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Qiagen launches digital test for rapid detection of COVID-19

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Access Anti-SARS-CoV-2 is an easy-to-use 10-minute test on a portable device that provides highly accurate results on Total Ig antibodies (IgA, IgM, IgG)

QIAGEN N.V. has announced the U.S. launch of the new Access Anti-SARS-CoV-2 Total test, an easy-to-use digital test done on a portable device that provides results in about 10 minutes to detect antibodies in people exposed to the SARS-CoV-2 virus, which is the case of COVID-19.

The launch of this antibody test, which was developed in partnership with the Australian digital diagnostics company Ellume, comes after the submission by QIAGEN of this unique antibody test to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA). First shipments are planned for late August 2020. A CE-IVD marking for Europe and other markets is planned in the coming weeks.

The new serological test has been shown to have sensitivity of 100% (CI 88.43–100.00%) and specificity of 100% (CI 95.20–100.00%).

The test is performed on the eHub, a small portable digital device that provides reliable results in 10 minutes. Each eHub can handle up to eight patient samples simultaneously and can perform up to 32 total tests per hour. The nanoparticle fluorescent detection technology uses serum or plasma from patient samples. The same platform is being used for QuantiFERON-TB Access, a new solution in development for diagnosis of latent tuberculosis (TB) infection in low-resource regions with a high TB disease burden.