65 Clyde Road, Suite A, Somerset, NJ 08873 U.S.A.
Tel: +1-732-873-4040 ‖ Fax: +1-732-873-4043 ‖ Email: info@accessbio.net

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: 

AccessBio

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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)

August 23, 2021

Sang Joon Han
Associate Principal Scientist, Division of R&D
Access Bio, Inc.
65 Clyde Road, Suite A,
Somerset, NJ 08873

Re: EUA210314/S001
Trade/Device Name: *CareStart* COVID-19 Antigen Home Test
Dated: July 12, 2021
Received: July 13, 2021

Dear Sang Joon Han:

This is to notify you that your request to update the authorized labeling for the *CareStart* COVID-19 Antigen Home Test with various edits and clarifications, including a new QR code used to access the On/Go Mobile Application and to make those same edits to the authorized brand name labeling, On/Go COVID-19 Antigen Self-Test, is granted. Upon review, we concur that the information submitted in EUA210314/S001 supports the requested updates for use with the *CareStart* COVID-19 Antigen Home Test. By submitting this EUA revision for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the *CareStart* COVID-19 Antigen Home Test issued on August 2, 2021.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health