New SARS-CoV-2 test is a simple, cost-effective, and efficient alternative for SARS-CoV-2 testing

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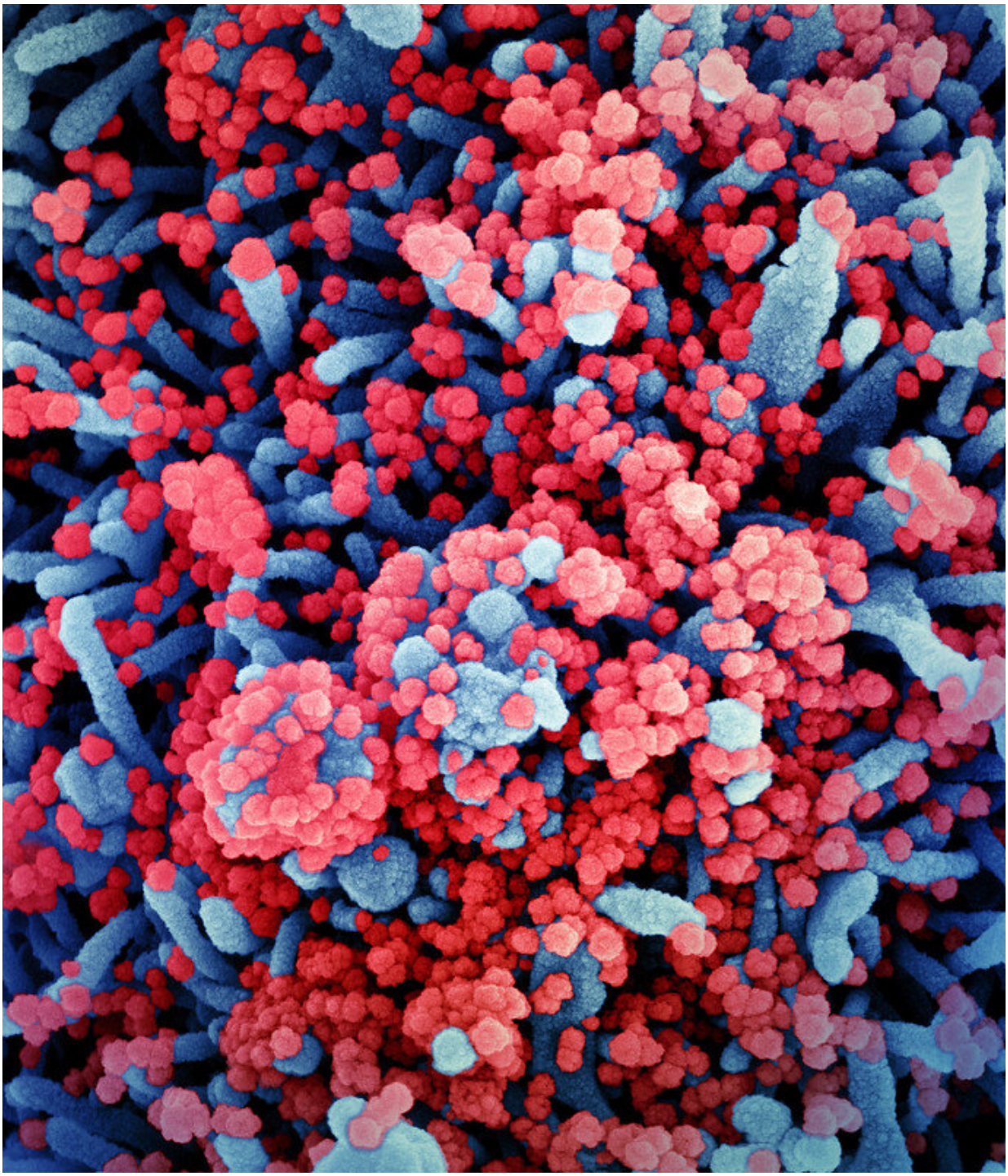

Colorized scanning electron micrograph of a cell (blue) heavily infected with SARS-CoV-2 virus particles (red), isolated from a patient sample. Image captured at the NIAID Integrated Research Facility (IRF) in Fort Detrick, Maryland. Credit: NIAID

Scientists from Northwell Health Laboratories have developed a new diagnostic multiplex assay that can be used for epidemiological surveillance and clinical management of COVID-19. The Northwell Health Laboratories laboratory-developed test (NWHL LDT) uses a different set of reagents than current assays and can test 91 patients at a time for SARS-CoV-2, versus a maximum of 29 patients using the modified Centers for Disease Control and Prevention (CDC) assay. The NWHL LDT performs as well as the modified CDC test with comparable analytical specificity and accuracy, report scientists in *The Journal of Molecular Diagnostics*.

"The COVID-19 pandemic has led to many constraints on testing availability, so we hope that providing another testing option to detect SARS-CoV-2 with a clinically-validated set of reagents will assist in this effort at a time when supply chain has been a major issue," explained lead investigator Gregory J. Berry, Ph.D., D(ABMM), Infectious Disease Diagnostics, Northwell Health Laboratories, Lake Success, NY, USA; and Department of Pathology and Laboratory Medicine, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY, USA.

Nucleic Acid Amplification Test (NAAT)-based assays for detection of SARS-CoV-2 in respiratory specimens have been the standard diagnostic method. The CDC initially developed the most-widely used NAAT assay , which includes primers and probes to detect the N1 and N2 regions of the nucleocapsid gene, a protein that plays a key role in virus enhancement, and also the human RNAse P gene to monitor RNA extraction and ensure specimen quality.

Dr. Berry and Wei Zhen, Ph.D., also based at Infectious Disease Diagnostics, Northwell Health Laboratories, developed the one-step real-

time qualitative RT-PCR NWHL LDT test using the 7500 Fast Dx real-time PCR instrument. The NWHL LDT assay targets the S gene of SARS-CoV-2 and uses the same primers and probes for assay internal control as the modified CDC assay test.

A limit of detection (LOD) study of the NWHL LDT with inactivated virus exhibited equal performance with the modified CDC assay, with a final LOD of 1,301 ±13 genome equivalents for the NWHL LDT compared to 1,249 ± for the modified CDC assay. A clinical evaluation with 270 nasopharyngeal swab specimens from individuals suspected of having COVID-19 exhibited 98.5 percent positive agreement and 99.3 percent negative agreement compared to the modified CDC assay.

The NWHL NDT also showed significant efficiencies over the CDC assay, since the test requires only one set of primer and probe mix per specimen, compared to three sets and the use of three wells for each patient in the modified CDC assay. This further contributes to the ease of setting up each run. Savings in hands-on time, reagents, and consumables are another advantage at a time in which there are global shortages of reagents. This assay can be easily implemented by other laboratories for diagnostic use.

The authors observed that the NWHL LDT is a single site evaluation with a single target gene, while there has been a trend toward dual-target design in commercial assays for detection of the highly contagious SARS-CoV2 pathogen. "Occasional monitoring to verify that mutations have not developed in the region targeted by the NWHL LDT primers and probe is an adequate quality monitor to ensure continued consistent analytical performance," commented. Dr. Zhen.

More information: Wei Zhen et al, Development of a New Multiplex Real-Time RT-PCR Assay for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Detection, *The Journal of Molecular*

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