

NIH Announces Awards to Advance Tech for HIV Viral Load Detection

More accurate viral load detection could help people living with HIV assess treatment efficacy and prevent transmission to others.

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The National Institutes of Health has awarded more than \$4 million in funds and support services to three diagnostic technology developers as part of the [Rapid Acceleration of Diagnostics \(RADx\) Tech](#)'s Advanced Platforms for HIV Viral Load Monitoring program. Launched in the spring of 2024 by the National Institute of Biomedical Imaging and Bioengineering (NIBIB), in collaboration with the NIH Office of AIDS Research (OAR) and the National Institute of Allergy and Infectious Diseases (NIAID), the program is aimed at advancing HIV viral load detection technologies for use at the point of care.

About 39 million people around the world live with HIV, including approximately 1.2 million adults, adolescents, and children in the United States. HIV is a virus that attacks a person's immune system by affecting cells that are essential for fighting infections. Viral load is a measure of how much virus is in the bloodstream.

NIH-supported research has shown that when the virus is undetectable in the bloodstream in people with HIV no sexual transmission occurs — a concept known as Undetectable = Untransmittable (U=U). U=U is a game changer because it enables people with HIV and their partners to be in a relationship without fear of transmitting HIV.

People with HIV can maintain an undetectable viral load by taking an HIV medicine called antiretroviral therapy, or ART, exactly as prescribed. However, antiretroviral therapy does not cure HIV. HIV is still in the body when viral load is suppressed, even when it is undetectable. Under some circumstances, HIV viral load may increase to detectable levels, leading to the potential for viral transmission.

"For those with HIV, easy access to viral load monitoring empowers them to protect their health and helps prevent viral transmission," said Bruce J. Tromberg, PhD, NIBIB Director and leader of the RADx Tech program. "NIH support is aimed at making rapid progress in point-of-care HIV viral load detection technologies so that this information is readily available on demand for all who want it."

The RADx Tech Advanced Platforms for HIV Viral Load Monitoring program solicitation attracted 29 applications. After initial rounds of assessment, eight projects advanced to a feasibility stage. Expert support teams worked with the companies to further assess their technologies and readiness for viral load detection at the point of care.

Today's announcement marks the advancement of three projects to receive individual contract awards and begin milestone-driven activities during the coming year. Each technology will be honed under the guidance of a national network of expert technical, clinical, commercialization, and regulatory advisors assembled by the RADx Tech program. These experts will provide individualized assistance for projects towards the prospect of regulatory authorization and deployment, including third-party analytical and pre-clinical confirmation of device performance.

"There is a desire of people with HIV to take control of viral load management, both individually and in partnership with their caregivers," said Shawn Mulvaney, PhD, RADx Tech program director. "Having monitoring technologies for the domestic point-of-care diagnostics market would be a major step in that direction."

Under the award, companies can receive more than \$1 million in funds and support services based on achievement of project milestones. Details of the awarded technologies are below.

Cepheid, Sunnyvale, California

Cepheid is developing a point-of-care technology to quantitatively detect the levels of HIV-1, the most common type of this virus, from a person's blood plasma sample, generating a result in under 90 minutes. In their diagnostic approach, blood plasma is separated from a sample of whole blood in a healthcare setting. The plasma is transferred to a cartridge for efficient handling throughout the diagnostic process workflow. Cepheid draws upon its expertise with fluidics, blood filtration and plastic injection molding in the design and manufacture of their diagnostic technology.

Baebies, Inc., Durham, North Carolina

Baebies is implementing a clinical diagnostics technology, known as [reverse transcription polymerase chain reaction](#), or RT-PCR, which amplifies and detects specific viral gene sequences, for blood samples that is performed on a blood sample within a self-contained disposable cartridge. Inside, the sample and reagents are subjected to electrical impulses that coordinate movements of sub-microliter droplets without any user intervention. This allows for liquid handling steps needed to support sample preparation, assay set-up, and completion. The diagnostic system is being optimized for HIV assay sensitivity, blood processing techniques, and viral load quantification capabilities.

Prompt Diagnostics, Baltimore

Prompt Diagnostics is developing a magnetofluidic cartridge platform that facilitates automated infectious disease testing in the clinic. Purification, amplification, and detection of nucleic acids from blood samples is enabled by a compact instrument that makes results available in less than

30 minutes. Point-of-care HIV viral load testing of a person's blood sample can be achieved with minimal sample handling steps. The company developed a process for manual separation of blood plasma from fingerstick volumes of whole blood without the need for complex equipment, followed by quantification of HIV RNA from the extracted blood plasma using magnetofluidic cartridges.

Read more about the [Advanced Platforms for HIV Viral Load Monitoring at the Point of Care](#).

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