

Title: *CareStart*[™] 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*[™] 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*[™] COVID-19 ANTIGEN test as of March 15th, 2021.**

Attachment A lists the lot numbers of *CareStart*[™] 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 | |