

New study identifies top-performing point-of-care COVID-19 tests

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After screening more than 1,100 independently assessed, point-of-care COVID-19 tests, researchers at NSF International and Novateur Ventures have identified 5 direct (antigen/RNA) tests for detection of

acute infection and 6 indirect (antibody) tests for detection of prior infection that meet the recently published World Health Organization (WHO) "desirable" Target Product Profile (TPP) criteria. The researchers hope their work will help communities and healthcare systems make more informed decisions when choosing rapid, point-of-care COVID-19 tests.

TPPs outline the desired characteristics of a product aimed at a specific disease. The WHO TPPs can be used to compare key features of COVID-19 tests and select products that best respond to the public health needs of each region.

"As communities around the world consider expanding existing COVID-19 testing strategies to include large-scale, rapid point-of-care tests, it's essential for them to understand which tests work best in different situations," said study co-author Robyn Meurant, Executive Director of Health Sciences at NSF International. "Our previous research found significant variability in performance and features of commercially available point-of-care tests, which makes it difficult to select and procure an appropriate test for a specific use case."

The study, COVID-19 Point-of-Care Diagnostics That Satisfy Global Target Product Profiles, appears in the January 2021 issue of the journal *Diagnostics*, an international peer-reviewed, open-access journal published monthly by the Multidisciplinary Publishing Institute (MDPI).

"The COVID-19 pandemic will continue to pose a major public health threat until vaccination mediated herd immunity is achieved," said study co-author Ali Ardakani, Founder & Managing Director at Novateur Ventures. "Most projections predict vaccines will reach a large subset of the population in late 2021 or early 2022. Until then, there will continue to be a need for fast and accurate COVID-19 testing."

The researchers screened more than 300 COVID-19 [diagnostic tests](#) that have obtained U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA), and more than 850 tests—listed on the Switzerland-based Foundation for Innovative New Diagnostics (FIND) database. From those tests, they analyzed two types of COVID-19 point-of-care (POC) tests: direct (antigen/RNA) tests to detect acute infection and indirect (antibody) tests to detect past infection.

Top Performing COVID-19 POC Tests

According to the study, the following COVID-19 POCTs met the WHO TPP "desirable" criteria for clinical sensitivity/specificity, limit of detection, and time to results:

Direct (Antigen/RNA) POC Tests:

- DetectaChem MobileDetect Bio BCC19 Test (RT-LAMP)
- Mammoth Biosciences SARS-CoV-2 Detectr Test (RT-LAMP/CRISPR)
- Quidel Sofia-2 Flu+SARS Antigen Test
- Seasun Biomaterials AQ?TOP Plus COVID-19 Rapid Test (RT-LAMP)
- Shenzhen Bioeasy Biotechnology Bioeasy Diagnostic Kit COVID-19 Antigen Test

Indirect (Antibody) POC Tests:

- Guangzhou Wondfo Biotech Wondfo SARS-CoV-2 Ab Test 1
- Hangzhou Biotest Biotech RightSign COVID-19 IgG/IgM Rapid Test
- Hangzhou AllTest Biotech AllTest COVID-19 IgG/IgM Rapid Test 1

- NG Biotech NG IgG/IgM Rapid Test
- Sugentech SGTi-flex COVID-19 IgG
- VivaChek Biotech COVID-19 IgM/IgG Rapid Test

"A few weeks has passed since we conducted our research in December 2020, so it is likely that additional tests have undergone independent assessment and can meet the WHO criteria now," Robyn Meurant said. "The most important takeaway from this study is that purchasers of point-of-care COVID tests should do their research and make sure they are selecting a [test](#) that meets the WHO TPP criteria for their specific use case."

More information: Abdi Ghaffari et al, COVID-19 Point-of-Care Diagnostics That Satisfy Global Target Product Profiles, *Diagnostics* (2021). [DOI: 10.3390/diagnostics11010115](https://doi.org/10.3390/diagnostics11010115)

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