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March 15, 2023

Subject: Labeling Update for the Accula™ SARS-CoV-2 Test and Control Kit – EUA200028 Supplement #14

To Whom It May Concern:

Accula™ SARS-CoV-2 Test EUA supplement #14 was authorized on March 15, 2023 and the authorization includes the following updates to the labeling of Accula™ SARS-CoV-2 Test:

- Accula Nasal Swab Buffer can now be used in addition to Accula SARS-CoV-2 buffer as an additional option for sample collection.
- Following Precaution was removed: "Do not use swabs or SARS CoV 2 Buffer other than those provided with the Accula SARS-CoV-2 Test Kit."
- Prospective clinical study section of the test IFU has been revised to include performance data from the post-market prospective clinical study.
- Presumptive negative limitation has been added to the test intended use and other applicable sections of the IFU.

Additionally, contact details for technical support has been updated in the labeling for both Accula™ SARS-CoV-2 Test and Control Kit:

- Contact details for Technical Support have changed from Mesa to Thermo Fisher Scientific including the website (www.thermofisher.com), tech support email (techsupport@thermofisher.com), and Phone support (800-955-6288, option 2) for both the Test Kit and the Control Kit.

The current versions of these updated documents are as follows:

Document Name	Current Version Number
Accula SARS-CoV-2 IFU	60061-9 (2023-03)
Accula SARS-CoV-2 QRG	60060-6 (2023-03)
Accula SARS-CoV-2 eIFU Kit Card	60086-3 (2023-03)
Accula SARS-CoV-2 Self Collection QRG	60085-3 (2023-03)
Accula SARS-CoV-2 Control Kit IFU	60062-3 (2023-03)

These updated documents can be found on our website at the following link:
https://www.thermofisher.com/order/catalog/product/COV4100

For more information on the Accula™ SARS-CoV-2 Test and the Accula™ SARS-CoV-2 Control kit please visit www.thermofisher.com or contact Mesa Biotech, part of Thermo Fisher Scientific, at techsupport@thermofisher.com or call 1-(800)-955-6288, option 2 for questions or additional assistance.

Sincerely,

Andrea Carbonaro
Sr. Director, Product Management
Point of Care Solutions
Thermo Fisher Scientific

The Accula SARS-CoV-2 test has not been FDA cleared or approved but has been authorized for emergency use by the FDA for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

For Emergency Use Authorization (EUA) Only. For prescription use only. For in vitro diagnostic use.

Attachment: EUA200028 Letter Dated March 15, 2023