

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

Date: December 2nd, 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 (EUA202625). 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 October 20th, 2021, and the FDA granted **sixteen (16) months of shelf-life at 1–30°C for the *CareStart*TM COVID-19 Antigen Test as of December 2nd, 2021.**

Attachment A lists the lot numbers of *CareStart*TM COVID-19 Antigen Test products labeled with six (6) or nine (9) months shelf-life. These products' shelf-life will now be extended to sixteen (16) months.

Name: Seungjae Baek

Job Title: Sr. Managing Director, Customer Service

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 (16 Months)
CH20J06, CH20J07	FEB 2021	DEC 2021 (2021-12-31)
CH20K01, CH20K02, CH20K03, CH20K04	MAR 2021	JAN 2022 (2022-01-31)
CH20L01, CH20L02, CH20L03, CH20L04, CH20L05, CH20L06, CH20L07, CH20L08, CH20L09	APR 2021	FEB 2022 (2022-02-28)
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	MAR 2022 (2022-03-31)
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	APR 2022 (2022-04-30)
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	MAY 2022 (2022-05-31)

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 (16 Months)
CH21B31, CH21B31-1, CH21B32, CH21B33, CH21B33-1	OCT 2021	MAY 2022 (2022-05-31)
CH21C01, CH21C02, CH21C03, CH21C04, CH21C05, CH21C06, CH21C07, CH21C08, CH21C09, CH21C10, CH21C11, CH21C12, CH21C13, CH21C14, CH21C15, CH21C16, CH21C17, CH21C18, CH21C19, CH21C20	NOV 2021	JUN 2022 (2022-06-30)
CH21E01, CH21E02	JAN 2022	AUG 2022 (2022-08-31)
CH21F01	FEB 2022	SEP 2022 (2022-09-30)

3. List of Lot Numbers printed with 12 months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (12 Months)	Extended Shelf Life (16 Months)
CH21H02	JUL 2022	NOV 2022 (2022-11-30)
CH21J05	AUG 2022	DEC 2022 (2022-12-31)
CH21K03, CH21K04, CH21K05, CH21K06, CH21K07, CH21K08, CH21K09, CH21K10	SEP 2022	JAN 2023 (2023-01-31)