visby medical

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Technical Memo

November 29, 2021

Detection of emerging SARS-CoV-2 variants using the Visby Medical COVID-19 test and the Visby Medical COVID-19 Point of Care Test.

Visby Medical follows the FDA policy[1] regarding monitoring SARS-CoV-2 sequences to evaluate the potential impact to Visby Medical COVID-19 test performance. Visby conducts periodic analyses of newly submitted sequences for potential impact on our N gene-based test. As of November 29, 2021, over 1,589,403 SARS-CoV-2 sequences submitted from the United States to the GISAID database[2] have been evaluated using *in silico* methods. This analysis includes the WHO designated Variants of Concern (VOC). To date, *in silico* assessments predict that the Visby tests will detect all of WHO designated VOC, including the recently identified Omicron variant (B.1.1.529).

Current WHO Variants of Concern
Alpha (B.1.17)
Beta (B.1.351)
Delta (B.1.617.2)
Omicron (B.1.1.529)

Customers with questions or concerns may reach out to support@visby.com or 1-833-GoVisby (1-833-468-4729).

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/