



2025/2537

17.12.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/2537
of 16 December 2025
designating a European Union reference laboratory for public health on respiratory viruses
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU ⁽¹⁾, and in particular Article 15(1) thereof,

Whereas:

- (1) Pursuant to Regulation (EU) 2022/2371, European Union reference laboratories ('EU reference laboratories') in the area of public health or for specific areas of public health relevant for the implementation of this Regulation are to provide support to national reference laboratories and to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods and use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.
- (2) In accordance with Article 15(4) of Regulation (EU) 2022/2371, the Commission launched in May 2025 ⁽²⁾ a call for applications for the designation of an EU reference laboratory for public health in the field of respiratory viruses.
- (3) In response to that call, Member States submitted applications for designation by 17 September 2025, which were evaluated by a selection board set up by the Commission services.
- (4) The selection board applied the requirements for EU reference laboratories set in Article 15(5) of Regulation (EU) 2022/2371 and contained in the call for applications for the purpose of selecting the EU reference laboratory.
- (5) Following the completion of the selection procedure, the successful consortium of laboratories should be designated as an EU reference laboratory and its responsibilities and tasks should be specified.
- (6) In order to use the funding allocated in the EU4Health annual work programme 2025 ⁽³⁾ in a timely manner, the designation of the EU reference laboratory for public health in the field of respiratory viruses should occur as soon as possible.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on serious cross-border threats to health,

HAS ADOPTED THIS REGULATION:

Article 1

1. The consortium referred to in the Annex is designated as the European Union reference laboratory for public health on respiratory viruses until 18 December 2032.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

⁽¹⁾ OJ L 314, 6.12.2022, p. 26, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

⁽²⁾ https://health.ec.europa.eu/consultations/eu-reference-laboratories-public-health-2025-calls-applications_en.

⁽³⁾ https://health.ec.europa.eu/publications/2025-eu4health-work-programme_en.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 December 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON RESPIRATORY VIRUSES, ITS RESPONSIBILITIES AND TASKS**1. The consortium designated as the EU reference laboratory for public health on respiratory viruses (hereinafter 'EURL')**

Consortium led by:

— Erasmus Medical Center, Dr Molewaterplein 40, 3015 GD, Rotterdam, NETHERLANDS,

Also composed of:

— Rijksinstituut voor Volksgezondheid en Milieu, Antonie van Leeuwenhoeklaan 9, 3721 MA, Bilthoven;

— Institut Pasteur, 25-28 rue du Docteur Roux, 75724 Paris Cedex 15, FRANCE;

— Charité University Hospital, Charitéplatz 1, 10117 Berlin, GERMANY;

— Aristotle University of Thessaloniki, Tritis Septemvriou, Aristotle University Campus, 54124 Thessaloniki, GREECE;

— Statens Serum Institut, Artillerivej 5, 2300 København S, DENMARK;

— Instituto Nacional de Saúde Doutor Ricardo Jorge, Avenida Padre Cruz, 1649-016 Lisboa, PORTUGAL;

— Robert Koch-Institut, Nordufer 10, 13353 Berlin, GERMANY.

2. Responsibilities and tasks

The EURL shall provide support to national reference laboratories and promote good practice and quality to strengthen public health microbiology in the field of respiratory viruses.

The EURL shall provide support to the national reference laboratories for activities in relation to the following priority respiratory viruses: influenza virus (seasonal, emerging/pandemic and human infections of zoonotic influenza), SARS-CoV-2 and respiratory syncytial virus (RSV). Should there be an EU-level need related to other respiratory viruses of epidemic and/or pandemic potential, such as SARS-CoV, MERS-CoV, enterovirus D68, adenovirus and human metapneumovirus, or a novel respiratory virus (pathogen X scenario), the EURL may be requested to also carry out work and provide advice on these other respiratory viruses.

The EURL shall provide support and have a coordination function for the laboratory members of relevant European Centre for Disease Prevention and Control (ECDC) disease network(s) for the above-mentioned respiratory viruses, for the implementation of the activities under its agreed work plan.

For the implementation of the activities under the work plan of the EURL, which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the National Focal Points (NFPs) and the Operational Contact Points (OCPs) for Microbiology for the pathogens under the scope of the EURL.

Upon request from the ECDC, the EURL shall participate in relevant ECDC networks and structures. The EURL shall participate in the network of EU reference laboratories that is operated and coordinated by the ECDC in accordance with Article 15(3) of Regulation (EU) 2022/2371.

The EURL shall ensure that there is:

- a sufficient number of qualified staff in relation to the volume of the tasks that the EURL is to carry out in its scope of designation;
- adequate training of staff for the execution of the tasks of the EURL;
- capacity for providing enhanced laboratory support in case of an escalation of a serious cross-border threat, notified in accordance with Article 19 of Regulation (EU) 2022/2371, or a recognition of a public health emergency at Union level in accordance with Article 23 of Regulation (EU) 2022/2371.

The EURL shall establish and implements its confidentiality and cybersecurity policy, including rules for the appropriate secure handling, storage and processing of samples, data and information, as well as measures to prevent undue disclosure of sensitive data and confidential information.

The EURL shall be responsible for the following tasks:

- (a) providing reference and confirmatory diagnostic services in the field of the EURL to members of the relevant network(s) supported by the EURL, according to the needs defined by either the network(s) supported by the EURL or by the ECDC;
- (b) developing laboratory tests in the field of the EURL, including their validation, to strengthen preparedness, capacity and capability within the laboratories associated to the relevant network(s) supported by the EURL, according to the needs defined by either the network(s) supported by the EURL or by the ECDC;
- (c) providing genotypic and/or phenotypic virus characterisation services in the field of the EURL to members of the relevant network(s) supported by the EURL, according to the needs defined by either the network(s) supported by the EURL or by the ECDC;
- (d) performing genomic data analysis to monitor and analyse the genetic evolution of pathogens in the field of the EURL and to obtain selected specimens for further characterisation, according to the needs defined by the network(s) supported by the EURL, by the ECDC or by the Commission;
- (e) performing genotypic and/or phenotypic characterisation of viruses in the field of the EURL on a representative selection of specimens collected from the members of the relevant network(s) supported by the EURL, according to the needs defined by the ECDC or by the Commission;
- (f) providing physical and/or digital reference materials in the field of the EURL to members of the relevant network(s) supported by the EURL, according to the needs defined by either the network(s) supported by the EURL or by the ECDC;
- (g) providing external quality assessments and bioinformatic ring trials, such as phenotypic or genomic proficiency testing, in the field of the EURL to members of the relevant network(s) supported by the EURL, according to the needs defined by either the network(s) supported by the EURL or by the ECDC;
- (h) providing scientific advice and technical assistance in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s) supported by the EURL;
- (i) providing support to regularly optimise and adapt the surveillance data collection in the field of the EURL, including provision of reference virus information, according to the needs defined by the ECDC;
- (j) performing research on virological characteristics with relevance for public health in the field of the EURL, according to the needs defined by the ECDC or the Commission;
- (k) assessing the laboratory preparedness for pandemic/outbreak situations in the EU/EEA and proposing EU-level coordination and a laboratory response strategy. The assessment should identify required actions and information needs, to be applied in the event of large outbreaks or pandemics, to increase the state of laboratory preparedness in the Union in the field of the EURL;
- (l) providing scientific advice and technical assistance in the field of the EURL, including, where necessary, support during outbreak situations and contributions to risk assessments;
- (m) organising and delivering training, such as workshops, professional exchange visits, webinars, simulation exercises, wet-lab training sessions and/or pilot surveillance exercises, in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by either the network(s) supported by the EURL or by the ECDC;
- (n) ensuring coordination, communication and dissemination with members of the relevant network(s) supported by the EURL, and with the ECDC, including the development of annual work plans and their agreement with ECDC;

- (o) organising meetings for members of the network(s) supported by the EURL;
 - (p) ensuring coordination with other EU reference laboratories in public health and, where relevant to the field of the EURL, with EU reference laboratories in other areas such as feed, food and animal health and/or *in vitro* medical devices;
 - (q) ensuring coordination with the World Health Organization (WHO), the WHO Collaborating Centres and/or the WHO reference laboratories, or other relevant initiatives in the field of the EURL;
 - (r) collaborating, in cooperation with the ECDC, with the European Food Safety Authority (EFSA) and/or the European Medicines Agency (EMA), or other EU agencies and bodies as relevant;
 - (s) collaborating, in cooperation with the ECDC, with laboratories in third countries in an international context that benefits public health in the Union, as relevant.
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