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July 20, 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 if any mutations are present that could impact the performance of the Accula SARS-CoV-2 Test.[1] The Omicron variant (including B.1.1.529, BA.1, BA.1.1, BA.2, BA.3, BA.4 and BA.5 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 Accula SARS-CoV-2 test performance.[2]

Thermo Fisher Scientific is committed to providing our customers with high-quality molecular detection of 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. If you have further questions or concerns regarding genetic variations and the Accula performance, please feel free to reach out at techsupport@thermofisher.com.

Sincerely,

Colleen Knoth, Ph.D., Manager, Scientific Affairs
Mesa Biotech, Part of Thermo Fisher Scientific

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[1] This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized authorities; this test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and 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 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] Totten, A. H. et al. Detection of SARS-CoV-2 variants by Mesa Accula. J. Clin. Virol. 141, 104901 (2021).

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