



January 24, 2022

Myrna Hanna  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
Silver Spring, MD 20993-0002

**RE: Docket No. FDA-2020-N-2297, Microbiology Devices; Reclassification of Human Immunodeficiency Virus Viral Load Monitoring Tests.**

On behalf of the Association of Public Health Laboratories (APHL), please accept the following comments concerning docket no. FDA-2020-N-2297 for Microbiology Devices. APHL strongly supports the proposed reclassification of HIV Viral Load Monitoring Tests from Class III devices to Class II devices with appropriate special controls to provide reasonable assurance of the safety and efficacy of the assays. APHL supports the proposed order of reclassification of these devices from Class III to Class II to achieve urgently needed improved accessibility to the latest HIV testing technology in the US to improve laboratory efficiency, patient management and public health surveillance and is excited to see the proposed rule for HIV Viral Load Tests following its omission in the previous proposed rules. This reclassification, by decreasing the regulatory burden, could motivate manufacturers to bring new tests to market and/or adapt existing tests for either new specimen types, such as dried blood spots and plasma separation cards, or new specimen collection options including at-home collection.

APHL commends CBER for this new proposed rule which along with the previous proposed reclassification (2019-N-5192) would harmonize the classification of all HIV in vitro diagnostic devices and viral load monitoring tests (for professional use), including all serological and all nucleic acid tests except those intended for blood/donor screening, as Class II devices with appropriate controls. Imparting a standardized regulatory pathway (510k) for these test methods, will maintain their safety and effectiveness while balancing public health goals. This proposed reclassification, along with the previous proposals would decrease barriers for manufacturers to obtain claims on the same method for both diagnosis and monitoring. Additionally, this proposed rule would rectify the orphaning of HIV viral load monitoring tests as Class III devices while all other HIV nucleic acid-based tests are proposed to be reclassified as Class II devices (with special controls).

We would recommend that the special controls proposed for nucleic acid tests for HIV diagnosis are aligned to the extent possible with those for HIV viral load monitoring to reduce barriers to obtaining approval for both intended use claims on the same device/method.

In summary, the goal of proposed reclassification should be to improve critical access to quality HIV tests. In order to ensure that the reclassification meets these needs, FDA should strongly consider reviewing the special controls for HIV methods to align with the requirements for HCV nucleic acid tests in the final reclassification order nucleic acid tests (2020-N-1088). If these additional considerations are incorporated, this could greatly improve patient diagnosis, laboratory efficiency, patient management and public health surveillance, bringing our national goals of HIV elimination within closer reach. Given the disproportionate impact of these diseases on disadvantaged populations and the goals of the ongoing HHS "[Ending the HIV Epidemic](#)" initiative, the urgency of action is amplified.



APHL hopes that the reclassification can be addressed as expeditiously as possible. Please send any updates or questions to Anne Gaynor, (240.485.2739, [anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org)).

Sincerely,

A handwritten signature in blue ink, appearing to read "MRowlinson".

Marie-Claire Rowlinson  
Chair, Infectious Disease Committee  
Association of Public Health Laboratories

A handwritten signature in black ink, appearing to read "Scott J. Becker".

Scott J. Becker, MS  
Chief Executive Officer  
Association of Public Health Laboratories

*APHL works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.*