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# FACING THE CHALLENGE OF DEVELOPING ULTRA-SENSITIVE MOLECULAR ASSAYS FOR HIV VACCINE AND CURE-RELATED RESEARCH

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**C**urrent internationally-approved HIV viral load assays detect down to 20 copies of HIV RNA in plasma samples but are not suitable for detecting ultra-low DNA and RNA within host cellular compartments. Even when it is undetectable by commercial assays, HIV persists within patient plasma, CD4 T cells and other cellular compartments. International human subject research regulations now stipulate that all research subjects who test positive for HIV must be placed on highly active anti-retroviral treatment (HAART) immediately. This makes the continued monitoring of their HIV infection more challenging. As we continue to bank and study these samples, there will be an increasing need for assays that can reliably detect ultra-low quantities of HIV DNA or RNA from limited amounts of archival serum, plasma or cellular material. There will be an increasing need for lower cost assays for monitoring ultra-low viral levels of the virus, in resource-limited settings, where such studies are being conducted. Ultra-sensitive laboratory developed PCR-based assays (LDAs) will thus play an increasingly critical role in human subject-based HIV research and vaccine efforts. This presentation outlines the presenters experience in developing ultra-sensitive HIV molecular assays. The presenter provides an overview of the field in general, including current approaches in the study and elimination of the HIV viral reservoir. The presenter discusses current challenges and provides an opportunity for the audience on approaches that may be used to address these issues.

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