FDA CDRH
Microbiology Devices Panel of the
Medical Devices Advisory Committee

September 7-8, 2023
*****Virtual*****

The Committee will discuss and make recommendations regarding a potential future reclassification of certain microbiology devices to inform FDA's thinking regarding whether reclassification from Class III to Class II may be appropriate for the following devices:

- *Qualitative HBV antigen assays, qualitative HBV antibody assays, quantitative assays that detect anti-HBs [antibodies to HBV surface antigen (HBsAg)], quantitative HBV molecular assays, hereafter referred to as HBV assays,*
- *Qualitative parvovirus B19V antibody assays, and*
- *Qualitative Mycobacterium tuberculosis (TB) cell mediated immune reactivity/Interferon Gamma Release Assays (IGRA).*

Specifically, the Committee will consider whether there is sufficient information such that the development of special controls (which along with general controls) could mitigate the risks from some or all of these devices such that the devices would provide a reasonable assurance of safety and effectiveness and therefore, can be eligible for a class II designation.

Day 1 – September 7, 2023

9:00 a.m.	Call to Order	Dr. Barbara J. Van Der Pol Panel Chair
	Conflict of Interest Statement Panel Introductions	**Candace Nalls** Designated Federal Officer
9:15 a.m.	Welcome & Introduction	Timothy Stenzel, M.D., Ph.D. Director, OHT7: Office of In Vitro Diagnostics, CDRH, FDA
9:25 a.m.	Overview of Device Regulation	CDRH OPEQ Regulatory Policy Group

Session One

9:35 a.m.	Hepatitis B Virus Assays (LOM & MKT)[1]:	Maria Ines Garcia, Ph.D. Branch Chief for General Viral and Hepatitis, OHT7, CDRH, FDA
10:05 a.m.	***Open Public Hearing**	
10:35 a.m.	Break	
10:45 a.m.	Panel Questions and Deliberations	Dr. Barbara J. Van Der Pol Panel Chair

Session Two

11:45 a.m.	Background of Parvovirus Assays (MYM & MYL)[2]	Ryan Karsner, M.D. Deputy Branch Chief for General Viral and Hepatitis, OHT7, CDRH, FDA
12:15 p.m.	Lunch	
1:15 p.m.	***Open Public Hearing**	
1:45 p.m.	Panel Questions and Deliberation	Dr. Barbara J. Van Der Pol Panel Chair

Session Three

2:45 p.m.	Background of *Mycobacterium tuberculosis* Assays (NCD & OJN)[3]	Noel Gerard, Ph.D. Branch Chief for Bacterial Respiratory and Medical Countermeasures, OHT7, CDRH, FDA
3:15 p.m.	Break	

[1] Classification product codes help to delineate technology and indication subgroups and consist of a 3-letter combination which associates a device's type with a product classification designation. LOM represents Test, Hepatitis B (B Core, Be Antigen, Be Antibody, B Core Igm) and MKT represents Hepatitis Viral B DNA Detection tests.

[2] MYM represents Assay, Enzyme Linked Immunosorbent, Parvovirus B19 Igm and MYL stands for Assay, Enzyme Linked Immunosorbent, Parvovirus B19 Igg.

[3] NCD represents Test, Immunity, Cell Mediated, Mycobacterium Tuberculosis and OJN represents *Mycobacterium Tuberculosis*, Cell Mediated Immune Response, Enzyme-Linked Immunospot Test

3:30 p.m.	***Open Public Hearing**	
4:00 p.m.	Panel Questions and Deliberation	Dr. Barbara J. Van Der Pol Panel Chair
5:00 p.m.	Panel Summation	Dr. Barbara J. Van Der Pol Panel Chair
5:15 p.m.	Adjourn	Dr. Barbara J. Van Der Pol Panel Chair

Day 2 – September 8, 2023

9:30 a.m.	Call to Order	Dr. Barbara J. Van Der Pol Panel Chair
9:45 a.m.	Conflict of Interest Statement Introduction of the Committee	**Candace Nalls** Designated Federal Officer
9:55 a.m.	FDA Presentation: IVDs Used in Pandemic Preparedness and Response Overview	Timothy Stenzel, M.D., Ph.D. Director, OHT7: Office of In Vitro Diagnostics, CDRH, FDA *and* Kristian Roth, Ph.D. Deputy Director, Division of Microbiology Devices, OHT7, CDRH, FDA
10:15 a.m.	Break	
10:30 a.m.	***Open Public Hearing**	
11:30 a.m.	Panel Questions	Dr. Barbara J. Van Der Pol Panel Chair

12:30 p.m.	Lunch	
1:30 p.m.	Panel Questions and Deliberations	Dr. Barbara J. Van Der Pol Panel Chair
2:30 p.m.	Break	
2:45 pm	Panel Questions and Deliberations (cont.)	Dr. Barbara J. Van Der Pol Panel Chair
3:30 p.m.	Panel Summation	Dr. Barbara J. Van Der Pol Panel Chair
3:45 p.m.	Panel Adjourn	Dr. Barbara J. Van Der Pol Panel Chair

*** Open Public Hearing –** Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.