

SARS-CoV-2 antibody test from Siemens Healthineers evaluated against other leading antibody assays in Public Health England study

- **New SARS-CoV-2 total antibody tests are appraised by Public Health England (PHE), in partnership with the University of Oxford, in a new head-to-head evaluation of four commercial tests.**
- **The laboratory-based COV2T antibody test from Siemens Healthineers was the only assay found to meet both sensitivity and specificity requirements as set out in the MHRA's TPP for enzyme immunoassays.**
- **The test identifies antibodies to a spike protein on the surface of the SARS-CoV-2 virus, also a focus of many vaccine studies.**

Public Health England, in partnership with the University of Oxford, recently conducted a head-to-head evaluation of four commercial immunoassay tests available in the UK and used for the detection of SARS-CoV-2 antibodies. Siemens Healthineers' laboratory-based total antibody test¹ distinguished itself as the only assay tested found to meet both the sensitivity and specificity requirements set out within the Target Product Profile (TPP) for immunoassays by the UK Medicines and Healthcare products Regulatory Agency (MHRA). The test is broadly available globally.

The [evaluation](#) was commissioned by the Department of Health and Social Care (DHSC) and conducted by Public Health England, the clinical research team at the University of Oxford and Oxford University Hospitals NHS Foundation Trust. Several commercial antibody tests were appraised over a three-week period in May - June 2020, with a view to assessing respective performance metrics on precision, using a large, well-characterised sample set. Primary data included evaluation of the assays' sensitivity and specificity, each of which is key to assessing the overall clinical performance of a test.

The SARS-CoV-2 total antibody test from Siemens Healthineers is CE marked and has FDA Emergency Use Authorization. The test detects the presence of both IgM and IgG antibodies in blood. This allows for the identification of patients who have developed an adaptive immune response, indicating prior exposure to COVID-19. Critically, the test identifies antibodies to a key protein on the surface of the SARS-CoV-2 virus – a spike protein, which binds the virus to human cells. Multiple potential vaccines in development for SARS-CoV-2 include the spike protein within their focus, raising the possibility that the Siemens Healthineers total antibody test could support the determination of the effectiveness of these vaccines in the future.

“High-quality antibody tests will be critical to successfully reopening economies across the globe. From the start, our mission has been to develop highly accurate tests for SARS-CoV-2 and now we have an external appraisal that confirms our test offers exceptional quality,” said Deepak Nath, PhD, President of Laboratory Diagnostics at Siemens Healthineers.

“Laboratories worldwide can be confident that our assay delivers the sensitivity and specificity we promised.”

The role of Public Health England

Public Health England is an executive agency of the Department of Health and Social Care and is not a regulator. PHE evaluations confirm that the Siemens Healthineers SARS-CoV-2 total antibody test meets the Target Product Profile.² The Siemens Healthineers SARS-CoV-2 total antibody test has received the CE mark before PHE testing. The CE mark confirms that the test meets EU regulatory standards and could already be lawfully placed on the market in the UK and other Member States. Siemens Healthineers announced on June 1 that it has received FDA Emergency Use Authorization in the United States.

¹ 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 detecting the presence of antibodies against 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 authorisation 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 authorisation is terminated or revoked sooner. Product availability may vary from country to country and is subject to varying regulatory requirements.

² Information from GOV.UK, 25/06/2020. Available at: <https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work-for-industry-and-manufactures-covid-19-tests-and-testing-kits>

This press release and a press picture is available at <https://www.siemens-healthineers.com/press-room/press-releases/covid-19-antibody-phe.html>.

For further information please see <https://www.siemens-healthineers.com/press-room/press-features/pf-covid-19.html>.

Contact for journalists

Thorsten Opderbeck

Phone:+49 0173 6178107; E-mail: Thorsten.opderbeck@siemens-healthineers.com

Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of Healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostic, image-guided therapy, and in-vivo diagnostics. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care to patients. In fiscal 2019, which ended on September 30, 2019, Siemens Healthineers, which has approximately 52,000 employees worldwide, generated revenue of €14.5 billion and adjusted profit of €2.5 billion.

Further information is available at www.siemens-healthineers.com.