# Expression of interest open – Possible second call for EU reference laboratories for high-risk *in vitro* diagnostic medical devices

## Background - EURL designation 2023

In July 2022, the European Commission launched a call for the designation of EU reference laboratories in 8 categories of class D devices. Applicant laboratories had six months to prepare and submit applications to their Member State.

The Commission reviewed the applications based on the following elements specified in the call:

- the applicant laboratories must satisfy all the criteria

- the combined capacity of all compliant laboratories in each category must cover the expected volume of requests for tasks related to the conformity assessment of devices.

Following the completion of the selection procedure in December 2023, the European Commission designated 5 EU reference laboratories covering the following categories of class D devices:

- Hepatitis and retroviruses
- Herpesviruses
- Bacterial agents
- Respiratory viruses that cause life-threatening diseases

The following act designates the laboratories:

Commission Implementing Regulation (EU) 2023/2713 designating EU reference laboratories in the field of in vitro diagnostic medical devices.

For the remaining 4 categories, namely arboviruses, haemorrhagic fever and other biosafety level 4 viruses, parasites and blood grouping, at the closing time of the call there were either no applicants that satisfied the criteria or their combined capacity was insufficient to cover the expected volume of requests. Therefore, no EU reference laboratory was designated for these categories of devices following the first call.

## Informal expression of interest for a possible second call for EU reference laboratories

The Commission, after consulting the Member States in the Medical Device Coordination Group, is considering launching a second call to cover the remaining categories of class D devices:

- Arboviruses
- Haemorrhagic fever and other biosafety level 4 viruses
- Parasites
- Blood grouping

**Interested laboratories are invited to informally express interest to their Member State by 30 April 2024.**

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 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.

Should there be significant interest, a formal call will be launched with instructions on how to apply and provide the supporting documents. More information about this will be published on this page.

To be designated as an EURL in the second round, a laboratory would have to fulfil the same criteria as in the first call. 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, the availability of adequately qualified staff and equipment, knowledge of standards and best practices, independence among others.

To provide more time for candidate EURLs to prepare applications and make the necessary organisational arrangements, the second call for laboratories could be open longer than the first call, which was set for 6 months. The requested capacities for performance verification and batch release are not expected to exceed those outlined in the information package for candidate laboratories.

## Background on EU reference laboratories in the field of IVDs

EU reference laboratories in the field of IVDs are designated to perform important tasks outlined in Article 100 of Regulation (EU) 2017/746. EURLs verify the performance of class D devices and compliance with common specifications and they perform batch testing of class D devices in response to requests by notified bodies.

EU reference laboratories form a network to coordinate and harmonise their working methods regarding testing and assessments.

EURLs provide scientific and technical assistance to the European Commission, the MDCG, Member States and notified bodies about implementing Regulation (EU) 2017/746.

EURLs also provide scientific advice regarding the state of the art, and contribute to developing appropriate testing and analysis methods, common specifications and international standards.

The laboratories provide recommendations on suitable reference materials and reference measurement procedures. They collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures.

EURLs also set up and manage a network of national reference laboratories and publish a list of the participating national reference laboratories and their respective tasks.

- More information can be found on the EU reference laboratories (EURLs) page