BIVDA
British In Vitro Diagnostics Association

European Commission
Charlemagne building
Rue de la Loi 170
1040 Brussels
Belgium

British In Vitro Diagnostics Association
299 Oxford St
London
W1C 2DZ

9th March 2022

Dear Sir/Madam,

Thank you for the opportunity to provide feedback on the proposed common specifications for certain class D IVDs in accordance with the IVD regulations (IVDR)(2017/746).

BIVDA represents approximately 200 organisations within the IVD industry including start-up companies, SMEs, UK developers and manufacturers as well as subsidiaries of the global IVD corporations. We also represent some distributors and other economic operators. Our response is therefore submitted on behalf of this membership and reflects the general views of companies within the IVD sector.

Annex I - General

- Requirement 10: Clarification would be appreciated on how this applies to nucleic acid tests. For example, NAT tests for SARS CoV-2 which use nasal/oropharyngeal swabs
- Requirement 13: Clarification would be appreciated on how this applies to IVDs that use nasal/oropharyngeal swabs as this appears to only be relevant for blood and plasma

Annex XI – Devices Intended for Detection of Markers of *Treponema Pallidum* Infection

- Table 1 (Positive specimens): Clarification would be appreciated on the term "different antibodies" and whether this is referring to reagin antibodies and anti-T pallidum antibodies, or other types of anti-T pallidum antibodies
- Table 1 (Hospitalised patients): We believe that this is not the intended use population for a blood donor screening assay, and therefore this is not an applicable study
- Table 1 (Potentially cross-reacting blood-specimens): Samples positive for Borrelia in enzyme immunoassay should also be accepted
- Table 1 (Footnote): Consecutive donations would not be possible for this type of study as there is a requirement to use leftover samples which must be sufficient volume for the planned testing

Annex XIII - Devices Intended for Detection or Quantification of Markers of Severe Acute Respiratory Syndrome Coronavirus 2 Infection

- Table 5 (Potential cross reaction): The list of potential cross reactions in positive samples at various concentrations (>20) could be difficult to meet

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We are grateful to be given the opportunity to comment on such proposed changes, and BIVDA is available to assist in activity and dialogue into any future changes within the landscape for IVDs in the EU. BIVDA remain at the disposal of the European Commission should you require any clarification in relation to our consultation response.

Yours sincerely,

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