

Title: *CareStart*[™] COVID-19 ANTIGEN HOME TEST and on/go COVID-19 ANTIGEN SELF-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*[™] 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 January 26th, 2023, and the FDA granted **twenty-one (21) 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 Feb 1st, 2023.**

Attachment A lists the lot numbers of on/go COVID-19 Antigen Self-Test products labeled with six (6) or nine (9) months of shelf-life. These products' shelf-life will extend to twenty-one (21) 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 (21 Months)
CP21H09, CP21H10, CP21H11, CP21H12, CP21H13, CP21H14	JAN 2022	APR 2023 (2023-04-30)
CP21J08, CP21J09, CP21J10, CP21J11, CP21J12, CP21J13, CP21J14, CP21J15, CP21J16, CP21J17, CP21J18, CP21J19, CP21J20, CP21J21, CP21J22	FEB 2022	MAY 2023 (2023-05-31)
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	JUN 2023 (2023-06-30)
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	JUL 2023 (2023-07-31)
CP21M31, CP21M32, CP21M33, CP21M34, CP21M35, CP21M36, CP21M37, CP21M38, CP21M39, CP21M40	MAY 2022	AUG 2023 (2023-08-31)
CP22A16, CP22A17, CP22A18, CP22A19, CP22A20	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)
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	SEP 2023 (2023-09-30)
CP22B21, CP22B22, CP22B23, CP22B24, CP22B25, CP22B46, CP22B47, CP22B48, CP22B49, CP22B50, CP22B51, CP22B52, CP22B53, CP22B56	OCT 2022	OCT 2023 (2023-10-31)