DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**
Food and Drug Administration
Center for Devices and Radiological Health

Microbiology Devices Panel Meeting – November 9, 2016

Introduction:

The Microbiology Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on November 9, 2016 to discuss and make recommendations regarding the reclassification of quantitative Cytomegalovirus (CMV) viral load devices from class III (Premarket approval) to class II (510(k)). During the second session, the committee met to discuss and make recommendations regarding appropriate initial classification for viral load devices for Epstein-Barr virus and BK virus.

FDA Question: CMV:

Do committee members believe that special controls, in addition to general controls, are necessary and sufficient to mitigate the risks to health presented by quantitative CMV viral load assays?

- In addressing this question, please discuss the proposed special controls and any additional special controls that would be recommended if reclassification could be considered for quantitative CMV viral load assays

Panel Deliberations

1) All panelists agreed and recommended down classification of CMV viral load assays to Class II, with the development of carefully crafted special controls.
    a. Device Labeling: it was suggested that wording would be developed towards the clinical expertise needed to interpret the test results and specimen type used. Panelists and FDA agreed on developing wording to mitigate risks, incorporate guidance, and crafting universal language for interpretation of results. It was also advised that labeling recommend repeat testing if unexpected results were obtained.
    b. Standardization: although the panelists encouraged further development of standards, using current standards was highly encouraged.
    c. Manufacturing information (GMP procedures): it was suggested that FDA specify limited aspects of manufacturing information needed to ensure safety and effectiveness to be included in 510(k) submissions as special controls.
    d. Clinical performance studies: the committee advised that specimens should include both cross-sectional samples at different viral loads to confirm the accuracy of quantitation as well as sequential patient specimens to confirm utility of the test for confirming response to therapy.

e. Post market surveillance: the committee discussed special controls to include periodic assessment of tests by manufacturers to assess drift from standards as well as studies to confirm performance when new standards are updated.

FDA Question: EBV and BKV

1. Do the risks and information known regarding EBV and BK infection in the transplant patient warrant Class III status for either
2. Regardless of your response, what unique considerations exist regarding EBV and BK virus that must be addressed during FDA premarket review and/or as special controls

Panel Deliberations

1) EBV brings much more scientific and clinical uncertainty compared to BK and CMV, and is not likely to support class II (*de novo)* classification were a submission to be filed.
2) There was support for *de novo* status or possible Expedited Access approval as a PMA for a submission for BK virus. The clinical importance of the latter analyte in the kidney transplant setting was emphasized.

Public Speakers

The following groups were represented by speakers during the Open Public Hearing: Hologic, Inc., the Infectious Diseases Society of America (IDSA), and Abbott Diagnostics.

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