Advanced viral diagnostics tool closer to widespread use

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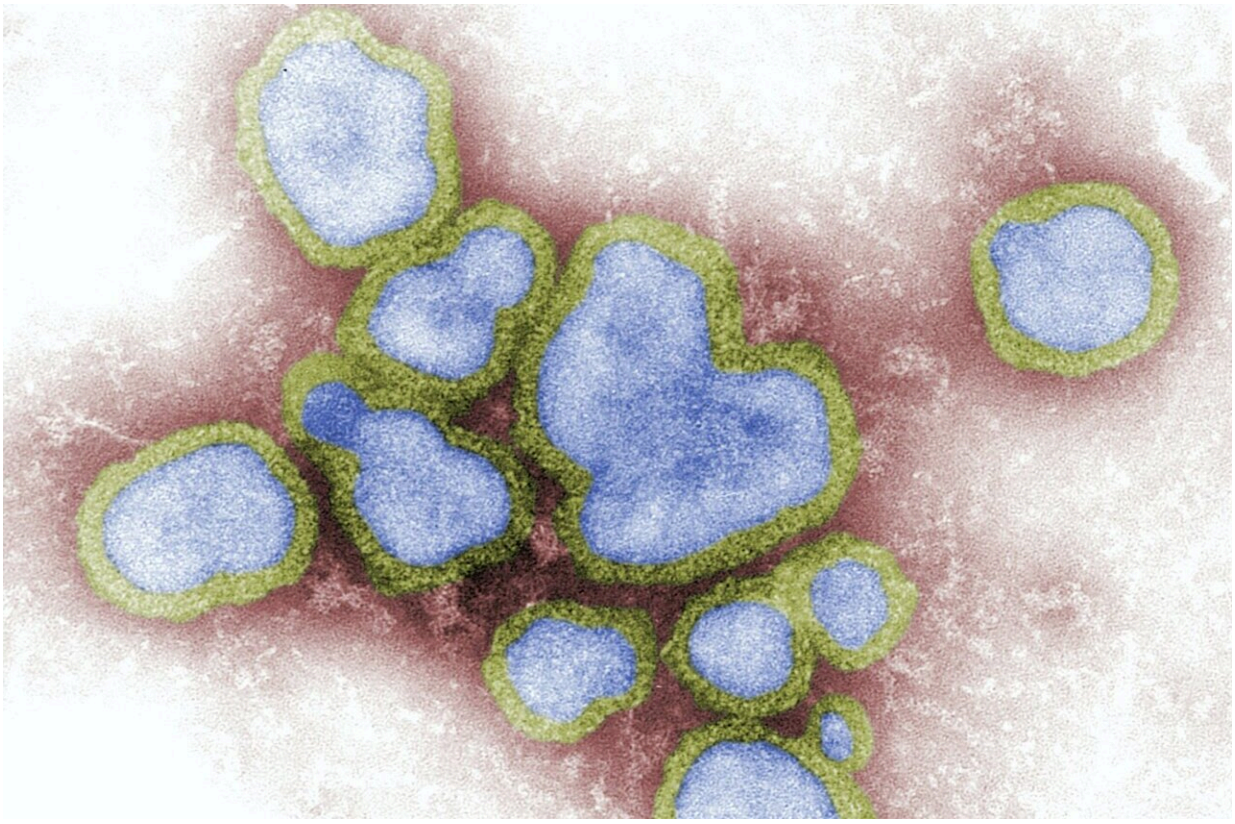

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Most of today's clinical diagnostic tools are designed to detect the presence of a specific and known pathogen. These targeted assays—like the PCR and antigen tests that have become widely used during the

COVID-19 pandemic—meet a critical need for diagnostics. Yet targeted diagnostic tests are reactive by design and typically are not available until after an outbreak has begun.

Next-generation sequencing (NGS) offers broad-range detection of pathogens but is not as sensitive as targeted assays. To bridge this gap, in 2015, scientists at the Center for Infection and Immunity (CII) at Columbia University Mailman School of Public Health introduced a powerful NGS-based screening and surveillance system called VirCapSeq-VERT which can detect any virus that can potentially infect humans, known or unknown, with greater sensitivity and speed than other NGS platforms.

A validation of the latest version of VirCapSeq appears in the *Journal of Clinical Microbiology*.

Since it was first introduced, VirCapSeq has been used in studies worldwide to investigate outbreaks of acute and chronic diseases and for surveillance in humans, domestic animals, and wildlife. Last year, the CII partnered with the Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response to speed its development as a viral diagnostic platform to help bolster U.S. preparedness for future outbreaks and potentially enable other opportunities for infectious disease diagnostics.

In 2022, New York State granted approval for VirCapSeq to be used in detecting nucleic acids of both DNA and RNA viruses in plasma, followed by nasal swabs in 2023 for the diagnosis of systemic and respiratory tract infections. The CII researchers anticipate the technology's regular use by hospitals in the near future.

The newly published validation study was conducted as part of the CII's

New York State regulatory application. This work involved assessing VirCapSec's ability to detect viruses at low levels (limit of detection), testing how consistent and repeatable the results are, determining its capability to identify different viruses in mixed infections, and evaluating its accuracy and precision in real clinical scenarios.

VirCapSeq-VERT achieved clinical sensitivity of 99 percent and 100 percent clinical specificity. Additionally, it identified co-infections with clinically relevant viruses that were not reported by the gold standard comparator assays used for the initial diagnostic testing.

"VirCapSeq is the only sequencing technology with regulatory approvals that has the broad range coverage of unbiased high throughput sequencing with significantly greater sensitivity in the detection and identification of all vertebrate viruses, including new and emerging species," says Vishal Kapoor, MS, deputy director for laboratory medicine at the CII.

"This technology can help identify novel viral threats early on in a public health emergency with the potential to contain outbreaks and prevent pandemics."

"Our technology is poised to transform precision medicine, giving caregivers the ability to quickly pinpoint the cause of an infection so as to guide treatment," says W. Ian Lipkin, MD, John Snow Professor of Epidemiology and the CII director. "At the same time, this diagnostic tool will be a boon for public health by providing information on viruses circulating in a community."

More information: Vishal Kapoor et al, Validation of the VirCapSeq-VERT system for differential diagnosis, detection, and surveillance of viral infections, *Journal of Clinical Microbiology* (2023). DOI: 10.1128/jcm.00612-23