PHASE SCIENTIFIC

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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 assessment of the recently designated variant of concern, Omicron (B.l.l.529), protein sequence, based on internal in silica analysis, suggests that the protein mutations do not affect the immunoreactive sites of the detection reagents contained in the INDICAID test.

Furthermore, Phase Scientific has performed preliminary analytical testing to evaluate INDICAID's ability to detect Omicron recombinant N protein. A limiting dilution study of Omicron N protein (ACROBiosystems, cat# NUN-C52Ht) in negative clinical matrix was prepared and used with the INDICAID test to determine the limit of detection (LoD). This LoD was compared to that of the original SARS-CoV-2 recombinant N protein, and the results demonstrate that INDICAID achieves a similar level of detection for both N protein variants.

Taken together, our internal in silico analysis and in-house analytical testing suggest that the mutations identified in the Omicron variant are unlikely to impact INDICAID test performance.

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