European Union reference laboratories (EURLs) in the field of *in vitro* diagnostic medical devices

Information pack for candidate laboratories

Version 1 - July 2022

Disclaimer: This information pack aims to summarise key information in an accessible way. It is subject to change. Please refer to the relevant legislation and text of the call for applications for full details and/or contact your Member State for further information (contact details below)

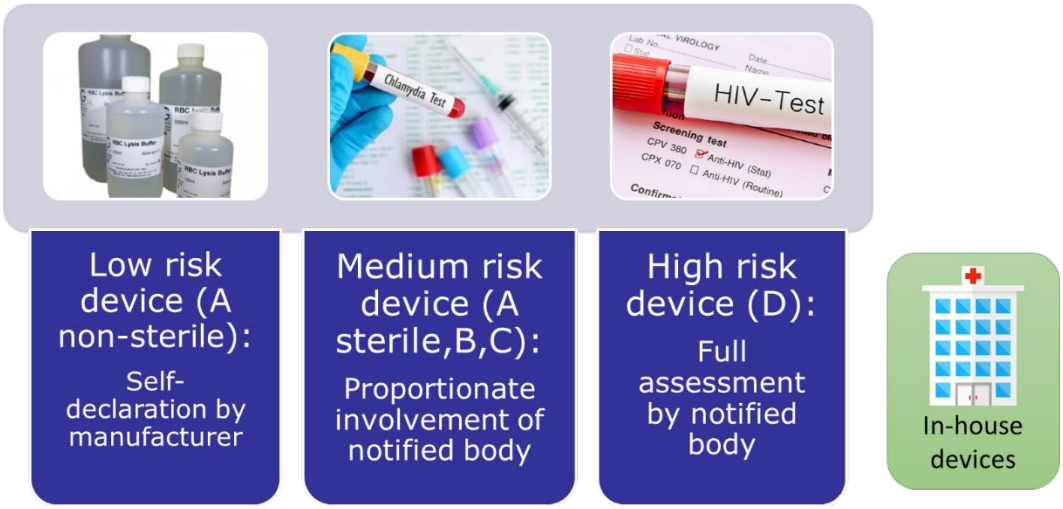
Contents

1. Introduction

1.1 The legal framework for *in vitro* diagnostics in the EU

In vitro diagnostic medical devices (IVDs) are tests intended for examination of human specimens for a medical purpose[1]. In the EU, there is dedicated legislation that manufacturers must follow to produce and sell such devices. This legislation is Regulation (EU) 2017/746. It was adopted by the European Parliament and by the Council in 2017 and entered into application on 26 May 2022, replacing Directive 98/79/EC. The Regulation has significantly reinforced the regulatory framework for IVDs compared to the Directive. For example, it introduced a new risk-based classification system for IVDs (class A-D in order of increasing risk), more detailed and stringent rules on the evaluation of device performance, and greater involvement of independent conformity assessment bodies ('notified bodies' – please see the schematic below). You can read more about the new Regulation here.

Fig.1: Risk-based classification system for IVDs.



1.2 Class D IVDs

In the context of EU reference laboratories, it is particularly important to understand which IVDs would be in class D, the highest risk class. The rules for determining the risk class of the device are to be found in Annex VIII of Regulation (EU) 2017/746. Rule 1 and Rule 2 focus on class D devices and are as follows:

Rule 1

Devices intended to be used for the following purposes are classified as class D:
— detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;
— detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;

[1] The full legal definition of an *in vitro* diagnostic medical device is available in Article 2(1) of Regulation (EU) 2017/746.

— determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.

Rule 2

Devices intended to be used for blood grouping, or to determine foeto-maternal blood group incompatibility, or for tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as class C, except when intended to determine any of the following markers:
— ABO system [A (ABO1), B (ABO2), AB (ABO3)];
— Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)];
— Kell system [Kel1 (K)];
— Kidd system [JK1 (Jka), JK2 (Jkb)];
— Duffy system [FY1 (Fya), FY2 (Fyb)];
in which case they are classified as class D.

The guidance document MDCG 2020-16 contains further explanation and examples for the above rules.

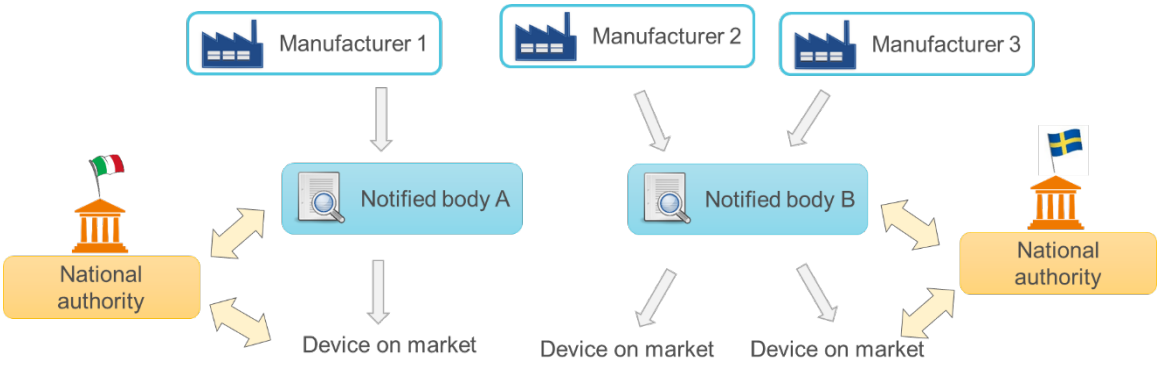
1.3 Conformity assessment of IVDs

'Conformity assessment' refers to the procedures that must be completed for the manufacturer to comply with the Regulation and to be able to CE-mark the IVD and place it on the market. The procedures depend on the risk class of the IVD.

Conformity assessment of most IVDs – all except the lowest-risk class A non-sterile devices – involves assessment by notified bodies, which are independent bodies designated by Member State competent authorities with involvement of the European Commission. Typically the notified body assesses the quality management system of the manufacturer and the technical documentation of the devices and issues the corresponding certificates. The procedures are laid down in Article 48 of Regulation (EU) 2017/746 and described in detail in the annexes that Article refers to.

For devices of all risk classes in a given country, the national competent authority performs important oversight functions, such as supervision of the notified bodies, market surveillance (e.g. manufacturer inspections) and vigilance (i.e. action related to serious incidents). National authorities of all EU Member States coordinate their work in the Medical Device Coordination Group (see section 1.5).

Fig.2: IVD regulatory system involving notified bodies (all devices except class A non-sterile).

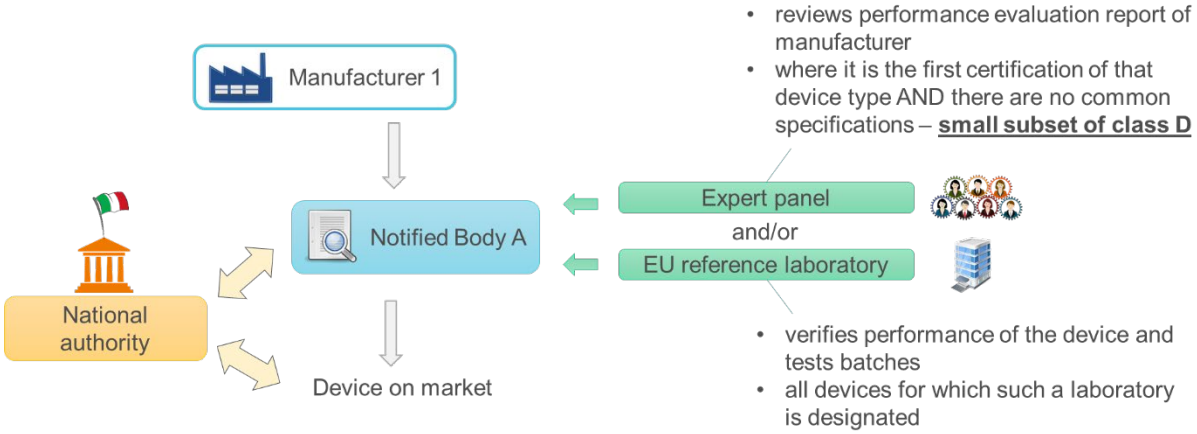


For the highest-risk – class D – IVDs the Regulation foresees additional layers of control by independent scientific bodies. These are the IVD expert panel and the EU reference laboratories (EURLs). They have distinct and complementary functions. The role of the IVD expert panel is described here and the role of the EU reference laboratories is described in the next section.

The expert panel is involved for novel class D IVDs (more specifically when it is the first certification of that type of device and when no common specifications are available for that device – see section 1.5). In other words, only a small subset of IVDs is reviewed by the expert panel – for instance the first SARS-CoV-2 antigen test[2]. The panel performs a paper review of the manufacturer's performance evaluation report. The notified body then takes into account the views of the expert panel when it decides whether or not to issue a certificate for that device.

The role of EURLs in conformity assessment of class D devices is described in the next section. A key difference from the expert panel is that once an EU reference laboratory is designated for a certain category or group of IVD (such as SARS-CoV-2 tests), all devices in that category or group must be tested by the EU reference laboratory before they may be placed on the market, regardless of whether or not they are novel (e.g. all brands and types of SARS-CoV-2 tests). There are two key types of testing – verification of performance and batch testing. See section 2.2 for a more detailed description of EURL tasks.

Fig.3: IVD regulatory system: class D devices



1.4 Common specifications

Common specifications are detailed practical rules setting out how particular types of devices should comply with certain requirements of Regulation (EU) 2017/746. The Commission can adopt common specifications where no harmonised standards exist or where relevant harmonised standards are not sufficient, or where there is a need to address public health concerns. Manufacturers must follow the specifications or show that they have adopted solutions of a level of safety and performance that is at least equivalent. To allow market actors to adapt to new specifications, there is a transition period in which their use is voluntary. A list of common specifications is available on the Commission website here.

[2] This is a simplification. For full explanation please see the guidance document MDCG 2021-22.

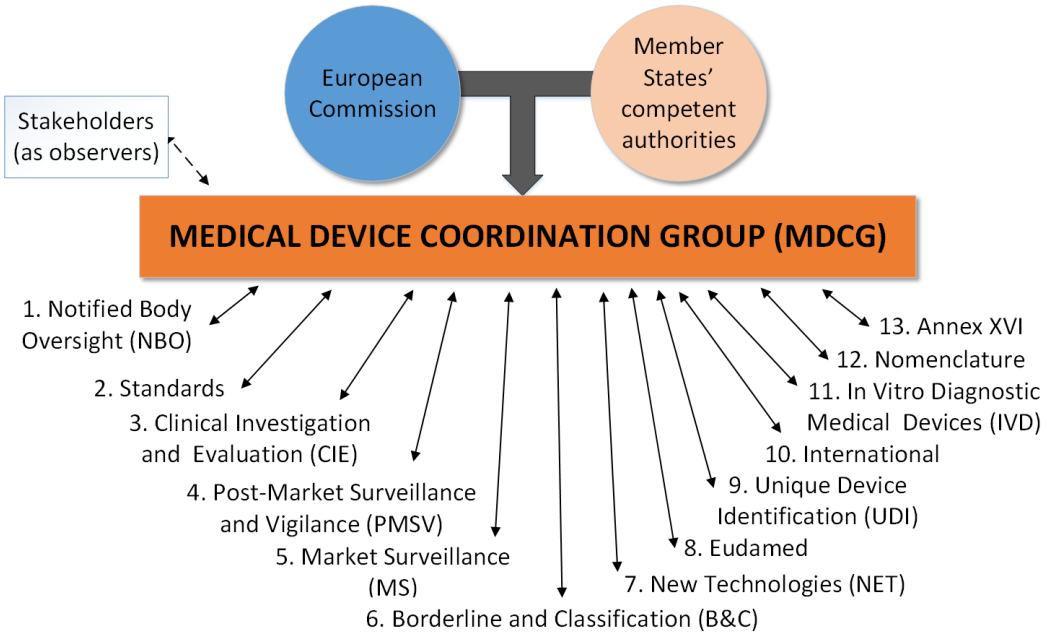
EURLs may be requested to contribute to the development of common specifications (see section 2.2).

1.5 The Medical Device Coordination Group

The Medical Device Coordination Group (MDCG) is also set up by the medical device Regulations. It is a group of Member State competent authorities chaired by the European Commission. Its main purpose is to oversee the implementation of the two medical device Regulations and serve as a forum for the competent authorities to coordinate. The MDCG has been in place and meeting regularly since 2017. It has 13 thematic subgroups which you can see in the diagram below. You can find their meeting agendas and minutes on the Commission Register of Expert Groups here.

The MDCG may submit requests for scientific and technical assistance to EURLs (see section 2.2).

Fig.4: Medical device coordination group (MDCG) and its subgroups.



2. Legal framework for EU reference laboratories

The key article of Regulation (EU) 2017/746 on the topic of EU reference laboratories is **Article 100**. It is essential to read it in detail.

Moreover, there are two additional pieces of implementing legislation that should be studied carefully. These are:

- Commission Implementing Regulation (EU) 2022/944 **on tasks and criteria** of EU reference laboratories
- Commission Implementing Regulation (EU) 2022/945 **on fees** that the EURLs can levy from notified bodies and Member States

The below sections explain some key concepts from the above.

2.1 Designation of EU reference laboratories

Article 100 of Regulation (EU) 2017/746 empowers the European Commission to designate one or more EU reference laboratories for specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices. To do this, the Commission will launch a call for applications for designation of EU reference laboratories to Member States.

A candidate laboratory cannot submit an application directly to the European Commission. It has to submit the application to the relevant Member State and the Member State will submit the application to the European Commission. A Member State can submit applications to the European Commission only for candidate laboratories located on its territory.

If an international agreement gives a country a status equivalent to that of a Member State for the purposes of Article 100 of Regulation (EU) 2017/746, then that country may also submit applications for designation of EURLs in its jurisdiction. This includes the three EFTA[3] countries Norway, Iceland and Liechtenstein, and Turkey.

2.2 The tasks of EURLs

The tasks of EURLs are laid down in Article 100(2) of Regulation (EU) 2017/746. There are two main categories of tasks: those related to conformity assessment of class D devices and advisory tasks.

As regards conformity assessment, the EURL performs laboratory testing of the devices as follows:

- verification that the device performs according to the claims of the manufacturer (and according to the common specifications when available and used by the manufacturer), which is done prior to CE-marking of the device, and
- batch testing, both pre- and post-CE-marking[4].

In addition to the above, EU reference laboratories can also do work of advisory nature. According to Article 100(2), they may:

- provide scientific and technical assistance to the Commission, the Medical Device Coordination Group, the Member States and notified bodies;
- provide scientific advice regarding the state of the art;
- set up and manage a network of national reference laboratories;
- contribute to the development of appropriate testing and analysis methods for conformity assessment and market surveillance;
- collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;
- provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;
- contribute to the development of common specifications and of international standards.

[3] European Free Trade Association

[4] There is a guidance document for notified bodies on batch testing which is also of interest to EURLs – MDCG 2022-3.

The tasks are described in more detail in the Commission Implementing Regulation (EU) 2022/944 on tasks and criteria for EURLs.

2.3 Financing of EURLs

Candidate laboratories are expected to be existing laboratories which are financially viable without EU financial assistance. Their sources of funding must be independent.

The EURLs may levy fees for tasks requested by notified bodies or Member States. The fees may cover, but not exceed, the cost of the task. How exactly the cost is calculated is up to each EURL, but it must publish the rules for fee calculation. For more details, please see the Commission Implementing Regulation (EU) 2022/945 on fees that may be levied by EU reference laboratories.

The EURLs may be granted a Union financial contribution. The European Commission will consider the establishment of the Union contribution following an evaluation of the needs for funding. In particular, it can fund EURL tasks that may not be covered by fees as well as the networking activities (see section 2.5).

2.4 Controls

The EURLs act in the public interest and operate independently from other economic operators, national competent authorities and the European Commission. Nevertheless the European Commission is empowered by Regulation (EU) 2017/746 to carry out controls, including on-site visits and audits, to make sure that the EURL remains compliant with the Regulation.

2.5 Network of EU reference laboratories

According to Regulation (EU) 2017/746, the EURLs should operate as a network to coordinate and harmonise their working methods. In addition to a general network, if more than one EURL is designated for a category of devices, those EURL will form a thematic sub-network. Each (sub-) network will elect a chair and vice-chair.

The general network will discuss and adopt common rules of procedure, proposed by the European Commission, before EURLs start performing their tasks. The general network and the sub-networks will also work on harmonisation of methods, procedures, processes, etc. in particular on common laboratory test procedures for performance verification and batch testing of devices.

2.6 Interplay between EURLs with different functions

EURLs exist in different sectors, according to the corresponding EU legislation, such as food additives, genetically modified organisms or pesticides. Sometimes EURLs may have different functions within the same or similar sectors. For example, in the field of diagnostics, in parallel with the EURLs under Regulation (EU) 2017/746, it is foreseen to designate EURLs under the proposed Regulation on serious cross-border threats to health. Their role will be to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States – i.e. functions that are different to those described in Regulation (EU) 2017/746. This network of EURLs will be operated and coordinated by the European Centre for Disease Prevention and Control (ECDC).

It is possible for one laboratory to be designated as an EURL more than once, under different pieces of EU legislation. However, the laboratory will need to be proposed for designation separately and

demonstrate its compliance with the corresponding criteria under each framework. It may then perform the different sets of functions in parallel.

3. Overall selection process

3.1 Scopes of designation

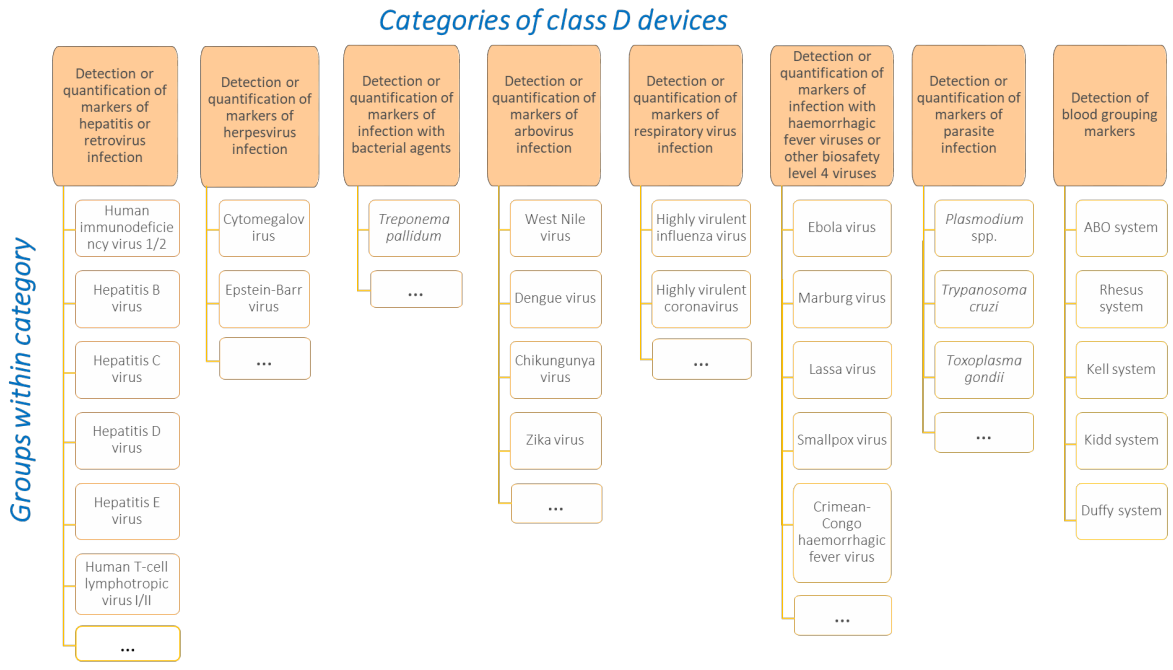
As of 2022, the European Commission intends to designate EURLs for the categories of class D devices in the chart below. A laboratory may select and be designated for one or more categories. These categories will constitute the formal scope of designation of the laboratories.

The categories below have a number of subdivisions ("groups"). The groups are non-exhaustive, i.e. the laboratory being designated for a given category must cover all the groups listed, but also other devices that may fall in the category. For example, a laboratory designated for "**Detection of respiratory viruses that cause life-threatening diseases**" will cover devices for detection of highly virulent influenza and highly virulent coronaviruses (including SARS, MERS, SARS-CoV-2) and in case of emergence of future coronavirus strains it will automatically cover also devices for detection of those new strains.

An exception to the above is category 8, where only the listed groups must be covered. This is because Rule 2 in Annex VIII of Regulation (EU) 2017/746 explicitly lists the blood grouping devices that fall in class D (see section 1.2).

The European Commission may launch subsequent calls in the future, for example if there are no candidate laboratories for some of the categories listed below or if additional needs are identified.

Fig.5: Categories and groups of class D devices for designation of EURLs.



3.2 EURL capacities

The bulk of the EURLs' work involves testing of devices which manufacturers wish to place on the EU market. While the demand for EURL services may fluctuate, it is important that testing capacity of

EURLs corresponds to this demand as much as reasonably possible. Undercapacity could lead to delays in market access of devices, while overcapacity would be inefficient from an economic point of view.

This is why EURL capacity for the tasks related to device market access needs to be taken into account in the designation process. The European Commission has estimated minimum EU-wide capacity for performance verification and batch testing for each category and group of devices, based on input from various stakeholders, as listed in the table below.

No	**Category** or group	**Estimated minimum capacity** in terms of annual EU-wide number of submissions to EURL(s) according to Article 100(2)(a) of Regulation (EU) 2017/746 (**performance verification**)	**Estimated minimum capacity** in terms of annual EU-wide number of submissions to EURL(s) according to Article 100(2)(b) of Regulation (EU) 2017/746 (**batch testing**)
1	**Detection or quantification of markers of hepatitis or retrovirus infection**	**Detection: 75** **Quantification: 29**	**Detection: 2700** **Quantification: 1005**
1.1	Human immunodeficiency virus 1/2	Detection: 30 Quantification: 10	Detection: 800 Quantification: 350
1.2	Hepatitis B virus	Detection: 20 Quantification: 8	Detection: 1000 Quantification: 350
1.3	Hepatitis C virus	Detection: 20 Quantification: 10	Detection: 500 Quantification: 300
1.4	Hepatitis D virus	Detection: 5 Quantification: 1	Detection: 100 Quantification: 5
1.5	Hepatitis E virus	Detection: 1	Detection: 5
1.6	Human T-cell lymphotropic virus I/II	Detection: 8	Detection: 300
2	**Detection or quantification of markers of herpesvirus infection**	**16**	**500**
2.1	Cytomegalovirus	8	250
2.2	Epstein-Barr virus	8	250
3	**Detection or quantification of markers of infection with bacterial agents**	**8**	**200**
3.1	*Treponema pallidum*	8	200
4	**Detection or quantification of markers of arbovirus infection**	**14**	**200**
4.1	West Nile virus	3	50
4.2	Dengue virus	5	50
4.3	Chikungunya virus	3	50
4.4	Zika virus	3	50
5	**Detection or quantification of markers of respiratory virus infection**	**120**	**1600**
5.1	Highly virulent influenza virus	20	100
5.2	Highly virulent coronavirus (SARS, MERS, SARS CoV-2)	100	1500

6	**Detection or quantification of markers of infection with haemorrhagic fever viruses or other biosafety level 4 viruses**	**15**	**65**
6.1	Ebola virus	3	15
6.2	Marburg virus	3	15
6.3	Lassa virus	3	15
6.4	Smallpox virus	3	10
6.5	Crimean-Congo haemorrhagic fever virus	3	10
7	**Detection or quantification of markers of parasite infection**	**15**	**190**
7.1	*Plasmodium* spp.	5	30
7.2	*Trypanosoma cruzi*	5	60
7.3	*Toxoplasma gondii*	5	100
8	**Detection of blood grouping markers**	**78**	**4380**
8.1	ABO system	30	1500
8.2	Rhesus system	30	1000
8.3	Kell system	6	450
8.4	Kidd system	6	100
8.5	Duffy system	6	100

The European Commission will aim to ensure that the collective capacity of the designated EURLs corresponds to the above to a reasonable extent.

For this, the candidate laboratories are requested to estimate their approximate minimum capacity for these two tasks in the selected category(ies). It is not necessary for one laboratory to fully cover the estimated minimum EU-wide capacity. However, it is essential that a candidate has some capacity for all groups within a given category. An illustration of an acceptable and an unacceptable set of capacities is shown below.

Fig.6: Examples on reporting of estimated capacities for performance verification and batch testing.

		Estimated minimum capacity in terms of annual EU-wide number of submissions to EURL(s) according to Article 100(2)(a) of Regulation (EU) 2017/746 (performance verification)	Estimated minimum capacity in terms of annual EU-wide number of submissions to EURL(s) according to Article 100(2)(b) of Regulation (EU) 2017/746 (batch testing)	Candidate laboratory A		Candidate laboratory B	
				Estimated capacity for performance verification	Estimated capacity for batch testing	Estimated capacity for performance verification	Estimated capacity for batch testing
8	Detection of blood grouping markers	78	4380	49	2300	80	4400
8.1	ABO system	30	1500	20	1000	40	2400
8.2	Rhesus system	30	1000	20	1000	40	2000
8.3	Kell system	6	450	3	100	0	0
8.4	Kidd system	6	100	3	100	0	0
8.5	Duffy system	6	100	3	100	0	0

In case the laboratory only partially covers the estimated minimum EU-wide capacity for a category of devices, its designation for the corresponding category may also be conditional on availability of other candidates who fulfil the selection criteria, so that together all the candidates cover the demand for the entire category.

Where several candidate laboratories fulfil all the selection criteria, and whose collective capacity is significantly higher than the estimated minimum EU-wide capacity for performance evaluation and batch testing, then the European Commission will use preference criteria to select the laboratories with the highest scores.

3.3 Selection criteria

To be designated as an EURL, a laboratory needs to fulfil certain criteria. These are laid down in Article 100(4) of Regulation (EU) 2017/746 and are further detailed in Commission Implementing Regulation (EU) 2022/944 on tasks and criteria for EURLs. They include for example availability of adequately qualified staff, equipment, independence and conflict of interest and so on.

The call for applications lists these selection criteria together with the corresponding pieces of evidence that a candidate laboratory must provide. To be designated, a candidate laboratory must satisfy all selection criteria. However, this does not imply that every candidate laboratory satisfying all selection criteria will be designated as EU reference laboratories (see section 3.4).

The candidate laboratory should submit the above evidence to the relevant authority in its Member State (see below for contact details). The Member State will verify the compliance of the laboratory with the selection criteria. It will then submit the compliant applications and supporting documents to the European Commission.

3.4 Preference criteria

The preference criteria relate to the excellence of the laboratory. The European Commission will only use these criteria in case the collective capacity of the candidates is much greater than the estimated minimum EU-wide capacity described in section 3.2. In case of evaluation of the preference criteria, the applications selected will be the ones with the highest score.

Candidates will be notified via their Member State authority if this is the case and will be asked to submit the documentation for the preference criteria by a specified deadline. Therefore, there is no need to submit this with the initial application.

3.5 Accreditation according to EN ISO/IEC 17025

Some requirements of the harmonised standard EN ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories) correspond to some of the selection criteria for EURLs for IVDs. The criteria covered by the standard are listed in Article 8 of the Commission Implementing Regulation (EU) 2022/944 on tasks and criteria of EURLs. Accreditation to this standard may be used to demonstrate conformity with those criteria.

Some laboratories may be accredited to the standard ISO 15189 (Medical laboratories – requirements for quality and competence). This standard is not directly applicable to the activities of the EURLs for IVDs. Accreditation to this standard, while of course permitted, cannot be used to demonstrate conformity with the EURL selection criteria.

3.6 Equipment

EURLs must have the necessary equipment and reference materials to perform their tasks. However, for performance verification and batch testing, the manufacturer of a device may provide to the EURL equipment or reference materials for testing that device free of charge. Moreover, where the

manufacturer specifically develops or prescribes certain equipment or reference materials for use with their device, then the manufacturer is obliged to provide it to the EURL. The manufacturer can either send it or make it available to EURL staff on the manufacturer's premises. The manufacturer must also provide training to EURL staff on any equipment provided, if the EURL considers it necessary.

3.7 Independence and impartiality of EU reference laboratories

The EURLs must act independently and in the public interest. Member States submitting an application for a candidate EURL must sign a declaration that this is the case.

The EURLs must put in place a policy to ensure that their staff do not have financial or other interests in the *in vitro* medical device industry, which could affect their impartiality in performing their tasks. The policy must include steps to prevent, identify and resolve conflicts of interest.

Situations where the manufacturer provides equipment or training to the EURL (see section 3.6) do not constitute a conflict of interest.

The EURLs can continue existing cooperation with notified bodies related to conformity assessment under Directive 98/79/EC. On the other hand, once designated, the EURLs cannot perform any tasks related to conformity assessment on behalf of a notified body under Regulation (EU) 2017/746, other than those assigned to them by Article 100(2) of the Regulation.

4. Practical aspects of the selection process

4.1 Opening of the call for applications

The process of setting up EURLs is launched when the European Commission sends a call for applications to Member States. The call contains the information on which EURLs the Commission intends to designate, information on the criteria and corresponding means of proof, and the practical details such as the application form and templates.

4.2 Application deadlines

The call sent to the Member States will state the recommended deadline for candidate laboratories to submit their application to Member States and the deadline for Member States to submit the applications to the European Commission. Any applications submitted to the European Commission after this deadline will not be considered.

It is recommended that candidate laboratories start preparing their applications and supporting documents in good time. They should submit them by the deadline communicated by the relevant authority in their Member State.

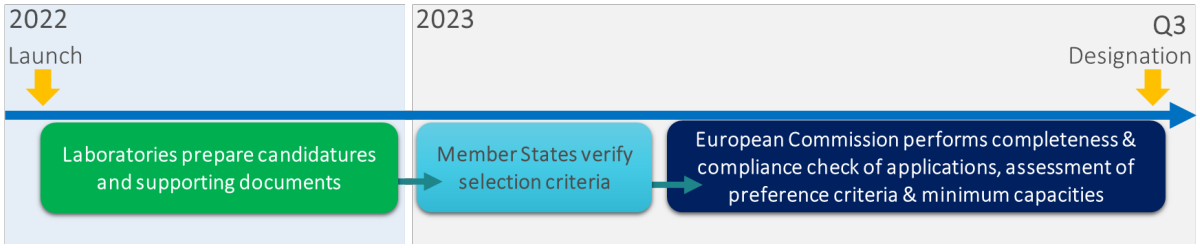
4.3 Steps of the selection process

The selection takes place in two steps. First, the Member States must verify and document that the candidate laboratories in their country comply with the selection criteria.

Following this, the Member States submit the applications to the European Commission. The Commission checks the verification done by the Member States and considers the capacity of the candidate laboratories for performance verification and batch testing. In case there are many

candidate laboratories with a much higher overall capacity than the estimated minimum, the Commission applies the preference criteria.

Fig.7: Steps and indicative timeline of the selection process.



4.4 Designation of EURLs by the European Commission

The European Commission designates the selected laboratories as EURLs by an implementing act. The act will identify the laboratory and mention its scope of designation (section 3.1). The process of adopting the act takes several weeks.

Following the current call for applications, the European Commission will designate the EURLs for a minimum period of five years. That period can be extended if the EURL continues to comply with the criteria. In case an EURL no longer complies with the requirements, the European Commission may suspend, withdraw or restrict its designation.

4.5 Communication between the European Commission, Member States and candidate laboratories

Candidate laboratories must contact their Member States for information. Contact details are provided below. During the selection period, candidate laboratories may not contact the European Commission directly.

In case the European Commission needs to apply preference criteria (see section 3.4), it will contact the relevant Member States with a request to notify their candidate laboratories. Those laboratories will then need to submit the additional supporting documents for the preference criteria within the specified timeline.

The European Commission will inform Member States about the final outcome of the call and Member States will inform applicant laboratories in their countries.

4.6 Preparing your application

Before starting to prepare your application, please contact the relevant authority in your Member State to find out what are the rules and the process for submitting an application in your country.

The call for applications which the European Commission sends to the Member States contains a detailed list of documents to be submitted and templates to be filled in. Candidate laboratories are invited to follow the instructions provided by their Member State and those in the call text and to complete all relevant templates provided as Annexes. All supporting documents should be clearly labelled and numbered.

4.7 Call language

The language of the call is English. Supporting documents should as much as possible be provided in English, except where it would be inappropriate, such as in the case of certificates.

4.8 Modalities for consortia applications

A "consortium" can be understood as two or more entities in one or more Member States working together to perform the EURL tasks for the same category or categories of devices. Individual consortium members may cover some or all of the device groups within the category. The consortium as a whole must cover the entire selected category or categories.

For example, a consortium of two entities could be designated for “Detection of arboviruses”. The division of work between the two entities could be in various configurations, for example one entity dealing with West Nile virus and Dengue virus and the other with Chikungunya and Zika virus, or both entities covering the four groups and offering a greater capacity together. The two entities could be located in one Member State or in two different Member States.

Please note that entities should not apply as a consortium in case they envisage dealing individually with different categories, e.g. one entity for “Detection of arboviruses” and another entity for “Detection of herpesviruses”. In such cases the entities should apply for designation separately.

All entities in a consortium have to meet all selection criteria stipulated in the call for applications. They need to submit the corresponding documentation to their Member State individually, including also an accession letter confirming their participation in the consortium. The Member State will submit a single application to the European Commission together with all the supporting documents from each entity. In case the entities are located in more than one Member State, the application will be submitted jointly by the Member States concerned.

In case a consortium is requested to provide documentation for the preference criteria, it has to submit a single jointly elaborated set of documents.

4.9 Outsourcing

EURLs may have contracts with other laboratories either to increase the capacity of laboratory testing or to obtain access to specific additional equipment or materials (see Article 7 of Commission Implementing Regulation (EU) 2022/944 on tasks and criteria of EURLs).

In cases where the candidate laboratory foresees any of the above, additional supporting documentation needs to be provided as stated in the call.

5. Key resources

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (in particular its Article 100) https://eur-lex.europa.eu/eli/reg/2017/746/oj To read the version with all amendments and corrigenda included, please click on “Current consolidated version”
- Commission Implementing Regulation (EU) 2022/944 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council

as regards the tasks of and criteria for European Union reference laboratories in the field of *in vitro* diagnostic medical devices (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0944&qid=1655713580088

- Commission Implementing Regulation (EU) 2022/945 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and the Council with regard to fees that may be levied by EU reference laboratories in the field of *in vitro* diagnostic medical devices (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0945&qid=1655692831431
- European Commission website on medical devices https://health.ec.europa.eu/medical-devices-sector_en
- European Commission website page on *in vitro* diagnostic medical devices https://health.ec.europa.eu/vitro-diagnostics_en

6. Member State contacts

You can find a list of authorities in EU Member States and other eligible countries responsible for selection of EU reference laboratories and their contact details here under "Contact points for candidate EU reference laboratories".

This list is not yet complete and is periodically updated. If you do not find the contact details of the responsible authority in your country, you can refer to the general list with contact details of authorities responsible for medical devices and IVDs under "Contact points" on the same page.