EVALUATION OF THE SEEGENE ALLPLEX™ SARS COV-2 VARIANTS I ASSAY IN THE IDENTIFICATION OF SARS COV-2 OMICRON VARIANTS

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Background: From January 2022, Omicron (B.1.1.529) has been the predominant SARS-CoV-2 variant in Australia. Treatment with Sotrovimab is thought to be less efficacious at neutralising BA.2 sub-lineage of Omicron. The SeeGene Allplex™ SARS CoV-2 Variants I Assay detects gene mutations E484K, N501Y and hv69/70 deletion, which correspond to different lineages. Rapid classification of variants may help guide therapy and improve patient outcomes.

This study evaluated the SeeGene Allplex™ SARS-CoV-2 Variants I assay for the identification of SARS CoV-2 Omicron variants at ACT Pathology, Canberra Hospital.

Methods: Previously SARS-CoV-2 detected and whole genome sequenced (WGS) throat/nose specimens (5 Delta and 76 Omicron (31 BA.1; 13 BA.1.1; and 32 BA.2)), including 10 specimens in duplicate, were tested using the Allplex™ SARS CoV-2 Variants I according to manufacturer's instructions.

Gene detection was verified manually, following automated interpretation, based on analysis of the amplification curves independently by the author and a senior molecular scientist without the knowledge of the WGS results.

Results: RdRp gene cycle thresholds for all specimens ranged from 14 to 36, indicative of a broad range of viral concentrations. 76 specimens had the N501Y gene mutation detected, consistent with an Omicron variant (BA.1 or BA.2). Automated and manual interpretations were concordant.

The hv69/70 deletion, present only in Omicron BA.1 variant, was interpreted as detected by automated analysis in all of the BA.1, and 30 of the BA.2 variants. Manual analysis demonstrated complete agreement with the WGS result.

The E484K mutation was not seen in any Omicron variants. All gene mutations were absent in the Delta variants.

Conclusion: Careful manual analysis of Allplex™ SARS CoV-2 variants I assay results allowed differentiation between Delta variant and Omicron variants BA.1 and BA.2. While rapid differentiation between these variants is possible, WGS remains critical in monitoring for circulating variants of concern and identifying new variants.

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