**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.*

**Note:** Table 1 refers to the first application wave, while Table 2 refers to the second application wave. Please fill in one of tables as applicable.

**Table 1**: Categories and groups applicable to the **first application wave** and estimated minimum capacity

|  |  |  |  |
| --- | --- | --- | --- |
| **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) |
| **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 |  |  |
| **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 |  |  |

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| **Notes or comments concerning the testing capacity of the candidate laboratory** (e.g. indicate if the testing capacity can potentially be increased in the future, or other considerations on capacity estimates). |

**Table 2**: Categories and groups applicable to the **second application wave** and estimated minimum capacity

|  |  |  |  |
| --- | --- | --- | --- |
| **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) |  |  |
| **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 |  |  |

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| **Notes or comments concerning the testing capacity of the candidate laboratory** (e.g. indicate if the testing capacity can potentially be increased in the future, or other considerations on capacity estimates). |