24 Hour Summary
Microbiology Devices Panel
Advisory Committee Meeting
September 7, 2023

Introduction:

A meeting of the Microbiology Devices Panel ("the Panel") of the Medical Devices Advisory Committee was convened on September 7, 2023, to discuss and make recommendations on the potential future reclassification of certain infectious disease in vitro diagnostic devices.

On September 7, 2023, in Session I, the Panel first discussed and made recommendations regarding a potential future reclassification from class III to class II with special controls of nucleic acid and serology-based in vitro diagnostic devices indicated for use to aid in diagnosis of hepatitis B virus (HBV) infection and/or for use to aid in the management of HBV infected patients. The Committee, during session II, discussed and made recommendations regarding a potential future reclassification from class III to class II with special controls of serology-based in vitro diagnostic devices indicated for use to aid in the detection of past, recent, or current infection with human parvovirus B19. The Committee, during session III, discussed and made recommendations regarding a potential future reclassification from class III to class II with special controls of cell-mediated immune reactivity in vitro diagnostic devices indicated for use to aid in identification of in vitro responses to peptide antigens that are associated with *Mycobacterium tuberculosis* infection and/or for use as detection of effector T cells that respond to stimulation by *M. tuberculosis* agents.

Panel Deliberations/FDA Questions:

Session I

The Panel generally believes FDA has identified a complete and accurate list of the risks to health presented by Qualitative HBV Antigen tests, Qualitative HBV Antibody tests, Quantitative Anti-HBs tests, and/or Quantitative HBV Molecular tests.

The Panel agreed with the FDA-identified risks and identified additional risk(s) and benefit(s) to include in the overall risk assessment of Qualitative HBV Antigen tests,

Qualitative HBV Antibody tests, Quantitative Anti-HBs tests, and/or Quantitative HBV Molecular tests:

- Testing performed as point of care test; commonly observed risks associated with test performance include environmental and test administration factors
- False results could lead to unnecessary vaccination or lack of needed vaccination
- Benefit to individuals with limited access to care; may reduce the chance of developing serious disease due to easily accessible and faster care

The panel discussed potential mitigation measure(s)/control(s) FDA should consider for each of the identified risks in a potential future reclassification. The Panel recommended:

- The special controls should include information in the package insert clearly stating HBsAg testing may receive positive result 1-2 weeks after receiving vaccination
- The special controls should include requiring labeling language in the intended use "aid in diagnosis", indicating the results should be interpreted in the context of other tests and in conjunction with the patient's clinical presentation, as each of the HBV serology and antigen tests are not stand-alone tests
- The special controls should include labeling language regarding potential lower specificity and sensitivity of the point-of-care or over the counter test and should therefore be followed by confirmatory testing
- May need to consider different classifications based on the type of HBV test

The Panel unanimously believes that based upon the available information, the FDA **should** initiate the reclassification process for Qualitative HBV Antigen tests, Qualitative HBV Antibody tests, Quantitative Anti-HBs tests, and/or Quantitative HBV Molecular tests from Class III to Class II, subject to special controls.

The Panel discussed the intended use for tests for the detection and quantitation of HBsAg. The Panel discussed the potential risks associated with the tests intended for the detection and quantitation of HBsAg and the Panel determined that at this time there is not sufficient information available to help develop mitigating measure(s)/special control(s) for tests for the detection and quantitation of HBsAg.

Session II

The Panel generally believes FDA has identified a complete and accurate list of the risks to health presented by Parvovirus antibody assays.

The Panel agreed with the FDA-identified risks.

The panel discussed potential mitigation measure(s)/control(s) FDA should consider for each of the identified risks. The Panel recommended:

- The special controls and regulation should clearly state the intended use and intended use population for parvovirus serology and molecular tests to mitigate risks

associated with misuse of the test/use of the test in individuals in whom testing is not indicated.
- The special controls should include requiring labeling mitigations to mitigate the risks associated with misuse of the tests and misinterpretation of test results. Specifically, the panel recommended a limitation be required in labeling urging clinicians to exercise caution while interpreting results in immunocompromised individuals or individuals who have received IVIG.
- Special controls should include explicitly the clinical sensitivity and specificity acceptance criteria for Parvovirus tests, particularly for IgM due to the risks associated with false IgM results when used in the diagnosis of acute infection in pregnant individuals.

The Panel unanimously believes that based upon the available information, FDA **should** initiate the reclassification process for this device from Class III to Class II, subject to special controls.

Session III

The Panel generally believes FDA has identified a complete and accurate list of the risks to health presented by *M. tuberculosis* assays.

The Panel agreed with the FDA-identified risks and/but identified additional risk(s) to include in the overall risk assessment of *M. tuberculosis* assays.

- Including, for false positive test results, the risk of delayed treatment for the true cause of disease

The panel discussed potential mitigation measure(s)/control(s) FDA should consider for each of the identified risks. The Panel recommended:

- Labeling should better describe indeterminate results and the risk of misinterpretation of indeterminate results
- Labeling should identify the need for follow-up testing
- Labeling should clarify how risks differ depending on the population being tested and the pre-test probability of disease
- New device submissions should be held to the same level of clinical and analytical validation with the same performance criteria as currently approved tests. This should include adequate validation of the pre-analytical stages of specimen preparation that have the potential to impact the performance of these tests.

The Panel unanimously believes that based upon the available information, FDA **should** initiate the reclassification process for this device from Class III to Class II, subject to special controls.

Open Public Hearing (OPH)

In the morning OPH session, the Panel heard presentations from clinicians and other stakeholders. Dr. Yasmin Ibrahim, speaking on behalf of the Hepatitis B Foundation, Dr. Su Wang, from the RWJBarnabas-Rutgers Medical Group, Dr. Diana Zuckerman presenting on behalf of the National Center for Health Research, and Dr. Michael Gish of Robert G. Gish Consultants, LLC.

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Transcripts:

Transcripts may be downloaded from:
September 7-8, 2023: Microbiology Devices Panel of the Medical Devices Advisory Committee Meeting Announcement - 09/07/2023 | FDA

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