

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*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 CH21A10 CH21B10 CH20L06 CH20M12 CH21A11 CH21B11 CH20L07 CH20M12 CH21A12 CH21B12 CH20L08 CH20M13 CH21A13 CH21B13 CH20L09 CH20M13 CH21A13 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A16 CH21B15 CH20M17				
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 CH21A10 CH21B10 CH20L05 CH20M10 CH21A11 CH21B11 CH20L06 CH20M12 CH21A12 CH21B12 CH20L07 CH20M13 CH21A13 CH21B13 CH20L08 CH20M13 CH21A13 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A15 CH21B16 CH21B16 CH20M17 CH21A17 CH21B17 CH21B18 CH20M18 CH21A18 CH21B18 CH20M20	CH20J06	CH20M01	CH21A01	CH21B01
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 CH21A13 CH21B14 CH20L09 CH20M15 CH21A15 CH21B14 CH20M16 CH21A15 CH21B15 CH21B15 CH20M17 CH21A16 CH21B16 CH21B17 CH20M18 CH21A18 CH21B19 CH21B19 CH20M20 CH21A20 CH21B20 CH21B20 CH20M21 CH21A21 CH21B22 CH20M22 <t< td=""><td>CH20J07</td><td>CH20M02</td><td>CH21A02</td><td>CH21B02</td></t<>	CH20J07	CH20M02	CH21A02	CH21B02
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 CH21A13 CH21B14 CH20L09 CH20M15 CH21A15 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A16 CH21B15 CH20M17 CH21A17 CH21B17 CH20M18 CH21A18 CH21B19 CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B21 CH20M22 CH21A21 CH21B22 CH21A24 CH21	CH20K01	CH20M03	CH21A03	CH21B03
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 CH21B11 CH20L07 CH20M13 CH21A13 CH21B12 CH20L08 CH20M13 CH21A13 CH21B13 CH20L08 CH20M14 CH21A14 CH21B14 CH20L09 CH20M15 CH21A15 CH21B16 CH20M16 CH21A16 CH21B16 CH21B16 CH20M17 CH21A16 CH21B17 CH21B17 CH20M18 CH21A18 CH21B18 CH21B18 CH20M20 CH21A20 CH21B20 CH21B20 CH20M21 CH21A21 CH21B22 CH21A22 CH21A23 CH21A24 CH21A25 CH21A26 <t< td=""><td>CH20K02</td><td>CH20M04</td><td>CH21A04</td><td>CH21B04</td></t<>	CH20K02	CH20M04	CH21A04	CH21B04
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 CH21A12 CH21B12 CH20L08 CH20M13 CH21A13 CH21B13 CH20L08 CH20M14 CH21A14 CH21B14 CH20L09 CH20M15 CH21A15 CH21B14 CH20M15 CH21A15 CH21B16 CH20M16 CH21A16 CH21B16 CH20M17 CH21A17 CH21B17 CH20M18 CH21A18 CH21B18 CH20M19 CH21A19 CH21B19 CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B22 CH21A22 CH21A22 CH21A22 CH21A23 CH21A24 CH21A26 <t< td=""><td>CH20K03</td><td>CH20M05</td><td>CH21A05</td><td>CH21B05</td></t<>	CH20K03	CH20M05	CH21A05	CH21B05
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 CH21A13 CH21B14 CH20L09 CH20M15 CH21A15 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A16 CH21B16 CH21B16 CH20M17 CH21A17 CH21B17 CH21B18 CH20M18 CH21A18 CH21B18 CH21B18 CH20M20 CH21A20 CH21B20 CH21B20 CH20M21 CH21A21 CH21B21 CH21B22 CH20M22 CH21A21-1 CH21B22 CH21A23 CH21A22 CH21A24 CH21A25 CH21A26 CH21A27 CH21A29 CH21A29 CH21A29 <td>CH20K04</td> <td>CH20M06</td> <td>CH21A06</td> <td>CH21B06</td>	CH20K04	CH20M06	CH21A06	CH21B06
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 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A16 CH21B16 CH21B16 CH20M17 CH21A17 CH21B17 CH21B17 CH20M18 CH21A18 CH21B18 CH21B19 CH20M20 CH21A20 CH21B20 CH21B20 CH20M21 CH21A21 CH21B21 CH21B22 CH20M22 CH21A21 CH21B22 CH21A24 CH21A23 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29 CH21A29 CH21A29	CH20L01	CH20M07	CH21A07	CH21B07
CH20L04 CH20M10 CH21A10 CH21B10 CH20L05 CH20M10-1 CH21A11 CH21B11 CH20L06 CH20M12 CH21A12 CH21B12 CH20L07 CH20M13 CH21A13 CH21B13 CH20L08 CH20M14 CH21A14 CH21B14 CH20L09 CH20M15 CH21A15 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A16 CH21B16 CH21B16 CH20M17 CH21A17 CH21B17 CH21B17 CH20M18 CH21A18 CH21B18 CH21B18 CH20M19 CH21A19 CH21B19 CH21B20 CH20M20 CH21A20 CH21B20 CH21B21 CH20M21 CH21A21 CH21B21 CH21B22 CH20M22 CH21A21 CH21B22 CH21A24 CH21A23 CH21A24 CH21A25 CH21A26 CH21A26 CH21A27 CH21A28 CH21A29	CH20L02	CH20M08	CH21A08	CH21B08
CH20L05 CH20M10-1 CH21A11 CH21B11 CH20L06 CH20M12 CH21A12 CH21B12 CH20L07 CH20M13 CH21A13 CH21B13 CH20L08 CH20M14 CH21A14 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A15 CH21B15 CH20M16 CH21A16 CH21B16 CH20M17 CH21A17 CH21B17 CH20M18 CH21A18 CH21B18 CH20M19 CH21A19 CH21B19 CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B21 CH20M22 CH21A21 CH21B22 CH20M23 CH21A22 CH21A23 CH21A24 CH21A24 CH21A25 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29 CH21A29	CH20L03	CH20M09	CH21A09	CH21B09
CH20L06 CH20M12 CH21A12 CH21B12 CH20L07 CH20M13 CH21A13 CH21B13 CH20L08 CH20M14 CH21A14 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A16 CH21B15 CH20M17 CH21A16 CH21B16 CH20M17 CH21A17 CH21B17 CH20M18 CH21A18 CH21B18 CH20M19 CH21A19 CH21B19 CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B21 CH20M22 CH21A21 CH21B22 CH20M23 CH21A22 CH21A22 CH21A24 CH21A24 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29 CH21A29	CH20L04	CH20M10	CH21A10	CH21B10
CH20L07 CH20M13 CH21A13 CH21B13 CH20L08 CH20M14 CH21A14 CH21B14 CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A15 CH21B15 CH20M16 CH21A16 CH21B16 CH20M17 CH21A17 CH21B17 CH20M18 CH21A18 CH21B18 CH20M19 CH21A19 CH21B19 CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B21 CH20M22 CH21A21 CH21B22 CH20M23 CH21A22 CH21A22 CH21A23 CH21A24 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29 CH21A29	CH20L05	CH20M10-1	CH21A11	CH21B11
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 CH21B22 CH20M23 CH21A22 CH21A23 CH21A23 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A28 CH21A29 CH21A29	CH20L06	CH20M12	CH21A12	CH21B12
CH20L09 CH20M15 CH21A15 CH21B15 CH20M16 CH21A16 CH21B16 CH20M17 CH21A17 CH21B17 CH20M18 CH21A18 CH21B18 CH20M19 CH21A19 CH21B19 CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B20 CH20M22 CH21A21 CH21B21 CH20M23 CH21A21-1 CH21B22 CH21A23 CH21A23 CH21A24 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29 CH21A29	CH20L07	CH20M13	CH21A13	CH21B13
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	CH20L08	CH20M14	CH21A14	CH21B14
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	CH20L09	CH20M15	CH21A15	CH21B15
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		CH20M16	CH21A16	CH21B16
CH20M19 CH21A19 CH21B19 CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B21 CH20M22 CH21A21-1 CH21B22 CH20M23 CH21A22 CH21A23 CH21A23 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29		CH20M17	CH21A17	CH21B17
CH20M20 CH21A20 CH21B20 CH20M21 CH21A21 CH21B21 CH20M22 CH21A21-1 CH21B22 CH20M23 CH21A22 CH21A23 CH21A24 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29 CH21A29 CH21A29		CH20M18	CH21A18	CH21B18
CH20M21 CH21A21 CH21B21 CH20M22 CH21A21-1 CH21B22 CH20M23 CH21A22 CH21A23 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29		CH20M19	CH21A19	CH21B19
CH20M22 CH21A21-1 CH21B22 CH20M23 CH21A22 CH21A23 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29		CH20M20	CH21A20	CH21B20
CH20M23 CH21A22 CH21A23 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29		CH20M21	CH21A21	CH21B21
CH21A23 CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29		CH20M22	CH21A21-1	CH21B22
CH21A24 CH21A25 CH21A26 CH21A27 CH21A28 CH21A29		CH20M23	CH21A22	
CH21A25 CH21A26 CH21A27 CH21A28 CH21A29			CH21A23	
CH21A26 CH21A27 CH21A28 CH21A29			CH21A24	
CH21A27 CH21A28 CH21A29			CH21A25	
CH21A28 CH21A29			CH21A26	
CH21A29			CH21A27	
			CH21A28	
CH21A30			CH21A29	
			CH21A30	