Discussion and Recommendations for the Classification of Quantitative Viral Load Assays for Transplant-associated Opportunistic Viral Infections

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Microbiology Devices Panel Meeting

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Welcome!

Thank you for your public service!!

FDA's Mission:

- **Protect public health**
- **Promote public health**

FDA is also responsible for advancing the public health by facilitating to speed innovation that make devices more effective, safer, and more affordable and by helping the public to get the accurate, science-base information they need to use devices to maintain and improve their health.

Meeting Goals:

- Open discussion of the reclassification of quantitative CMV viral load devices, currently regulated as Class III devices, into Class II

- Obtain recommendations regarding the appropriate initial classification of quantitative viral load devices for EBV and BKV infection

- To discuss the benefits and risks of quantitative viral load assays to support and guide the development of special controls for analytes suggested to be eligible for a Class II designation

Agenda

Reclassification of quantitative CMV viral load devices from Class III to Class II

- Background of CMV regulatory path and Intended Uses (S. Gitterman, FDA)
- Clinical aspects of viral load testing for CMV (A. Limaye, Uni. of Washington)
- Technical issues with CMV viral load testing and standards (L. Cook, Uni. of Washington
- FDA perspective on CMV viral load assay reclassification (K. Whitaker, FDA)
- Open Public Hearing/Panel Deliberation/Questions to Panel

Benefit/Risk Discussion of EBV and BK Viruses in Transplant Patients

- Introduction and Background (S. Gitterman, FDA)
- Clinical aspects of EBV quantitative viral load testing and BK testing in transplant patients (A. Limaye, Uni. of Washington)
- Measurement of EBV Viral load in the laboratory (L. Cook, Uni. of Washington
- Open Public Hearing/Panel Deliberation/Questions to Panel


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