

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

Date: Aug 31st, 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*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 July 29th, 2022, and the FDA granted **fifteen (15) months of shelf-life at 1–30°C for the *CareStart*TM COVID-19 Antigen Home Test as of Aug 29th, 2022.**

Attachment A lists the lot numbers of *CareStart*TM COVID-19 Antigen Home Test products labeled with six (6) or nine (9) months shelf-life. These products' shelf-life will extend to fifteen (15) 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 (15 Months)
CP21G01	DEC 2021	SEP 2022 (2022-09-30)
CP21H01, CP21H02, CP21H03, CP21H04, CP21H05, CP21H06, CP21H07, CP21H08, CP21H09, CP21H15, CP21H16, CP21H17	JAN 2022	OCT 2022 (2022-10-31)
CP21J01, CP21J02, CP21J03, CP21J04, CP21J05, CP21J06, CP21J07	FEB 2022	NOV 2022 (2022-11-30)
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	DEC 2022 (2022-12-31)
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	JAN 2023 (2023-01-31)
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	FEB 2023 (2023-02-28)
CP22A01, CP22A02, CP22A03, CP22A04, CP22A05, CP22A06, CP22A07, CP22A08, CP22A09, CP22A10, CP22A11, CP22A12, CP22A13, CP22A21, CP22A22, CP22A23, CP22A31, CP22A32	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)
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	MAR 2023 (2023-03-31)
CP22B05, CP22B06, CP22B07, CP22B08, CP22B09, CP22B10, CP22B11, CP22B12, CP22B13, CP22B14, CP22B15, CP22B16, CP22B17, CP22B18, CP22B19, CP22B20, CP22B26, CP22B27, CP22B28, CP22B29, CP22B30, CP22B31, CP22B32, CP22B33, CP22B34, CP22B35, CP22B36, CP22B37, CP22B38, CP22B39, CP22B40, CP22B41, CP22B42, CP22B43, CP22B44, CP22B45, CP22B57, CP22B58, CP22B59, CP22B60, CP22B64, CP22B65, CP22B66, 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	APR 2023 (2023-04-30)

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 (15 Months)
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

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 (15 Months)
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

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

Lot Numbers	Printed Shelf Life (15 Months)
CP22B66	2023-05-17
CP22C42, CP22C43, CP22C44	2023-06-09
CP22C45, CP22C46, CP22C47, CP22C48, CP22C49	2023-06-10
CP22C50	2023-06-13
CP22C51, CP22C52, CP22C53, CP22C54, CP22C55, CP22C56	2023-06-14
CP22C57, CP22C58	2023-06-15
CP22C69, CP22C70, CP22C71, CP22C72	2023-06-17
CP22C73, CP22C74, CP22C75	2023-06-18