65 Clyde Road, Suite A, Somerset, NJ 08873 U.S.A.
Tel: +1-732-873-4040 ‖ Fax: +1-732-873-4043 ‖ Email: info@accessbio.net

Letter of Notification

Date: April 19, 2021

Dear Authorized Distributors and Laboratories Distributing and Using *CareStart™* COVID-19 Antigen.

This letter is to inform you of the amendment to the Emergency Use Authorization (EUA202625) of the *CareStart*™ COVID-19 Antigen test. As of April 12, 2021, the authorization scope was expanded, as follows (expanded use is underlined).

"*CareStart*™ COVID-19 Antigen test is a visually-read lateral flow immunochromatographic assay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal or anterior nasal swab specimens directly collected from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests." For documentation purposes, please find the attached file 'Letter of Authorization,' or follow the link https://www.fda.gov/media/142916/download.

According to the expanded intended use, Access Bio, Inc. will be distributing the re-authorized labeling, including Instructions for Use (IFU), Quick Reference Instructions (QRI), and Fact Sheets for Healthcare Providers and Patients. For further action, kindly make the re-authorized labeling available on your website using the links; IFU/QRI (https://www.fda.gov/media/142919/download), Fact sheet for patients (https://www.fda.gov/media/142918/download) and Fact sheet for healthcare providers (https://www.fda.gov/media/142917/download).

The revised labeling reflecting the new intended use will be applied to products manufactured by Access Bio Inc. after April 12, 2021. If you have product batches in inventory listed in **Attachment A**, the re-authorized labeling is not applicable, and you should not use the products for POC serial screening purposes. While there were no changes to the product itself, it is important from the compliance point of view that the labeling matches the intended use.

Please contact Access Bio, Inc. immediately prior to distribution or use if you have any questions or concerns.

Name: Seungjae Baek

Job Title: Head of Quality Management

Signature: 

AccessBio

65 Clyde Road, Suite A, Somerset, NJ 08873 U.S.A.
Tel: +1-732-873-4040 ‖ Fax: +1-732-873-4043 ‖ Email: info@accessbio.net

Attachment A

NOTE: The following product batches in the table below should not be used for POC serial screening purposes.

Batch Number			
CH20J06	CH20M01	CH21A01	CH21B01
CH20J07	CH20M02	CH21A02	CH21B01-1
CH20K01	CH20M03	CH21A03	CH21B02
CH20K02	CH20M04	CH21A04	CH21B03
CH20K03	CH20M05	CH21A05	CH21B04
CH20K04	CH20M06	CH21A06	CH21B05
CH20L01	CH20M07	CH21A07	CH21B06
CH20L02	CH20M08	CH21A08	CH21B07
CH20L03	CH20M09	CH21A09	CH21B08
CH20L04	CH20M10	CH21A10	CH21B09
CH20L05	CH20M10-1	CH21A10-1	CH21B10
CH20L06	CH20M12	CH21A11	CH21B11
CH20L07	CH20M13	CH21A12	CH21B12
CH20L08	CH20M14	CH21A13	CH21B13
CH20L09	CH20M15	CH21A14	CH21B14
CH20K04	CH20M16	CH21A15	CH21B15
CH20L01	CH20M17	CH21A16	CH21B16
CH20L02	CH20M18	CH21A17	CH21B17
CH20L03	CH20M19	CH21A18	CH21B18
CH20L04	CH20M20	CH21A19	CH21B19
	CH20M21	CH21A20	CH21B20
	CH20M22	CH21A21	CH21B21
	CH20M23	CH21A21-1	CH21B22
		CH21A22	CH21B23-1
		CH21A23	CH21B31-1
		CH21A24	
		CH21A25	
		CH21A26	
		CH21A27	
		CH21A28	
		CH21A29	
		CH21A30	