

## Title: CareStart<sup>™</sup> COVID-19 ANTIGEN HOME TEST SHELF-LIFE EXTENSION CONFIRMATION

Date: January 20, 2022

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*<sup>™</sup> COVID-19 Antigen Home Test (EUA210314). 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 December 1<sup>st</sup>, 2021, and the FDA granted nine (9) months of shelf-life at 1–30°C for the CareStart™ COVID-19 Antigen Home Test as of January 20<sup>th</sup>, 2022.

**Attachment A** lists the lot numbers of *CareStart*<sup>™</sup> COVID-19 Antigen Home Test 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: Senior 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 (9 Months)
CP21G01	DEC 2021	MAR 2022
		(2022-03-31)
CP21H01, CP21H02, CP21H03, CP21H04,	JAN 2022	APR 2022
CP21H05, CP21H06, CP21H07, CP21H08,		
CP21H09, CP21H15, CP21H16, CP21H17		(2022-04-30)
CP21J01, CP21J02, CP21J03, CP21J04,	FEB 2022	MAY 2022
CP21J05, CP21J06, CP21J07		(2022-05-31)
CP21K26, CP21K27, CP21K28, CP21K36,	MAR 2022 JUN 2022 (2022-06-3	IIIN 2022
CP21K37, CP21K38, CP21K39, CP21K40,		
CP21K51, CP21K52, CP21K53, CP21K54,		
CP21K55, CP21K56, CP21K57, CP21K58,		
CP21K59, CP21K61, CP21K62, CP21K63,		(2022-00-30)
CP21K64, CP21K65, CP21K66, CP21K67,		
CP21K68, CP21K69, CP21K70		
CP21L11, CP21L12, CP21L13, CP21L14,	APR 2022	JUL 2022 (2022-07-31)
CP21L17, CP21L18, CP21L19, CP21L20,		
CP21L31, CP21L32, CP21L33, CP21L34,		
CP21L35, CP21L36, CP21L37, CP21L38,		
CP21L39, CP21L40, CP21L41, CP21L42,		
CP21L43, CP21L44, CP21L45, CP21L46,		
CP21L47, CP21L48, CP21L49, CP21L50,		(2022-07-31)
CP21L51, CP21L52, CP21L53, CP21L54,		
CP21L55, CP21L56, CP21L57, CP21L58,		
CP21L60, CP21L61, CP21L62, CP21L63,		
CP21L69, CP21L77, CP21L78		
CP21M01, CP21M02, CP21M03, CP21M04,	MAY 2022 AUG 2022 (2022-08-31)	AUG 2022
CP21M05, CP21M06, CP21M07, CP21M08,		
CP21M09, CP21M10, CP21M11, CP21M12,		
CP21M13, CP21M14, CP21M15, CP21M16,		
CP21M17, CP21M18, CP21M19, CP21M20,		
CP21M21, CP21M22, CP21M23, CP21M24,		(2022-08-31)
CP21M25, CP21M26, CP21M27, CP21M28,		
CP21M29, CP21M30, CP21M41, CP21M42,		
CP21M43, CP21M44, CP21M45, CP21M46,		
CP21M47, CP21M48, CP21M49, CP21M50		
CP22A01, CP22A02, CP22A03, CP22A04,		SEP 2022
CP22A05, CP22A06, CP22A07, CP22A08,	JUN 2022	(2022-09-30)
CP22A09, CP22A10, CP22A11, CP22A12,		(2022-03-30)



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CP22A13, CP22A14, CP22A15, CP22A21,	
CP22A22, CP22A23, CP22A24, CP22A25,	
CP22A26, CP22A27, CP22A28, CP22A29,	
CP22A30, CP22A31, CP22A32, CP22A43,	
CP22A44, CP22A45, CP22A46, CP22A47,	
CP22A48, CP22A49, CP22A50, CP22A51,	
CP22A56, CP22A57, CP22A58, CP22A59,	
CP22A60, CP22A61, CP22A62, CP22A63,	
CP22A64, CP22A65, CP22A66, CP22A67,	
CP22A68, CP22A69, CP22A70, CP22A71,	
CP22A72, CP22A73, CP22A74, CP22A75,	
CP22A86, CP22A87, CP22A88, CP22A89,	
CP22A90, CP22A91, CP22A92, CP22A93,	
CP22A94, CP22A95, CP22A96, CP22A97,	
CP22A98, CP22A99, CP22A100	