PHASE SCIENTIFIC

Omicron Variant Update   April 07, 2023

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-variants BA.2 (B.1.1.529.2) and BQ.1.1 in live clinical samples.

Phase Scientific has also performed in-house analytical testing for the detection of Omicron sub-variant nucleocapsid (N) protein. Limiting dilution studies of recombinant N protein from the Omicron sub-variants listed in the table below demonstrated that the INDICAID® test achieves a similar level of detection compared to that of the original strain of SARS-CoV-2.

Taken together, our in-house testing and the independent evaluation by the RADx VTF suggest that the N protein mutations of currently circulating Omicron sub-variants, including the recently identified XBB.1.5, XBB.1.16, BQ.1 and BQ.1.1, 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	No impact	In-house wet-testing with recombinant N protein
BA.5	No impact	In-house wet-testing with recombinant N protein
BQ.1	No impact	In-house wet-testing with recombinant N protein
BQ.1.1	No impact	Independent evaluation by NIH RADx
XBB.1.5	No impact	In-house wet-testing with recombinant N protein
XBB.1.16	No impact	In-house wet-testing with recombinant N protein

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