Thermo Fisher Scientific
Rapid Diagnostics Solutions
6190 Cornerstone Court East Suite 220
San Diego, CA 92121
(858) 800-4929
thermofisher.com

October 26, 2022

Subject: Impact of SARS-CoV-2 Omicron variants on the performance of the Thermo Fisher Scientific™ Accula™ SARS-CoV-2 Test

To Whom It May Concern:

Mesa Biotech, part of Thermo Fisher Scientific, conducts routine surveillance of global SARS-CoV-2 sequences to determine the presence of mutations and the impact on the performance of the Accula SARS-CoV-2 Test.[1,2] The Omicron variant (including B.1.1.529, BA.1, BA.1.1, BA.2, BA.2.10, BA.2.12, BA.2.75, BA.2.75.2, BA.3, BA.4, BA.4.6, BA.5, BF.7, BQ.1, BQ.1.1, and XBB lineages) has caused public health concern due to the large number of mutations in the Spike gene. The Accula test targets a separate part of the genome, the Nucleocapsid (N) gene. Based on sequences published in GISAID database, the Omicron variant contains an ancestral GGG (28881) AAC mutation in the region of the N gene targeted by the Accula test. This mutation has been circulating in SARS-CoV-2 sequences since January 2020 and has been demonstrated to have no impact on the performance of the Accula SARS-CoV-2 Test.[3]

Thermo Fisher Scientific is committed to providing our customers with high-quality molecular detection of the SARS-CoV-2 virus on the Accula rapid RT-PCR platform. The Accula SARS-CoV-2 Test was designed to tolerate genetic variation in the virus without impact to test performance. For additional information regarding genetic variations and the Accula performance, please contact techsupport@thermofisher.com.

Sincerely,

Colleen Knoth, Ph.D.

Manager, Scientific Affairs

---

[1] PRECAUTIONS: This test has not been FDA cleared or approved but has been authorized for emergency use by FDA for use by authorized laboratories; This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

[2] LIMITATIONS: The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

[3] Totten, A. H. et al. Detection of SARS-CoV-2 variants by Mesa Accula. J. Clin. Virol. 141, 104901 (2021).