# Microbiology Devices Panel of the Medical Devices Advisory Committee

FDA Questions for Panel – September 7, 2023

The reclassification of a device from Class III to Class II is dependent on the extent to which special controls, along with the applicable general controls, are sufficient to provide reasonable assurance of safe and effective use of the diagnostic device. In this context, the Panel is asked to please discuss the following:

## Session 1: HBV Assay Questions

1. Please comment on whether you believe FDA has identified a complete and accurate list of the risks to health presented by the following devices:

   (1) Qualitative HBV Antigen tests,
   (2) Qualitative HBV Antibody tests
   (3) Quantitative Anti-HBs tests, and/or
   (4) Quantitative HBV Molecular tests.

   Please comment on whether you disagree with any of these identified risks or whether you believe any other risk should be included in the overall risk assessment of the devices listed above.

2. Please discuss potential mitigation measure(s)/control(s) that FDA should consider that could mitigate each of the identified risks.

3. Based upon the information presented and future discussion at this panel meeting, please discuss whether, based on the available information, the Panel believes FDA should initiate the reclassification process for these devices from Class III to Class II, subject to special controls.

4. Currently, there are no FDA authorized tests for the detection and quantitation of HBsAg. Please discuss the appropriate intended use for such a device, potential risks associated with that intended use, and whether mitigation measures(s)/special control(s) could be developed that, in addition to general controls, to mitigate the risks to health

## Session 2: Parvovirus Assay Questions

1. Please comment on whether you believe FDA has identified a complete and accurate list of the risks to health presented by Parvovirus antibody assays.

   Please comment on whether you disagree with any of these identified risks or whether you believe any other risk should be included in the overall risk assessment of Parvovirus antibody assays.

2. Please discuss potential mitigation measure(s)/control(s) that FDA should consider that could mitigate each of the identified risks.

3. Based upon the information presented and future discussion at this panel meeting, please discuss whether, based on the available information, the Panel believes FDA should initiate the reclassification process for these devices from Class III to Class II, subject to special controls.

## Session 3: *M. tuberculosis* Assay Questions

1. Please comment on whether you believe FDA has identified a complete and accurate list of the risks to health presented by *M. tuberculosis* assays.

   Please comment on whether you disagree with inclusion of any of these risks or whether you believe any other risk should be included in the overall risk assessment of M. tuberculosis assays.

2. Please discuss potential mitigation measure(s)/control(s) that FDA may should consider that could mitigate each of the identified risks.

3. Based upon the information presented and future discussion at this panel meeting, please discuss whether, based on the available information, the Panel believes FDA should initiate the reclassification process for this device from Class III to Class II, subject to special controls.