

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

One or more of the categories 1-8 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.

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	<i>Treponema pallidum</i>	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	<i>Plasmodium</i> spp.	5	30
7.2	<i>Trypanosoma cruzi</i>	5	60
7.3	<i>Toxoplasma gondii</i>	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