

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

Date: July 19, 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 July 15th, 2021, and the FDA granted **twelve (12) months of shelf-life at 1–30°C for the *CareStart*TM COVID-19 ANTIGEN test as of July 16th, 2021.**

Attachment A lists the lot numbers of *CareStart*TM COVID-19 ANTIGEN products labeled with six (6) or nine (9) months shelf-life. These products' shelf-life will now be extended to twelve (12) months.

Name: Seungjae Baek

Job Title: Sr. Managing Director, Quality Management

Signature:



Attachment A

1. List of Lot Numbers printed with 6 months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (6 Months)	Extended Shelf Life (12 Months)
CH20J06, CH20J07	FEB 2021	AUG 2021 (2021-08-31)
CH20K01, CH20K02, CH20K03, CH20K04	MAR 2021	SEP 2021 (2021-09-30)
CH20L01, CH20L02, CH20L03, CH20L04, CH20L05, CH20L06, CH20L07, CH20L08, CH20L09	APR 2021	OCT 2021 (2021-10-31)
CH20M01, CH20M02, CH20M03, CH20M04, CH20M05, CH20M06, CH20M07, CH20M08, CH20M09, CH20M10, CH20M10-1, CH20M12, CH20M13, CH20M14, CH20M15, CH20M16, CH20M17, CH20M18, CH20M19, CH20M20, CH20M21, CH20M22, CH20M23	MAY 2021	NOV 2021 (2021-11-30)
CH21A01, CH21A02, CH21A03, CH21A04, CH21A05, CH21A06, CH21A07, CH21A08, CH21A09, CH21A10, CH21A11, CH21A12, CH21A13, CH21A14, CH21A15, CH21A16, CH21A17, CH21A18, CH21A19, CH21A20, CH21A21, CH21A21-1, CH21A22, CH21A23, CH21A24, CH21A25, CH21A26, CH21A27, CH21A28 CH21A29, CH21A30	JUN 2021	DEC 2021 (2021-12-31)
CH21B01, CH21B02, CH21B03, CH21B04, CH21B05, CH21B06, CH21B07, CH21B08, CH21B09, CH21B10, CH21B11, CH21B12, CH21B13, CH21B14, CH21B15, CH21B16, CH21B17, CH21B18, CH21B19, CH21B20, CH21B21, CH21B22, CH21B23, CH21B24, CH21B25, CH21B26, CH21B27, CH21B28, CH21B29, CH21B30	JUL 2021	JAN 2022 (2022-01-31)

2. List of Lot Numbers printed with 9 months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (9 Months)	Extended Shelf Life (12 Months)
CH21B31, CH21B31-1, CH21B32, CH21B33, CH21B33-1	OCT 2021	JAN 2022 (2022-01-31)
CH21C01, CH21C02, CH21C03, CH21C04, CH21C05, CH21C06, CH21C07, CH21C08, CH21C09, CH21C10, CH21C11, CH21C12, CH21C13, CH21C14, CH21C15, CH21C16, CH21C17, CH21C18, CH21C19, CH21C20	NOV 2021	FEB 2022 (2022-02-28)
CH21E01, CH21E02	JAN 2022	APR 2022 (2022-04-30)
CH21F01	FEB 2022	MAY 2022 (2022-05-31)