Exploring the implementation of a new type of HIV molecular testing

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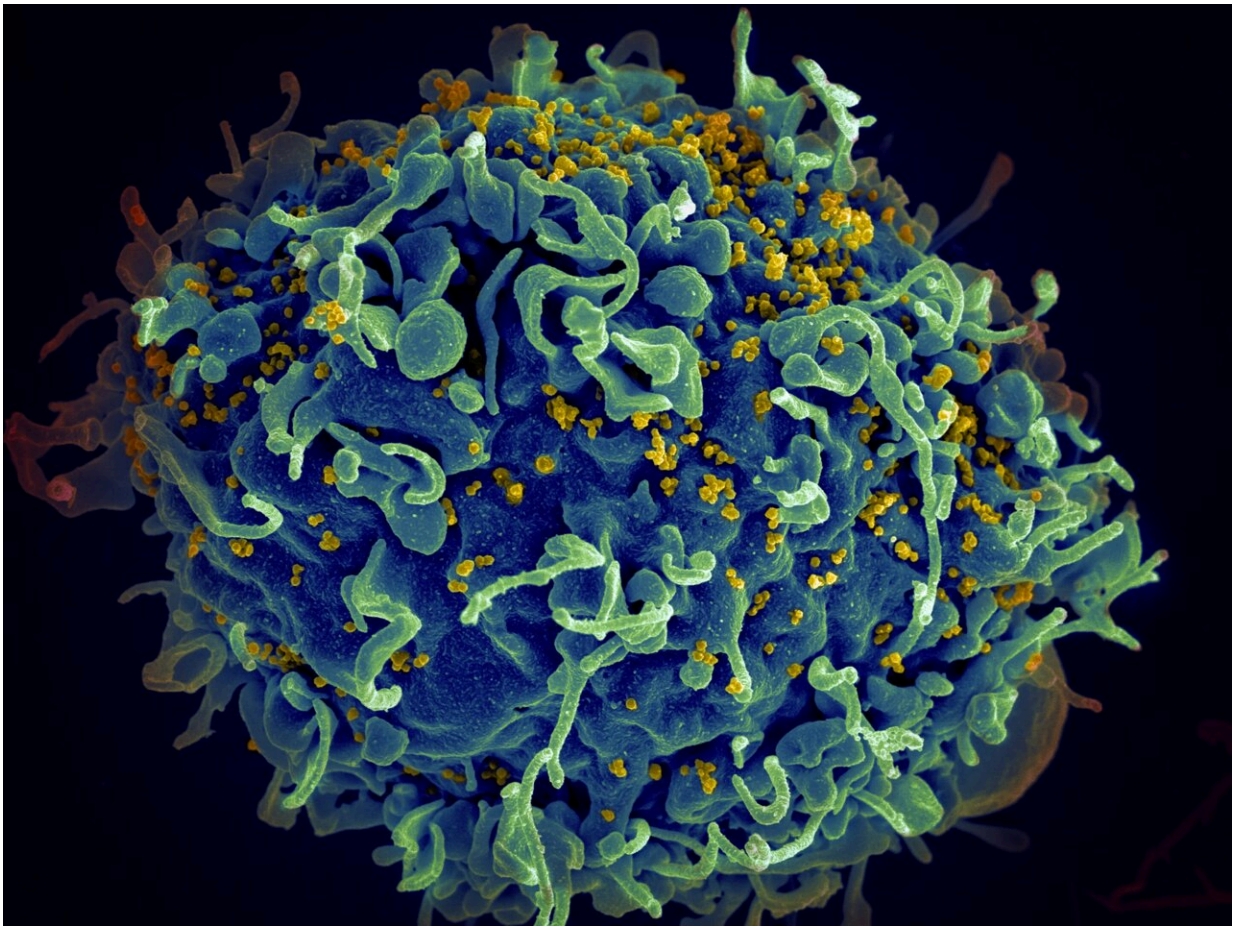

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Boston Medical Center has been using a new HIV molecular test as part

of a series of tests used to diagnose and confirm HIV infection from a patient's blood. Published in the *American Journal of Clinical Pathology*, the study summarizes the results of a production monitor for the first 3 months post-implementation.

BMC recently implemented a new HIV-1/HIV-2 Qualitative RNA PCR (HIV RNA QUAL) cleared by the US Food and Drug Administration to (1) replace antibody discrimination follow-up testing after a reactive fourth-generation (4G) serology screen and (2) use as a stand-alone diagnostic for suspected seronegative acute HIV infection.

The monitor characterized test utilization, diagnostic turnaround time, impact on send-out testing, results reflexed to HIV RNA discrimination follow-up, and discrepancies between screening and HIV RNA results that called for additional investigation. The 4G screening components and the HIV RNA QUAL were also used to create an algorithm specific to and compliant with current guidelines for screening patients on HIV preexposure prophylaxis (PrEP).

Researchers highlight that the test may help detect new HIV infection and allows doctors to follow current guidelines for testing patients beginning or currently taking HIV prevention medication. Test options for HIV-1 infection are included in the current CDC HIV diagnostic algorithms, but since HIV-2 remains uncommon in the US, follow up molecular tests in the current algorithm are opt-in choices.

"The CDC and public health officials advocate that everyone should know their HIV status. Getting tested for HIV and seeking appropriate care if needed as quickly as possible are vital to positive outcomes, so making the process easier and more accessible is a priority," said senior author Nancy S. Miller MD, Chief and Vice Chair for Laboratory Medicine and Medical Director of Clinical Microbiology and Molecular Diagnostics at Boston Medical Center and Clinical Professor of

Pathology and Laboratory Medicine at Boston University Chobanian & Avedisian School of Medicine.

Currently, there is no single test that provides all the recommended results necessary for diagnosing an HIV infection, a series of tests is needed to accurately detect and confirm infection.

"Laboratories face many different challenges when implementing a new test, so it's crucial we share information to learn from each other's experiences," said co-author Marisa Nielsen, Ph.D., Assistant Director for Clinical Microbiology at Boston Medical Center and an assistant professor for Pathology and Laboratory Medicine at Boston University Chobanian & Avedisian School of Medicine.

"This study identified several anticipated and unanticipated test gaps, successful efforts, and opportunities for process improvement, which others may find helpful when establishing testing in their own institutions."

HIV test data was collected for the first three months of the new testing implementation from October 2021 to January 2022 with a follow up in August 2022. Study eligibility include BMC patients for who had HIV diagnostic testing performed and the results were reported under a BMC medical record number.

Overall, the implementation of a new HIV diagnostic algorithm using HIV RNA QUAL was supported by clinical colleagues and was well accepted at BMC. The performance of the Cobas HIV-1/HIV-2 Qualitative RNA PCR assay has been evaluated in the context of HIV type differentiation and confirmation. However, evaluations of workflow and implementation are needed.

This analysis highlighted the importance of checkpoints and production

audits when initiating complex test changes such as this one. Despite being a single-site effort limited to a short period of time, this study can constructively inform other institutions seeking to revise their HIV diagnostic algorithm.

More information: Isabela Medeiros et al, Implementation of an HIV RNA Qualitative PCR Assay in an HIV Diagnostic Algorithm: A Single-Institution Experience, *American Journal of Clinical Pathology* (2023). DOI: 10.1093/ajcp/aqad002

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