may consist of multiple EQA rounds or distributions per year, and its outcomes should be used to monitor laboratory performance, monitor specific test/workflow step performances, identify challenges, and provide a basis for planning and implementing corrective actions.

EU-level EQA schemes should complement existing national and international EQA schemes and be focused on the diagnostic and typing quality of clinical diagnostic laboratory testing for data collected at EU level. As deemed necessary for surveillance purposes, the EQAs should include genomic proficiency testing (PT). Even though EU-level EQAs are not primarily designed to support accreditation efforts, participation in EU-level EQAs may be used by participating laboratories to meet their national accreditation requirements.

## Objectives of EU-level public health microbiology laboratory EQAs

The objectives of implementing EQAs for EU-level public health microbiology laboratories are to assess the laboratories' proficiency in order to:

- strengthen and maintain the high quality and comparability of public health laboratory data at the EU level;
- strengthen and maintain capability for detection and characterisation of pathogens; and
- identify capacity and capability building needs for the purpose of improving the detection and characterisation of pathogens of public health relevance.

# Planning and performing EU-level public health microbiology laboratory EQAs

## Guiding principles

EU-level public health microbiology EQAs should:

- be an integral part of the capacity and capability strengthening process for ECDC disease networks;
- have clear objectives that are defined in relation to ECDC's disease-specific surveillance objectives;
- strive for participation from as many EU/EEA disease network countries as possible;
- adhere to available international quality and safety standards (e.g. relevant ISO standards);
- cover relevant diagnostic methods, as defined by the EURL and disease network;
- monitor compliance with international interpretation criteria, units of measurement, and result reporting formats where appropriate (i.e. EU case definitions and laboratory guidance for surveillance);
- be reported back to participants and additional agreed parties in a timely manner;
- result in the identification of training and capacity and capability building needs;
- include technical follow-up for the participating laboratories where appropriate;
- include feedback from participating laboratories on the use of the results;
- include proposals for corrective measures if an EQA detects non-proficiency or incomparable results; and
- be publicised with the main EQA findings based on aggregated data, including advice and/or recommendations on future EQA needs.

# Design and implementation of EU-level public health microbiology laboratory EQAs

The EURLs for public health are tasked with planning, implementing and evaluating all aspects of the EQA cycle (Figure 1), and should ensure continuity and quality as well as the optimised use of the EQA results.

**Figure 1. EQA cycle to be planned, implemented and evaluated by EURLs**


The aspects set out below should be included in the preparation and execution of the EQAs for public health microbiology laboratories.

## Planning

The EURL must prepare an EQA plan including a timeline, as per Annex 1, with a detailed description of the different EQA steps described in the sections below.

The implementation of EQAs must be well aligned with other network activities coordinated by ECDC and the EURLs. It is imperative that the EQA plan is discussed and agreed with ECDC before any implementation of EQA activities begins. EURLs should therefore start to prepare their plan and initiate discussions with ECDC at least two months before any EQA activities are scheduled to begin.

It will be the responsibility of the EURLs to determine the list of laboratories to be invited per country for each EQA exercise with the relevant national focal points and operational focal points in each participating country.

Participation in EU-level public health microbiology laboratory EQAs must be free-of-charge[1] for the participating laboratories. In addition, the EQA provider should strive for inclusive laboratory participation (i.e. covering as many relevant laboratories for as many diseases network countries as possible), with an expected minimum 80% of EU Member States participating.[2] Within the summary EQA report, the EURL should request, record and analyse the reasons for non-participation of countries.

EU-level public health microbiology laboratory EQAs are primarily implemented for laboratories based in EU/EEA countries. However, the participation of laboratories from non-EU/EEA countries (for example the Western Balkans [6], EU candidate countries [7], and/or European Neighbourhood Policy [ENP] countries [8]) may have a strong public health added value and therefore be of interest, both to the EU and to the country in question, and could be considered, whenever possible.

# EQA preparation, methodology protocol and material distribution

The EQA objectives should be clearly defined in relation to the network needs and ECDC's disease-specific/health topic surveillance objectives. In addition, they should take into account areas of improvement identified from previous EQAs.

An initial information letter to the laboratories should include the following, as a minimum:

- the rationale and objectives of the EQA;
- participation requirements (e.g. being part of the disease network);
- provisions for intellectual property, data ownership and sharing;
- descriptions of planned post-EQA outputs, such as reports and publications; and
- information about planned post-EQA participant feedback.

The EQA may include biological samples and/or specimens, materials, isolates and/or sequence data, with the EURL for public health selecting and preparing the EQA panel that is the most relevant for the objectives of the EQA, in line with the agreed EQA plan. The EURL for public health will perform appropriate quality controls of the panels, according to best practice standards.

The EURL for public health shall make sure that the EQA are distributed to all participants enrolled. The EQA should include a protocol which clearly describes the general contents without compromising the exercise, and indicates what samples, matrices and/or sequence data are included, and what methods and interpretation criteria will be applied, when relevant. The protocol should include instructions for reporting requirements and timelines. The results reporting should include details of the methods/kits and/or standards used by the participating laboratory. The EQA protocol should be reviewed by ECDC as part of the EQA plan prior to the implementation of any activities.

All EQAs involving biological samples should be shipped following international standards and include detailed instructions regarding packaging, biosafety precautions and storage.

# Data analysis

The results of participating laboratories shall be collected, compiled, and analysed as per the description in the EQA plan. This includes ensuring data completeness and addressing any anomalies, if indicated. Statistical analyses, such as calculating descriptive statistics, applying comparative methods, and conducting trend analyses over multiple cycles, should be performed to assess laboratory performance when applicable.

EQA data analysis should:

- measure individual laboratory results against predefined criteria or consensus values across other laboratories to identify variations in test outcomes;
- detect trends that suggest systematic errors or biases in the testing process;
- identify areas for improvement to aid laboratories in their analytical accuracy, precision, and operational procedures;
- compare performance across different laboratories to identify potential performance benchmarks and promote best practices.

[1] Laboratories participating in the EQA activity will need to provide the facilities, staff, reagents and disposables required for the execution of the EQA.
[2] If a particular analysis is not available in some of the EU/EEA countries, coverage should be 80% or more of the total number of countries with the technical expertise to participate.

## Feedback of results to participants and relevant country support

The individual laboratory proficiency reports, including the individual laboratory's results and anonymised results for the other participating laboratories, shall be prepared by the EURL for public health and shared with each participating laboratory. A general summary of results at national level can also be shared with relevant national disease network contact points, where appropriate. After the EQA exercise, the EURL for public health shall also assist the laboratories that do not achieve an acceptable level of performance, by providing advice and reasonable follow-up action, when needed. The EURL for public health may also propose laboratory-specific capability-building or training activities.

## EQA participation certificates

EURLs should issue certificates for participating laboratories that have completed an EQA round/scheme within the indicated timeframe. Annex 2 includes a description of the certificate content. The certificate should attest to participation and completion of an EQA round/scheme, but should not include any assessment of results or indicate any level of performance by the laboratory. Information and data on a specific laboratories' performances should only be provided in an identifiable manner to the specific participant in the individual laboratory proficiency report described above. Should the EQA include proficiency requirements, these results can be included on the certificate, if requested by the network and/or participant.

## Provide reports to ECDC

EQA data, results and reports for individual countries must be made available to ECDC by the EURL for public health upon request. The participating laboratories should be informed in the official invitation to participate that data may be shared with ECDC. For EQAs that include local laboratories, pseudo-anonymised laboratory-level feedback reports should also be shared with ECDC upon request.

## Reporting and dissemination

As detailed in the EQA plan, the EURL shall deliver a timely technical report, based on anonymised and aggregated data, summarising the results of the EQA performance for the participating countries. The report should include training needs or capacity building requirements identified, and recommendations for training or capacity building activities, if any. EQA findings that indicate limitations in the methods routinely used for laboratory-based surveillance or event confirmation (e.g. technical inconsistencies) should be highlighted as these technical issues may compromise the accuracy and comparability of surveillance data. Upon agreement with relevant stakeholders (i.e. data providers, disease networks) and ECDC, the EURL for public health may prepare a scientific publication based on the anonymised and aggregated results. It is also expected that these results will be presented at relevant network meetings at the earliest opportunity.

## Survey of feedback on usefulness from participants

The EURL should conduct a survey to collect feedback on the EQA from the participating laboratories. As a minimum, this survey should cover the practical implementation of the EQA itself; corrective action(s) planned as a result of the EQA; the perceived usefulness of the EQA; suggestions for future EQAs, and whether the participating laboratory has identified a need for additional training activities (if yes, which training activities would be most valuable). The anonymised results of this survey will be shared with ECDC.

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# Annex 1. EQA plan outline

The EQA plan submitted by EURLs for ECDC approval should contain the following sub-headers, clearly specifying the overall timeline of the EQA.

## Objectives

The EQA objectives should be clearly defined in relation to ECDC's disease-specific/health topic surveillance objectives.

## Participants

Eligibility: detailed criteria on which laboratories can participate in the EQA.

Registration: outline the process for registration, including deadlines and necessary documentation.

## Preparation

As a minimum, an information letter to disease network laboratories should include the details outlined in the guide above.

## Methodology

EQA design: describe the overall design of the EQA and timeline, including types of samples, testing parameters, and expected outcomes.

EQA protocol: an EQA protocol describing the methodology should be attached to the EQA plan. Details outlined in the EQA protocol do not need to be repeated in the EQA plan.

## Distribution

Schedule: provide the estimated timeline for the distribution of EQA materials.

Logistics: outline logistical arrangements to ensure secure and timely delivery.

## Instructions for completion (minimum requirements)

Testing procedures: define the testing outcomes that should be reported.

Documentation: list the documentation to be completed and submitted along with the EQA results.

Submission deadline: specify the deadline for the submission of completed testing results.

## Data analysis

Statistical methods: detail the statistical methods to be used to analyse EQA data if indicated, based on participation and entry rates.

Performance indicators: define performance indicators.

## Reporting of results

### Reports to participants

- Content: outline what the report will include (e.g. individual laboratory performance, comparative analyses).
- Delivery method: specify how reports will be delivered to participants.
- Timeline: provide timelines for report submission following EQA completion.

### Reports to ECDC

- Content: outline what the report will include.
- Timeline: provide timelines for report submission following EQA completion.

## Reports to national network contact points (when relevant)

- Content: outline what the report will include.
- Timeline: provide timelines for report submission following EQA completion.

## Participant survey

Purpose: describe the objectives for conducting a survey among participants.

Topics covered: list key topics to be covered in the survey, including satisfaction, perceived value, and suggestions for improvement.

Methodology: outline how the survey will be conducted and the timeline for its execution and analysis.

## Data management, ownership and sharing

Data handling: specify how data collected through EQA will be managed, stored and protected.

Ownership: clarify ownership of EQA data.

Data sharing: detail the conditions under which EQA data may be shared with third parties, including other researchers and public health authorities.

# Annex 2. Template laboratory EQA certificate

## Issuing certificates of participation in EQA schemes

### Certificate content

- **Logos** – the certificate must carry the **ECDC logo, EURL logo**, and any other **relevant logos**.
- If the EQA provider is ISO-certified (e.g. ISO 17043) for the provision of the scheme in question, the ISO certification must be indicated for the service provided.
- Please indicate the **name of the EURL and the relevant ECDC disease network** and, where applicable, the name of the disease network via which the EQA is conducted.
- '**Certificate of participation**' – the certificate should clearly indicate that it is awarded for participation, without specifying level of performance.
- '**Awarded to**' - name of the laboratory to which the certificate is awarded, including the full name of the hosting institution and the country.
- '**Attesting participation in**' – the certificate should clearly indicate that it is awarded for completion of a set of tests (so called minimum criteria to be met in order for the participation to be considered successful). This means that if a laboratory does not return results from tests which are considered to be part of the minimum required, it would not be eligible to receive a certificate.
- **External Quality Assessment scheme for**… – the name of the specific EQA scheme should follow and the date or time period during which the scheme was conducted should be indicated. Note that the term assessment should be used and not assurance.

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