

July 29, 2021

Subject: Detection of SARS-CoV-2 Variants on the Accula™ Point of Care Platform

Dear Valued Customer,

Mesa Biotech, part of Thermo Fisher Scientific, is committed to providing our customers with gold-standard molecular detection of SARS-CoV-2 virus on the Accula rapid PCR platform. The Accula SARS-CoV-2 Test was designed to tolerate genetic variation in the virus without significant impact to clinical performance. Mesa works closely with governmental partners, including the NIH Rapid Acceleration of Diagnostics (RADxSM) initiative, to ensure our assay meets the highest quality standards. We are pleased to report that as part of our collaboration with RADx, successful detection of Variants of Concern (VOC)/Interest (VOI) clinical samples was recently demonstrated on the Accula platform. Variants detected are listed in the table below.

VARIANT NAME Pango lineage (WHO label)	CDC CLASSIFICATION*	WHO DESIGNATION**
B.1.1.7 (alpha)	VOC	VOC
B.1.351 (beta)	VOC	VOC
P.1 (gamma)	VOC	VOC
B.1.617.2 (delta)	VOC	VOC
B.1.525 (eta)	VOI	VOI
B.1.427 (epsilon)	VOI	Alert for further monitoring
B.1.429 (epsilon)	VOI	Alert for further monitoring

* <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html>** <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/>

The successful detection of VOC/I remnant clinical sample aligns with the internal analysis conducted by Mesa Biotech in our ongoing evaluation of SARS-CoV-2 mutations, indicating that test performance is not affected by currently known SARS-CoV-2 variants. If you have further questions or concerns regarding genetic variations and the Accula performance, please feel free to reach out at meghan.norvell@thermofisher.com.

Sincerely,



Meghan Norvell, Ph.D., Director of Scientific Affairs
Mesa Biotech, Part of Thermo Fisher Scientific