Applied BioCode

Applied BioCode SARS-CoV-2 Test Detects Omicron and Other COVID Variants

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Applied BioCode announced today that its SARS-CoV-2 test can detect the recently emerged Omicron variant of the coronavirus that causes COVID-19. This variant was initially identified in South Africa and subsequently detected in several other countries around the world.

Applied BioCode routinely monitors developments on variants and detection of those by BioCode® SARS-CoV-2 assay. The Company has analyzed the publicly available sequences of the SARS-CoV-2 Omicron variant (B.1.1.529) and compared them to the design of our assay in order to assess potential implication of these mutations. Based on this investigation, the BioCode® SARS-CoV-2 assay is not impacted by mutations in the new variant.

"Scientists believe that SARS-CoV-2 will continue to evolve. This is the natural path for viruses," said Dr. Winston Ho, President of the Applied BioCode. He added, "We designed our SARS-CoV-2 assay with this in mind, and as a result, we are confident that the Omicron variant will not impact the performance of our assay."

Applied BioCode will continue to monitor sequences for the Omicron and other variants of concern to confirm assay performance.

About Applied BioCode

Applied BioCode is an IVD manufacturer that designs, develops, and commercializes multiplex testing products. The company has combined "digital barcodes" with immuno- and molecular chemistry to create a new, bio-inspired Barcoded Magnetic Beads (BMB) technology. The micro BMBs, about the diameter of a human hair, are tagged with immunochemistry or molecular probes, allowing the digital barcodes to be easily scanned and accurately identified up to 4,096 barcodes with no ambiguity for biological targets. The company has FDA 510K clearances for their Respiratory 17-plex Pathogen Panel (RPP) and Gastrointestinal 17-plex Pathogen Panel (GPP) based on their BioCode® MDx-3000 automated system. The GPP and RPP are CE-Marked for use in European countries conforming to CE-Mark regulations. Applied BioCode, Inc. has also been granted an Emergency Use Authorization (EUA) from the U.S. FDA for its BioCode® SARS-CoV-2 Assay*, and an additional EUA for Pooled COVID-19 Testing*. Applied BioCode also partners with a variety of diagnostic companies with applications that include the infectious disease, autoimmune disease, allergy, gut microbiome, and veterinary markets.

* 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. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.

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