Annex IV

Template for estimated minimum capacity of the candidate laboratory for tasks referred to in points (a) and (b) of Article 100(2) of Regulation (EU) 2017/746 (points 3.1 and 3.2 of the selection criteria)

Please indicate the estimated minimum capacity of the candidate laboratory for tasks referred to in points (a) and (b) of Article 100(2) of Regulation (EU) 2017/746 for one or more categories of devices which will constitute the proposed scope of designation.

***For applications submitted for a single laboratory**: Please note that the candidate must cover all the groups within the category. Therefore all the individual group capacities within the selected category or categories must be filled in.*

***For applications submitted for a consortium**: Individual consortium members may cover some or all of the groups within the category. The consortium as a whole must cover the entire selected category or categories.*

No	**Category** or group	Estimated minimum capacity of the candidate laboratory for tasks referred to in point (a) of Article 100(2) of Regulation (EU) 2017/746 (performance verification)	Estimated minimum capacity of the candidate laboratory for tasks referred to in point (b) of Article 100(2) of Regulation (EU) 2017/746 (batch testing)
1	**Detection or quantification of markers of hepatitis or retrovirus infection**		
1.1	Human immunodeficiency virus 1/2	Detection: Quantification:	Detection: Quantification:
1.2	Hepatitis B virus	Detection: Quantification:	Detection: Quantification:
1.3	Hepatitis C virus	Detection: Quantification:	Detection: Quantification:
1.4	Hepatitis D virus	Detection: Quantification:	Detection: Quantification:
1.5	Hepatitis E virus	Detection:	Detection:
1.6	Human T-cell lymphotropic virus I/II	Detection:	Detection:
2	**Detection or quantification of markers of herpesvirus infection**		
2.1	Cytomegalovirus		
2.2	Epstein-Barr virus		
3	**Detection or quantification of markers of infection with bacterial agents**		
3.1	*Treponema pallidum*		
4	**Detection or quantification of markers of arbovirus infection**		

4.1	West Nile virus		
4.2	Dengue virus		
4.3	Chikungunya virus		
4.4	Zika virus		
5	**Detection or quantification of markers of respiratory virus infection**		
5.1	Highly virulent influenza virus		
5.2	Highly virulent coronavirus (SARS, MERS, SARS CoV-2)		
6	**Detection or quantification of markers of infection with haemorrhagic fever viruses or other biosafety level 4 viruses**		
6.1	Ebola virus		
6.2	Marburg virus		
6.3	Lassa virus		
6.4	Smallpox virus		
6.5	Crimean-Congo haemorrhagic fever virus		
7	**Detection or quantification of markers of parasite infection**		
7.1	*Plasmodium* spp.		
7.2	*Trypanosoma cruzi*		
7.3	*Toxoplasma gondii*		
8	**Detection of blood grouping markers**		
8.1	ABO system		
8.2	Rhesus system		
8.3	Kell system		
8.4	Kidd system		
8.5	Duffy system		