

Title: *CareStart*TM COVID-19 ANTIGEN TEST SHELF-LIFE EXTENSION NOTIFICATION

Date: March 18, 2021

To Whom It May Concern,

This letter is to inform you regarding the extension of the shelf-life expiration date of the Access Bio, Inc. *CareStart*TM COVID-19 ANTIGEN test. As a part of the EUA requirement, the US Food and Drug Administration (FDA) requested Access Bio, Inc. to indicate shelf life of the product based on the real-time stability data.

To comply with the requirement, Access Bio, Inc. submitted the real-time stability data on March 8th, 2021, and the FDA granted **nine (9) months of shelf-life at 1–30°C for the *CareStart*TM COVID-19 ANTIGEN test as of March 15th, 2021.**

Attachment A lists the lot numbers of *CareStart*TM COVID-19 ANTIGEN products labeled with six (6) months shelf-life. These products' shelf-life will now be extended to nine (9) months.

Name: Seungjae Baek

Job Title: Sr. Managing Director, Quality Management

Signature:



Attachment A

List of Lot Numbers

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