

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 twelve (12) months shelf-life. These products' shelf-life will now be extended to sixteen (16) months.

Name: Seungjae Baek

Job Title: Senior Managing Director

Customer Service

Signature:



Attachment A

1. 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)
CM21C12, CM21C13	FEB 2022	JUN 2022 (2022-06-30)