

**Title: *CareStart*TM COVID-19 ANTIGEN HOME TEST SHELF-LIFE EXTENSION
CONFIRMATION**

Date: Feb 1st, 2023

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 Home Test (EUA210314). 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 January 26th, 2023, and the FDA granted **twenty-one (21) months of shelf-life at 1–30°C for the *CareStart*TM COVID-19 Antigen Home Test as of Feb 1st, 2023.**

Attachment A lists the lot numbers of *CareStart*TM COVID-19 Antigen Home Test products labeled with six (6), nine (9), twelve (12) or fifteen (15) months shelf-life. These products' shelf-life will extend to twenty-one (21) months.

According to the FDA 21 CFR 801.18, Access Bio, Inc. complied with this regulation and modified the Coding System to change the format for the printed expiration date from MMM YYYY to YYYY-MM-DD. The applicable lot numbers are summarized in the table.

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 (21 Months)
CP21G01	DEC 2021	MAR 2023 (2023-03-31)
CP21H01, CP21H02, CP21H03, CP21H04, CP21H05, CP21H06, CP21H07, CP21H08, CP21H09, CP21H15, CP21H16, CP21H17	JAN 2022	APR 2023 (2023-04-30)
CP21J01, CP21J02, CP21J03, CP21J04, CP21J05, CP21J06, CP21J07	FEB 2022	FEB 2023 (2023-02-28)
CP21K26, CP21K27, CP21K28, CP21K36, CP21K37, CP21K38, CP21K39, CP21K40, CP21K51, CP21K52, CP21K53, CP21K54, CP21K55, CP21K56, CP21K57, CP21K58, CP21K59, CP21K61, CP21K62, CP21K63, CP21K64, CP21K65, CP21K66, CP21K67, CP21K68, CP21K69, CP21K70	MAR 2022	JUN 2023 (2023-06-30)
CP21L11, CP21L12, CP21L13, CP21L14, CP21L17, CP21L18, CP21L19, CP21L20, CP21L31, CP21L32, CP21L33, CP21L34, CP21L35, CP21L36, CP21L37, CP21L38, CP21L39, CP21L40, CP21L41, CP21L42, CP21L43, CP21L44, CP21L45, CP21L46, CP21L47, CP21L48, CP21L49, CP21L50, CP21L51, CP21L52, CP21L53, CP21L54, CP21L55, CP21L56, CP21L57, CP21L58, CP21L60, CP21L61, CP21L62, CP21L63, CP21L69, CP21L77, CP21L78	APR 2022	JUL 2023 (2023-07-31)
CP21M01, CP21M02, CP21M03, CP21M04, CP21M05, CP21M06, CP21M07, CP21M08, CP21M09, CP21M10, CP21M11, CP21M12, CP21M13, CP21M14, CP21M15, CP21M16, CP21M17, CP21M18, CP21M19, CP21M20, CP21M21, CP21M22, CP21M23, CP21M24, CP21M25, CP21M26, CP21M27, CP21M28, CP21M29, CP21M30, CP21M41, CP21M42, CP21M43, CP21M44, CP21M45, CP21M46, CP21M47, CP21M48, CP21M49, CP21M50	MAY 2022	AUG 2023 (2023-08-31)
CP22A01, CP22A02, CP22A03, CP22A04, CP22A05, CP22A06, CP22A07, CP22A08, CP22A09, CP22A10, CP22A11, CP22A12, CP22A13, CP22A21, CP22A22, CP22A23, CP22A31, CP22A32	JUN 2022	SEP 2023 (2023-09-30)

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 (21 Months)
CP22A14, CP22A15, CP22A24, CP22A25, CP22A26, CP22A27, CP22A28, CP22A29, CP22A30, 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, CP22A107, CP22A108, CP22A109, CP22A110	SEP 2022	SEP 2023 (2023-09-30)
CP22B05, CP22B06, CP22B07, CP22B08, CP22B09, CP22B10, CP22B11, CP22B12, CP22B13, CP22B14, CP22B15, CP22B16, CP22B17, CP22B18, CP22B19, CP22B20, CP22B26, CP22B27, CP22B28, CP22B29, CP22B30, CP22B31, CP22B32, CP22B33, CP22B35, CP22B36, CP22B37, CP22B38, CP22B39, CP22B44, CP22B45, CP22B57, CP22B58, CP22B59, CP22B60, CP22B64, CP22B70, CP22B71, CP22B72, CP22B73, CP22B74, CP22B75, CP22B76, CP22B77, CP22B78, CP22B79, CP22B80, CP22B81, CP22B82, CP22B83, CP22B84, CP22B85, CP22B86, CP22B87, CP22B88, CP22B89, CP22B105, CP22B106, CP22B107, CP22B108	OCT 2022	OCT 2023 (2023-10-31)

3. 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 (21 Months)
CP22C01	2022-11-30	2023-11-30
CP22C07, CP22C08, CP22C09, CP22C10, CP22C11	2022-12-01	2023-12-01
CP22C28	2022-12-06	2023-12-06
CP22C29, CP22C30, CP22C31, CP22C32, CP22C33, CP22C34	2022-12-07	2023-12-07
CP22C35, CP22C36, CP22C37, CP22C38	2022-12-08	2023-12-08
CP22C39	2022-12-08	2023-12-08

4. List of lot numbers printed with Twelve (12) months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (12 Months)	Extended Shelf Life (21 Months)
CP22A19	2023-01-06	2023-10-06
CP22B54	2023-02-14	2023-11-14
CP22B55	2023-02-15	2023-11-15
CP22B61, CP22B62, CP22B63	2023-02-16	2023-11-16
CP22B67, CP22B68, CP22B69	2023-02-17	2023-11-17
CP22B90, CP22B91	2023-02-23	2023-11-23
CP22C39, CP22C40	2023-03-08	2023-12-08
CP22C41	2023-03-09	2023-12-09

5. List of lot numbers printed with fifteen (15) months shelf life and new extended shelf life

Lot Numbers	Printed Shelf Life (15 Months)	Extended Shelf Life (21 Months)
CP22B19	2023-05-04	2023-11-04
CP22B34	2023-05-09	2023-11-09
CP22B37	2023-05-10	2023-11-10
CP22B40, CP22B41, CP22B42, CP22B43, CP22B44	2023-05-11	2023-11-11
CP22B60	2023-05-16	2023-11-16
CP22B65, CP22B66	2023-05-17	2023-11-17
CP22C42, CP22C43, CP22C44	2023-06-09	2023-12-09
CP22C45, CP22C46, CP22C47, CP22C48, CP22C49	2023-06-10	2023-12-10
CP22C50	2023-06-13	2023-12-13
CP22C51, CP22C52, CP22C53, CP22C54, CP22C55, CP22C56	2023-06-14	2023-12-14
CP22C57, CP22C58	2023-06-15	2023-12-15
CP22C69, CP22C70, CP22C71, CP22C72	2023-06-17	2023-12-17
CP22C73, CP22C74, CP22C75	2023-06-18	2023-12-18
CP22J02	2023-12-19	2024-06-19
CP22J03	2023-12-20	2024-06-20
CP22J04	2023-12-21	2024-06-21
CP22K01, CP22K02	2024-01-19	2024-07-19
CP22K03	2024-01-20	2024-07-20
CP22K04	2024-01-25	2024-07-25
CP22K05	2024-01-26	2024-07-26
CP22K06, CP22K07, CP22K08	2024-01-27	2024-07-27
CP22K09, CP22K10	2024-01-28	2024-07-28
CP22K11, CP22K12, CP22K13	2024-01-30	2024-07-30
CP22L01, CP22L02, CP22L03	2024-01-31	2024-07-31
CP22L04, CP22L05, CP22L06	2024-02-01	2024-08-01

CP22L07, CP22L08, CP22L09	2024-02-02	2024-08-02
CP22L10, CP22L11, CP22L12	2024-02-03	2024-08-03
CP22L13	2024-02-06	2024-08-06
CP22L14	2024-02-07	2024-08-07
CP22L15, CP22L16	2024-02-29	2024-08-29
CP22M01, CP22M02	2024-02-29	2024-08-31
CP22M03, CP22M04	2024-03-01	2024-09-01
CP22M05, CP22M06	2024-03-04	2024-09-04
CP22M07, CP22M08	2024-03-05	2024-09-05
CP22M09, CP22M10	2024-03-06	2024-09-06
CP22M11, CP22M12	2024-03-07	2024-09-07
CP22M13, CP22M14	2024-03-08	2024-09-08
CP22M15, CP22M16	2024-03-11	2024-09-11
CP22M17, CP22M18	2024-03-12	2024-09-12
CP22M19, CP22M20	2024-03-13	2024-09-13
CP22M21, CP22M22	2024-03-14	2024-09-14
CP22M23, CP22M24	2024-03-15	2024-09-15
CP22M25, CP22M26	2024-03-18	2024-09-18
CP22M27, CP22M28	2024-03-19	2024-09-19
CP22M29, CP22M30	2024-03-20	2024-09-20
CP22M31, CP22M32	2024-03-21	2024-09-21
CP22M33, CP22M34	2024-03-22	2024-09-22
CP23A01	2024-04-02	2024-10-02
CP23A02	2024-04-03	2024-10-03
CP23A03	2024-04-04	2024-10-04
CP23A04	2024-04-05	2024-10-05
CP23A05	2024-04-08	2024-10-08
CP23A06	2024-04-09	2024-10-09
CP23A07	2024-04-10	2024-10-10
CP23A08	2024-04-15	2024-10-15
CP23A09	2024-04-16	2024-10-16
CP23A10, CP23A11	2024-04-17	2024-10-17
CP23A12, CP23A13	2024-04-18	2024-10-18
CP23A14, CP23A15	2024-04-19	2024-10-19
CP23A16	2024-04-19	2024-10-22
CP23A17, CP23A18	2024-04-22	2024-10-22
CP23A19, CP23A20, CP23A21	2024-04-23	2024-10-23
CP23A22, CP23A23, CP23A24	2024-04-24	2024-10-24
CP23A25, CP23A26, CP23A27	2024-04-25	2024-10-25