Annex I

Scopes of designation and estimated minimum EU-wide capacity for tasks in points (a) and (b) of Article 100(2) of Regulation (EU) 2017/746

In 2022, the European Commission launched a first call for the designation of EU reference laboratories in 8 categories of class D devices (see main text of the call for the list of categories). Five laboratories were designed as EU reference laboratories covering four device categories (categories: 1, 2, 3, 5). For the remaining 4 categories (categories 4, 6, 7, 8), there were either no laboratories that satisfied the criteria or their combined capacity was insufficient to cover the expected volume of requests for tasks referred to in Article 100(2)(a) and (b) of Regulation (EU) 2017/746. Therefore, no EU reference laboratory was designated for these categories of devices following the first call.

The current second call for applications will be run in two waves:

1) a first early application wave for the following currently not covered categories of class D devices:
   - detection or quantification of markers of arboviruses (category 4);
   - detection or quantification of markers of parasite infection (category 7);
   - detection of blood grouping markers (category 8);

2) a second wave open for all 8 categories of class D devices.

The tables below list the estimated minimum EU-wide capacities for each device category for the two waves, for the EURL tasks referred to in Article 100(2) (a) and (b) of Regulation (EU) 2017/746.

One or more of the categories 1-8 in these tables can constitute the scope of designation of the EU reference laboratories. Each category includes several groups of devices listed as 1.1, 1.2, 1.3 etc. A laboratory must cover as a minimum all the groups in the category it is designated for, and also any other devices falling in the category (with the exception of category 8, where only the listed groups must be covered).

N.B.: It is possible for a device detecting/quantifying a given marker to fall into different risk classes depending on its intended purpose. For example, a device detecting *Treponema pallidum* can be class D if intended for screening blood donations or class C if intended to diagnose syphilis in the individual. The below devices are in scope of the EURL only if they fall in class D according to Annex VIII of Regulation (EU) 2017/746.

1. Categories and groups for the first application wave

Category n°/ group n°	**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)**
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
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**	**3150**
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

2. Categories and groups for the second application wave

Category n°/ group n°	**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: 84** **Quantification: 29**	**Detection: 2705** **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**	**45**	**220**
5.1	Highly virulent influenza virus	20	100
5.2	Highly virulent coronavirus (SARS, MERS)	25	120
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**	**3150**
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