

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

Date: Aug 29<sup>th</sup>, 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) 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 29<sup>th</sup>, 2022, and the FDA granted **fifteen (15) months of shelf-life at 1–30°C for the *CareStart*<sup>™</sup> COVID-19 Antigen Home Test and on/go COVID-19 Antigen Self-Test as of Aug 29<sup>th</sup>, 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, CP22B56	OCT 2022	APR 2023 (2023-04-30)

**Access Bio, Inc.: CareStart COVID-19 Antigen Home Test  
12-month to 15-month shelf-life extension granted by the FDA on August 29, 2022**

Lot Number	Tests with this printed expiration date (Year-Month-Day)	Now have this extended expiration date (Year-Month-Day)
CP21G01	2021-12-31	2022-09-30
CP21H01 – CP21H17	2022-01-31	2022-10-31
CP21J01 – CP21J22	2022-02-28	2022-11-30
CP21K01 – CP21K70	2022-03-31	2022-12-31
CP21L01 – CP21L80	2022-04-30	2023-01-31
CP21M01 – CP21M50	2022-05-31	2023-02-28
CP22A01 – CP22A13 CP22A16 – CP22A23 CP22A31 – CP22A32	2022-06-30	2023-03-31
CP22A14 – CP22A15 CP22A24 – CP22A30 CP22A33 – CP22A110	2022-09-30	2023-03-31
CP22B05 – CP22B53 CP22B56 – CP22B60 CP22B64 – CP22B65 CP22B70 – CP22B89 CP22B105 – CP22B108	2022-10-31	2023-04-30
CP22C01	2022-11-30	2023-05-31
CP22C07, CP22C08, CP22C09, CP22C10, CP22C11	2022-12-01	2023-06-01
CP22C28	2022-12-06	2023-06-06
CP22C29, CP22C30, CP22C31, CP22C32, CP22C33, CP22C34	2022-12-07	2023-06-07
CP22C35, CP22C36, CP22C37, CP22C38	2022-12-08	2023-06-08
CP22C39	2022-12-08	2023-06-08
CP22A19	2023-01-06	2023-04-06
CP22B54	2023-02-14	2023-05-14
CP22B55	2023-02-15	2023-05-15
CP22B61, CP22B62, CP22B63	2023-02-16	2023-05-16
CP22B67, CP22B68, CP22B69	2023-02-17	2023-05-17
CP22B90, CP22B91	2023-02-23	2023-05-23
CP22C39, CP22C40	2023-03-08	2023-06-08
CP22C41	2023-03-09	2023-06-09