PHASE SCIENTIFIC

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Omicron Variant Update

Phase Scientific continuously monitors emerging variants of the virus that causes COVID-19 and how their mutations may impact the performance of the INDICAID® COVID-19 Rapid Antigen Test. A sub-variant of Omicron designated BA.2 (B.1.1.529.2) was detected in the U.S. in January 2022, and the CDC recently estimated that BA.2 represents more than 50% of all new COVID-19 infections in the U.S.

An independent evaluation by the National Institutes of Health (NIH) RADx Variant Task Force has determined that the INDICAID® COVID-19 Rapid Antigen Test detects the Omicron variant B.1.1.529 and Omicron sub-variant BA.2 (B.1.1.529.2) in live clinical samples.

Furthermore, Phase Scientific has performed in-house analytical testing for the detection of Omicron nucleocapsid (N) protein. A limiting dilution study of recombinant N protein derived from Omicron sub-variants BA.1 (B.1.1.529.1) and BA.2 (B.1.1.529.2) demonstrated that the INDICAID® test achieves a similar level of detection for both Omicron N protein sub-variants compared to the N protein derived from the original strain of SARS-CoV-2.

Taken together, both our in-house analytical testing and the independent evaluation by the RADx Variant Task Force suggest that the mutations identified in the Omicron variant are unlikely to impact INDICAID® test performance.

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