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Technical Memo

June 27, 2021

Detection of emerging SARS-CoV-2 variants using Visby Medical COVID-19 tests

The Visby COVID-19 point of care products' coverage is not compromised by any reported World Health Organization (WHO) SARS-CoV-2 Variants of Concern (VOC). Visby follows the FDA policy[1] regarding monitoring SARS-CoV-2 sequences that may impact the Visby COVID-19 test performance. We conduct periodic analyses of newly submitted sequences for potential impact on our N gene-based test. As of 6-27-2021 we have screened over 553,753 SARS-CoV-2 sequences submitted to the GISAID database[2] since the release of the Visby Medical COVID-19 Point of Care test. These analyses include sequence submissions from all common spike gene variants in circulation in the US, including the WHO designated Variants of Concern. Thus, far this periodic process has not identified variants of the N gene that would affect the accuracy of our device.

WHO Variants of Concern
Alpha (B.1.1.7)
Beta (B.1.351)
Gamma (P.1)
Delta (B.1.617.2)

References:

1) FDA Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests

2) The GISAID Initiative, which promotes the rapid sharing of data from all influenza viruses and the coronavirus causing COVID-19: https://www.gisaid.org/