



COMMISSION IMPLEMENTING REGULATION (EU) 2024/892

of 22 March 2024

designating European Union reference laboratories for certain specific areas of public health

(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 are to provide support to national reference laboratories and to promote good practice and alignment by Member States 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 October 2023 ⁽²⁾, calls for applications for EU reference laboratories in six areas of public health, namely antimicrobial resistance (AMR) in bacteria; vector-borne viral pathogens; emerging, rodent-borne and zoonotic viral pathogens; high-risk, emerging and zoonotic bacterial pathogens; *Legionella*; and diphtheria and pertussis.
- (3) In response to those calls, Member States submitted applications for designation by 5 January 2024, which were evaluated by a selection board set up by the Commission services.
- (4) The selection board took into account the criteria for EU reference laboratories set in Article 15(5) of Regulation (EU) 2022/2371 and in the call for application.
- (5) Following the completion of the selection procedure, the successful laboratories should be designated as EU reference laboratories and their responsibilities and tasks should be specified.
- (6) In order to use the funding allocated in the EU4Health annual work programme 2023 ⁽³⁾, the designation of EU reference laboratories in the field of public health should be provided for 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 Annex I is designated as European Union reference laboratory for public health on antimicrobial resistance in bacteria until 26 March 2031.

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.

⁽²⁾ https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health-calls-application_en.

⁽³⁾ https://health.ec.europa.eu/publications/2023-eu4health-work-programme_en; reference CP-g-23-05-01.

Article 2

1. The consortium referred to in Annex II is designated as European Union reference laboratory for public health on vector-borne viral pathogens until 26 March 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 3

1. The consortium referred to in Annex III is designated as European Union reference laboratory for public health on emerging, rodent-borne and zoonotic viral pathogens until 26 March 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 4

1. The consortium referred to in Annex IV is designated as European Union reference laboratory for public health on high-risk, emerging and zoonotic bacterial pathogens until 26 March 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 5

1. The consortium referred to in Annex V is designated as European Union reference laboratory for public health on *Legionella* until 26 March 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 6

1. The consortium referred to in Annex VI is designated as European Union reference laboratory for public health on diphtheria and pertussis until 26 March 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 7

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, 22 March 2024.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON ANTIMICROBIAL RESISTANCE (AMR) IN BACTERIA, ITS RESPONSIBILITIES AND TASKS**1. THE CONSORTIUM DESIGNATED AS THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON ANTIMICROBIAL RESISTANCE (AMR) IN BACTERIA (HEREINAFTER 'EURL')**

Consortium led by:

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

Also composed of:

Danmarks Tekniske Universitet, Anker Engelunds Vej 101, 2800 Kongens Lyngby, DENMARK

Clinical Microbiology Region Kronoberg, Central Hospital Växjö, Värendsgatan 7, SE-351 85 Växjö, SWEDEN

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 AMR in bacteria, with the exception of AMR issues related to *Salmonella* species, *Campylobacter* species and *Neisseria gonorrhoeae*.

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Antimicrobial Resistance Surveillance Network (EARS-Net) ⁽¹⁾ and the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net) ⁽²⁾ on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the laboratory networks of EARS-Net and EURGen-Net consisting of the National Focal Points (NFPs) for AMR and the Operational Contact Points (OCPs) for Microbiology for the pathogens covered by EARS-Net and EURGen-Net.

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 to be 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 their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

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

The EURL shall be responsible for the following tasks:

- (a) providing reference testing in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (b) providing harmonised laboratory methods and protocols for diagnostic and characterisation purposes in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (c) providing physical reference materials in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (d) providing a repository of reference material resources in the field of the EURL;

⁽¹⁾ <https://www.ecdc.europa.eu/en/about-us/networks/disease-networks-and-laboratory-networks/ears-net-data>.

⁽²⁾ <https://www.ecdc.europa.eu/en/about-us/who-we-work/disease-and-laboratory-networks/EURGen-net>.

- (e) providing external quality assessments, such as phenotypic or genomic proficiency testing, in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (f) conducting ad hoc surveys in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (g) 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 these network(s);
- (h) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (i) providing assessments of laboratory capacity, developing plans for capacity strengthening and/or supporting capacity building in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (j) coordinating collaborative research studies in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (k) providing information on relevant national, Union and international research activities in the field of the EURL, according to the needs defined by these network(s);
- (l) providing support to national surveillance and/or national and cross-border outbreak investigations in the field of the EURL, according to the needs defined by the network(s) supported by the EURL;
- (m) providing training, via workshops, webinars, simulation exercises and/or pilot surveillance exercises in the field of the EURL to members of the network(s) supported by the EURL;
- (n) ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL, and with the ECDC;
- (o) organising laboratory network meetings in the field of the EURL;
- (p) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;
- (q) collaborating, in cooperation with the ECDC, with laboratories in third countries and with the European Food Safety Authority (EFSA) and/or the European Medicines Agency (EMA), as relevant;
- (r) providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.

ANNEX II

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON VECTOR-BORNE VIRAL PATHOGENS, ITS RESPONSIBILITIES AND TASKS**1. THE CONSORTIUM DESIGNATED AS THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON VECTOR-BORNE VIRAL PATHOGENS (HEREINAFTER 'EURL')**

Consortium led by:

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

Also composed of:

Institut national de la santé et de la recherche médicale, 101 rue de Tolbiac, 75654 Paris Cedex 13, FRANCE

Aristotle University of Thessaloniki, Tritis Septemvriou, Aristotle University Campus, 546 36 Thessaloniki, GREECE

Azienda Ospedale – Università Padova, via Nicolo Giustiniani 1, 35128 Padova PD, ITALY

Univerza v Ljubljani, Kongresni trg 12, SI-1000 Ljubljana, SLOVENIA

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 vector-borne viral pathogens.

This includes vector-borne viral diseases caused by flaviviruses (such as dengue virus, Japanese encephalitis virus, tick-borne encephalitis virus, West Nile virus, yellow fever virus, Zika virus), alphaviruses (such as chikungunya virus, Sindbis virus), bunyaviruses (such as Crimean-Congo haemorrhagic fever virus, Rift Valley fever virus, Toscana virus), and arboviruses in other virus families.

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Emerging and Vector-borne Diseases Network (EVD-Net) ⁽¹⁾ on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the laboratory networks of EVD-Net consisting of the National Focal Points (NFPs) for Emerging and Vector-borne Diseases and the Operational Contact Points (OCPs) for Microbiology relevant for vector-borne viral diseases.

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 to be 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 their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

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

The EURL shall be responsible for the following tasks:

- (a) providing reference diagnostic and characterisation services in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;

⁽¹⁾ <https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/disease-and-laboratory-networks/european-emerging-and>.

- (b) providing reference materials in the field of the EURL to members of the network supported by the EURL;
- (c) providing external quality assessment schemes for diagnostics and characterisation of selected viruses or virus groups in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;
- (d) providing scientific advice and technical assistance in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;
- (e) providing technical reports in the field of the EURL, based on literature reviews, expert opinions and/or network surveys;
- (f) providing contributions to ECDC technical reports in the field of the EURL;
- (g) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (h) providing information, guidance and support to members of the network supported by the EURL in case of unusual occurrences in the field of the EURL;
- (i) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (j) organising and delivering training, such as workshops, webinars and wet-lab trainings, in the field of the EURL to members of the network supported by the EURL;
- (k) organising and delivering twinning visits in the field of the EURL for members of the network supported by the EURL;
- (l) ensuring coordination, communication and dissemination with members of the network supported by the EURL and with the ECDC;
- (m) organising laboratory network meetings in the field of the EURL;
- (n) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;
- (o) collaborating, in cooperation with the ECDC, with laboratories in third countries and with the European Food Safety Authority (EFSA) and/or the European Medicines Agency (EMA), as relevant;
- (p) providing scientific and technical assistance on other issues relevant to members of the network supported by the EURL.

ANNEX III

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON EMERGING, RODENT-BORNE AND ZOONOTIC VIRAL PATHOGENS, ITS RESPONSIBILITIES AND TASKS**1. THE CONSORTIUM DESIGNATED AS THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON EMERGING, RODENT-BORNE AND ZOONOTIC VIRAL PATHOGENS (HEREINAFTER 'EURL')**

Consortium led by:

Folkhälsomyndigheten, Nobels väg 18, SE-171 82 Solna, SWEDEN

Also composed of:

Istituto Nazionale per le Malattie Infettive 'Lazzaro Spallanzani', via Portuense 292, 00149 Roma RM, ITALY

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

Nemzeti Népegészségügyi és Gyógyszerészeti Központ, Albert Flórián út 2-6, 1097 Budapest, HUNGARY

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 emerging, rodent-borne and zoonotic viral pathogens.

In particular, this includes viral diseases caused by arenaviruses, filoviruses, hantaviruses, henipaviruses, lyssaviruses, poxviruses and viral 'Disease X'.

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Emerging and Vector-borne Diseases Network (EVD-Net) ⁽¹⁾ on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the laboratory networks of EVD-Net consisting of the National Focal Points (NFPs) for Emerging and Vector-borne Diseases and the Operational Contact Points (OCPs) for Microbiology relevant for emerging, rodent-borne and zoonotic viral diseases.

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 to be 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 their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

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

The EURL shall be responsible for the following tasks:

- (a) providing reference diagnostic and characterisation services in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;
- (b) providing reference materials in the field of the EURL to members of the network supported by the EURL;
- (c) providing external quality assessment schemes for diagnostics and characterisation of selected viruses or virus groups, in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;

⁽¹⁾ <https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/disease-and-laboratory-networks/european-emerging-and>.

- (d) providing scientific advice and technical assistance in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;
- (e) providing technical reports in the field of the EURL, based on literature reviews, expert opinions and/or network surveys;
- (f) providing contributions to ECDC technical reports in the field of the EURL;
- (g) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (h) providing information, guidance and support to members of the network supported by the EURL in case of unusual occurrences in the field of the EURL;
- (i) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (j) organising and delivering training, such as workshops, webinars and wet-lab trainings, in the field of the EURL to members of the network supported by the EURL;
- (k) organising and delivering twinning visits in the field of the EURL for members of the network supported by the EURL;
- (l) ensuring coordination, communication and dissemination with members of the network supported by the EURL and with the ECDC;
- (m) organising laboratory network meetings in the field of the EURL;
- (n) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;
- (o) collaborating, in cooperation with the ECDC, with laboratories in third countries and with the European Food Safety Authority (EFSA) and/or the European Medicines Agency (EMA), as relevant;
- (p) providing scientific and technical assistance on other issues relevant to members of the network supported by the EURL.

ANNEX IV

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON HIGH RISK, EMERGING AND ZOONOTIC BACTERIAL PATHOGENS, ITS RESPONSIBILITIES AND TASKS**1. THE CONSORTIUM DESIGNATED AS THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON HIGH RISK, EMERGING AND ZOONOTIC BACTERIAL PATHOGENS (HEREINAFTER 'EURL')**

Consortium led by:

Robert Koch-Institut, Nordufer 20, 13353 Berlin, GERMANY

Also composed of:

Institut für Mikrobiologie der Bundeswehr, Neuherbergstraße 11, 80937 München, GERMANY

Folkhälsomyndigheten, Nobels väg 18, SE-171 82 Solna, SWEDEN

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

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 high risk, emerging and zoonotic bacterial pathogens.

This includes high risk, emerging and zoonotic bacterial diseases (such as anthrax, brucellosis, glanders, leptospirosis, Lyme borreliosis, melioidosis, plague, Q fever, rickettsiosis and tularaemia).

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Emerging and Vector-borne Diseases Network (EVD-Net) ⁽¹⁾ and European Food- and Waterborne Diseases and Zoonoses Network (FWD-Net) ⁽²⁾ on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the laboratory networks of EVD-Net and FWD-Net consisting of the National Focal Points (NFPs) for Emerging and Vector-borne Diseases and NFPs for Food- and Waterborne Diseases and Zoonoses and the Operational Contact Points (OCPs) for Microbiology for bacterial diseases 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 to be 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 their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

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

The EURL shall be responsible for the following tasks:

- (a) providing reference diagnostic and characterisation services in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (b) providing reference materials in the field of the EURL to members of the network(s) supported by the EURL;

⁽¹⁾ <https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/disease-and-laboratory-networks/european-emerging-and>.

⁽²⁾ <https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/fwd-net>.

- (c) providing external quality assessment schemes for diagnostics and characterisation of selected bacteria in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (d) 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 these network(s);
- (e) providing technical reports in the field of the EURL, based on literature reviews, expert opinions and/or network surveys;
- (f) providing contributions to ECDC technical reports in the field of the EURL;
- (g) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (h) providing information, guidance and support to members of the network(s) supported by the EURL in case of unusual occurrences in the field of the EURL;
- (i) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (j) organising and delivering training, such as workshops, webinars and wet-lab trainings, in the field of the EURL to members of the network(s) supported by the EURL;
- (k) organising and delivering twinning visits in the field of the EURL for members of the network(s) supported by the EURL;
- (l) ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL and with the ECDC;
- (m) organising laboratory network meetings in the field of the EURL;
- (n) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;
- (o) collaborating, in cooperation with the ECDC, with laboratories in third countries and with the European Food Safety Authority (EFSA) and/or the European Medicines Agency (EMA), as relevant;
- (p) providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.

ANNEX V

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON LEGIONELLA, ITS RESPONSIBILITIES AND TASKS**1. THE CONSORTIUM DESIGNATED AS THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON LEGIONELLA (HEREINAFTER 'EURL')**

Consortium led by:

Hospices Civils de Lyon, 3 quai des Célestins, 69002 Lyon, FRANCE

Also composed of:

Istituto Superiore di Sanità, Viale Regina Elena 299, 00161, Roma RM, ITALY

Technische Universitaet Dresden, Helmholtzstraße 10, 01069 Dresden, GERMANY

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

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 *Legionella*.

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Legionnaires' Disease Surveillance Network (ELDSNet) (1) on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the laboratory network of ELDSNet consisting of the National Focal Points (NFPs) for Legionnaires' disease and the Operational Contact Points (OCPs) for Microbiology for Legionnaires' disease.

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 to be 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 their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

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

The EURL shall be responsible for the following tasks:

- (a) providing reference methods, such as for detection and characterisation purposes, in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;
- (b) providing reference diagnostic services in the field of the EURL to members of the network supported by the EURL;
- (c) providing external quality assessment schemes for detection, isolation, and characterisation from clinical and environmental specimens in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;
- (d) providing scientific advice and technical assistance, including on diagnostic techniques and characterisation methods in the field of the EURL to members of the network supported by the EURL, according to the needs defined by this network;
- (e) providing scientific advice and technical support to the ECDC on laboratory topics, including method developments, genomic typing, material availability and other topics in the field of the EURL;

(1) <https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/eldsnet>.

- (f) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (g) performing country visits to review, evaluate, and improve laboratory surveillance for case and outbreaks detection in the field of the EURL;
- (h) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (i) organising and delivering training, including wet lab training, in the field of the EURL to members of the network supported by the EURL;
- (j) organising and delivering scientific webinars in the field of the EURL for members of the network supported by the EURL;
- (k) ensuring coordination, communication and dissemination with members of the network supported by the EURL and with the ECDC;
- (l) organising laboratory network meetings in the field of the EURL;
- (m) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;
- (n) collaborating, in cooperation with ECDC, with laboratories in third countries and with the European Environmental Agency (EEA) and the European Medicines Agency (EMA), as relevant;
- (o) providing scientific and technical assistance on other issues relevant to members of the network supported by the EURL.

ANNEX VI

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON DIPHTHERIA AND PERTUSSIS, ITS RESPONSIBILITIES AND TASKS**1. THE CONSORTIUM DESIGNATED AS THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON DIPHTHERIA AND PERTUSSIS (HEREINAFTER 'EURL')**

Consortium led by:

University of Turku, Yliopistonmäki, FI-20014 Turku, FINLAND

Also composed of:

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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 diphtheria and pertussis.

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Diphtheria Surveillance Network (EDSN) (1) and the Pertussis Network on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the laboratory networks of EDSN and the Pertussis Network consisting of the National Focal Points (NFPs) for Vaccine preventable diseases and the Operational Contact Points (OCPs) for Microbiology for diphtheria and for pertussis.

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 to be 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 their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

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

The EURL shall be responsible for the following tasks:

- (a) providing reference methods, such as for diagnostics, antimicrobial susceptibility testing or characterisation purposes in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (b) providing external quality assessment schemes for diagnostics or characterisation, in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (c) providing scientific advice and technical assistance, including on diagnostics and characterisation, whole genome sequencing, bioinformatic analyses and genomic typing, genomic typing-based surveillance and other topics related to the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);

(1) <https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/edsn>.

- (d) providing scientific advice and technical support to the ECDC on laboratory topics, method developments including genomic typing, material availability and other topics related to the field of the EURL;
- (e) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (f) performing seroprevalence studies in the field of the EURL;
- (g) performing gap analyses in the field of the EURL, to identify needs/gaps within the EU/EEA and for the members of the network(s) supported by the EURL;
- (h) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (i) organising and delivering training, including wet lab training, in the field of the EURL to members of the network(s) supported by the EURL;
- (j) organising and delivering twinning visits in the field of the EURL for members of the network(s) supported by the EURL;
- (k) ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL, and with the ECDC;
- (l) organising laboratory network meetings in the field of the EURL;
- (m) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres or relevant initiatives in the field of the EURL;
- (n) collaborating, in cooperation with the ECDC, with laboratories in third countries and the European Medicines Agency (EMA), as relevant;
- (o) providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.
