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FDA Issues Emergency Use Authorizations for QDx Pathology, Biocan Diagnostics Coronavirus Tests

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NEW YORK — The US Food and Drug Administration on Tuesday granted separate Emergency Use Authorizations for SARS-CoV-2 tests developed by QDx Pathology Services and Biocan Diagnostics.

The QDx SARS-CoV-2 Assay is a RT-PCR-based assay designed to detect the N gene of the virus in nasal swab specimens self-collected using the Cranford, New Jersey-based medical lab's Qdetect home collection kit or other authorized home collection kits. It is performed using ChromaCode's HDPCR SARS-CoV-2 assay, which received EUA from the FDA in June, and may only be performed in QDx's CLIA-certified lab.

Biocan's Tell Me Fast Novel Coronavirus IgG/IgM Antibody Test is an immunochromatography-based lateral flow assay designed to detect immunoglobulin G and M antibodies against SARS-CoV-2 in serum, plasma, and venous whole blood samples. Results are provided within 15 minutes, according to the British Columbia, Canada-based company.

The test may be used by any lab CLIA-certified to perform moderate- or high-complexity tests.

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