

Title: *CareStart*[™] COVID-19 ANTIGEN HOME TEST and on/go COVID-19 ANTIGEN SELF-TEST SHELF-LIFE EXTENSION CONFIRMATION

Date: Aug 29th, 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*[™] COVID-19 Antigen Home Test (EUA210314) and the authorized distributor Intrivo's on/go COVID-19 Antigen Self-Test. As a part of the EUA requirement, the US Food and Drug Administration (FDA) requested Access Bio, Inc. to indicate the shelf-life of the product based on real-time stability data.

To comply with the requirement, Access Bio, Inc. submitted the real-time stability data on July 29th, 2022, and the FDA granted **fifteen (15) months of shelf-life at 1–30°C for the *CareStart*[™] COVID-19 Antigen Home Test and on/go COVID-19 Antigen Self-Test as of Aug 29th, 2022.**

Attachment A lists the lot numbers of on/go COVID-19 Antigen Self-Test products labeled with six (6) or nine (9) months shelf-life. These products' shelf-life will extend to fifteen (15) months.

Name: Seungjae Baek

Job Title: Senior Managing Director

Customer Service

Signature:



Attachment A

1. List of Lot Numbers printed with six (6) months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (6 Months)	Extended Shelf Life (15 Months)
CP21H09, CP21H10, CP21H11, CP21H12, CP21H13, CP21H14	JAN 2022	OCT 2022 (2022-10-31)
CP21J08, CP21J09, CP21J10, CP21J11, CP21J12, CP21J13, CP21J14, CP21J15, CP21J16, CP21J17, CP21J18, CP21J19, CP21J20, CP21J21, CP21J22	FEB 2022	NOV 2022 (2022-11-30)
CP21K01, CP21K02, CP21K03, CP21K04, CP21K05, CP21K06, CP21K07, CP21K08, CP21K09, CP21K10, CP21K11, CP21K12, CP21K13, CP21K14, CP21K15, CP21K16, CP21K17, CP21K18, CP21K19, CP21K20, CP21K21, CP21K22, CP21K23, CP21K24, CP21K25, CP21K29, CP21K30, CP21K31, CP21K32, CP21K33, CP21K34, CP21K35, CP21K41, CP21K42, CP21K43, CP21K44, CP21K45, CP21K46, CP21K47, CP21K48, CP21K49, CP21K50, CP21K60	MAR 2022	DEC 2022 (2022-12-31)
CP21L01, CP21L02, CP21L03, CP21L04, CP21L05, CP21L06, CP21L07, CP21L08, CP21L09, CP21L10, CP21L15, CP21L16, CP21L21, CP21L22, CP21L23, CP21L24, CP21L25, CP21L26, CP21L27, CP21L28, CP21L29, CP21L30, CP21L59, CP21L64, CP21L65, CP21L66, CP21L67, CP21L68, CP21L70, CP21L71, CP21L72, CP21L73, CP21L74, CP21L75, CP21L76, CP21L79, CP21L80	APR 2022	JAN 2023 (2023-01-31)
CP21M31, CP21M32, CP21M33, CP21M34, CP21M35, CP21M36, CP21M37, CP21M38, CP21M39, CP21M40	MAY 2022	FEB 2023 (2023-02-28)
CP22A16, CP22A17, CP22A18, CP22A19, CP22A20	JUN 2022	MAR 2023 (2023-03-31)

2. List of Lot Numbers printed with nine (9) months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (9 Months)	Extended Shelf Life (15 Months)
CP22A33, CP22A34, CP22A35, CP22A36, CP22A37, CP22A38, CP22A39, CP22A40, CP22A41, CP22A42, CP22A48, CP22A52, CP22A53, CP22A54, CP22A55, CP22A76, CP22A77, CP22A78, CP22A79, CP22A80, CP22A81, CP22A82, CP22A83, CP22A84, CP22A85, CP22A101, CP22A102, CP22A103, CP22A104, CP22A105, CP22A106	SEP 2022	MAR 2023 (2023-03-31)
CP22B21, CP22B22, CP22B23, CP22B24, CP22B25, CP22B46, CP22B47, CP22B48, CP22B49, CP22B50, CP22B51, CP22B52, CP22B53, CP22B54, CP22B55	OCT 2022	APR 2023 (2023-04-30)

**Access Bio, Inc.: CareStart COVID-19 Antigen Home Test
9-month to 12-month self-life extension granted by the FDA on May 12, 2022**

Lot Number	Tests with this printed expiration date	Now have this extended expiration date
CP21H01 – CP21H17	January 2022	July 2022
CP21J01 – CP21J22	February 2022	August 2022
CP21K01 – CP21K70	March 2022	September 2022
CP21L01 – CP21L80	April 2022	October 2022
CP21M01 – CP21M50	May 2022	November 2022
CP22A01 – CP22A23, CP22A31, CP22A32	June 2022	December 2022
CP21A14, CP21A15 CP22A24 – CP22A30 CP22A33 – CP22A110	September 2022	December 2022
CP22B05 – CP22B91 CP22B105 – CP22B108	October 2022	January 2023
CP22C01, CP22C07 – CP22C11, CP22C28 – CP22C58, CP22C69 – CP22C75	November 2022	February 2023