SIEMENS Healthineers

Press

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Siemens Healthineers SARS-CoV-2 Testing Portfolio Detects Omicron Variant

- **The Siemens Healthineers SARS-CoV-2 testing portfolio is well designed to detect the Omicron variant. The portfolio includes:**
- **CLINITEST® Rapid COVID-19 Antigen Test**
- **FTD SARS-CoV-2 Assay, a PCR test**
- **Lab-based Atellica and ADVIA Centaur SARS-CoV-2 Antigen Assay (CoV2Ag)**

Siemens Healthineers has announced that the company's SARS-CoV-2 tests are well designed to detect the Omicron SARS-CoV-2 variant. The company recently evaluated the potential impact of the emergent variant on the CLINITEST Rapid COVID-19 Antigen Test,[1] the FTD SARS-CoV-2 Assay,[2] a PCR test, and the Atellica IM / ADVIA Centaur SARS-CoV-2 Antigen Assay (CoV2Ag)[3]. On November 26, 2021, both the WHO and ECDC designated the Omicron variant as a variant of concern.[4,5] Mutations are normal, abundant, and expected, especially with an RNA virus, and the SARS-CoV-2 is no different. As countries struggle to combat emerging variants, fast and accurate testing is an important tool in containing spread.

To assess the potential impact to the CLINITEST rapid test and the Atellica/ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) Assay, the Siemens Healthineers R&D team analyzed the sequence data of the Omicron variant nucleocapsid protein. This analysis demonstrated >98% sequence homology of the nucleocapsid protein to other SARS-CoV-2 variants.[6] Meaning, it is unlikely that the Omicron variant would affect the results.

CLINITEST Rapid COVID-19 Antigen Test

The CLINITEST Rapid COVID-19 Antigen Self-Test has a sensitivity of 97.25 percent and a specificity of 100 percent (compared to a PCR, or nucleic acid-detection method) and

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provides results in 15 minutes.[7] The simple process for collecting a nasal swab and obtaining a result are included in the Instructions for Use. A nasal swab is collected from both nostrils and then the swab is washed in a buffer to reveal a specific protein inside the SARS-CoV-2 virus. The sample is then dispensed onto the test cassette and after 15 minutes the result is visible. The position and number of lines clearly indicate whether the test is positive or negative.

Atellica/ADVIA Centaur SARS-CoV-2 Antigen (CoV2Ag) Assay

The Siemens Healthineers' CoV2Ag test shows strong alignment compared with on the market available automated real-time (RT)-PCR testing with sensitivity exceeding 96% and specificity exceeding 99% for the Atellica CoV2Ag test[8]. While molecular RT-PCR diagnostic testing is the gold standard in accuracy, it lacks the high throughput capability of a lab-based, automated antigen test. With availability of CoV2Ag on the Atellica IM Analyzer, laboratories can significantly increase the SARS-CoV-2 testing capacity with a platform that can run up to 440 tests per hour.

FTD SARS-CoV-2 Assay

Siemens Healthineers has also confirmed, based on *in silico* analysis, that the FTD SARS-CoV-2 Assay, a PCR-based test, detects the Omicron variant.[9] Dual target design makes it possible to detect two different genomic regions of SARS-CoV-2. One benefit of this is a higher sensitivity because it is possible to detect two different genomic regions on the same detection channel, but most important right now, is that it helps to cope with mutations.

Siemens Healthineers offers an evolving menu of single mutation PCR reflex tests that complement our FTD SARS-CoV-2 Assay to identify SARS-CoV-2 variants. Our relationship with A1 Life Sciences allows us to offer research use only tests (RUO)[10] that enable laboratories to efficiently detect mutations to discriminate between circulating variants, including Omicron.

"As a leader in laboratory diagnostics, Siemens Healthineers is committed to monitoring all current and emerging variants of concern to ensure the test results remain accurate and reliable," said Deepak Nath, PhD, President Laboratory Diagnostics, Siemens Healthineers. "Accurate diagnostic tools are a critical factor in allowing public health authorities to combat the spread of virus and protect the health of their populations."

[1] Not available for sale in the U.S. Product availability varies by country. Distributed by Siemens Healthineers.

[2] This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21. U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. Product availability may vary from country to country and is subject to varying regulatory requirements.

[3] Not available for sale in the U.S. Product availability varies by country.

[4] WHO. Tracking SARS-CoV-2 variants. Available from: https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/.

[5] ECDC. SARS-CoV-2 variants of concern as of 26 November 2021. Available from: https://www.ecdc.europa.eu/en/covid-19/variants-concern.

[6] National Center for Biotechnology Information. Available from: www.ncbi.nlm.nih.gov.

[7] Manufacturer's clinical performance study.

[8] Based on PCR results obtained from symptomatic and asymptomatic patients. Percent positive agreement with PCR Ct<30 samples (relative sensitivity) was 96.49% and 98.90%, and percent negative agreement with PCR negative samples (relative specificity) was 99.64% and 100%, for nasopharyngeal swabs and anterior nasal swabs, respectively. Atellica IM CoV2Ag Instructions for Use, 11208085_EN Rev. 04, 2021-09.

[9] Siemens Healthineers internal study. In silico sequence analysis of the nucleocapsid protein from Omicron variant. 2021 November.

[10] For Research Use Only. Not for use in diagnostic procedures.

This press release is available at https://www.siemens-healthineers.com/press/releases/omicron-variant.

For further information on emergent SARS-CoV-2 variants, please see https://www.siemens-healthineers.com/molecular-diagnostics/molecular-diagnostics-in-vitro-diagnostics/ftd-sars-cov-2-assay/variants.

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