PHASE SCIENTIFIC

Omicron Variant Update 24 May 2022

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.

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

Phase Scientific has also performed in-house analytical testing for the detection of Omicron nucleocapsid (N) protein. A limiting dilution study of recombinant N protein from 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 that of the original strain of SARS-CoV-2.

The recent emergence of the BA.2.12.1, BA.3, and BA.5 are not expected to have an impact on the INDICAID® test's performance as these sub-lineages share the same N protein sequence as BA.2.

Taken together, our in-house testing and the independent evaluation by the RADx VTF suggest that the N protein mutations of the Omicron sub-variants B.1.1.529, BA.1, BA.2, BA.2.12.1, BA.3 and BA.5 are unlikely to impact INDICAID® test performance.

A summary of the expected impact of the various Omicron sub-lineages on the INDICAID® test performance is presented in the table below.

Omicron Sub-lineage	Expected Impact on INDICAID Performance	Method of Evaluation
B.1.1.529	No impact	Independent evaluation by NIH RADx
BA.1 (B.1.1.529.1)	No impact	In-house wet-testing with recombinant N protein
BA.2 (B.1.1.529.2)	No impact	Independent evaluation by NIH RADx
BA.2.12.1	No impact	In-house wet-testing with recombinant N protein
BA.3	No impact	In-house wet-testing with recombinant N protein
BA.4	98.1 % sequence homology	In-house wet-testing on-going
BA.5	No impact	In-house wet-testing with recombinant N protein

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