November 22, 2021

Sung Jang
Access Bio, Inc.
65 Clyde Road, Suite A, Somerset, NJ 08873 USA
sajang@accessbio.net

Dear Sung Jang,

On November 1, 2021, on behalf of Access Bio, Inc, you submitted a proposal requesting that FDA exercise enforcement discretion regarding keeping previous labeling of COVID-19 Antigen Home Test Kits that have already been distributed. On November 22, 2021, FDA reissued the EUA for your CareStart COVID-19 Antigen Home Test to authorize use of your device with individual anterior nasal swab specimens from individuals age 14 years and older (self-collected), or 2 years and older (collected with adult assistance) for non-prescription home use (EUA210314/S002). In your November 1, 2021 request, you summarized your plans to continue to distribute your previously authorized CareStart COVID-19 Antigen Home Test (EUA210314/S001) without relabeling the home collection kits to include the new indication. You stated that labeling consistent with the reissued EUA (EUA210314/S002) will be available on your official website and the distributor's website. You subsequently amended this approach in emails communication with FDA dated November 5, 2021.

You indicated that the basis of your request is that for the COVID-19 Antigen Home Test, you have three weeks of tests stocked in your current inventories that include the previous labels (EUA210314/S001). In addition, a lead time for the new labels (EUA210314/S002) is expected to be at least two weeks.

As described in your proposal to FDA, Access Bio will:

- Provide the EUA210314/S002 authorized labeling online (official website and the distributor's website) until the expiration of devices with the EUA210314/S001 labeling.

In light of the urgent need for COVID-19 testing during the public health emergency, the need to increase testing accessibility for COVID-19, your proposed alternative approach for providing the EUA210314/S002 authorized labeling to retailers and customers, and because the differences between your previously authorized home collection kit and your currently authorized home collection kit are limited to the authorized labeling, and in light of the burden that would be imposed to accommodate additional relabeling for already printed kits, FDA does not intend to object to the distribution of your authorized product that is already labeled per S001 for a time period of five weeks from the date of your receipt of this letter where the steps described in the above approach with respect to S002 are followed to ensure that these home collection kits do not create an undue risk in light of the public health emergency.

FDA believes that five weeks is sufficient time for Access Bio to transition to the revised indications for use under the recent authorization while still ensuring that timely progress is made to implement the labeling updates authorized in EUA210314/S002.

Sincerely,

Uwe Scherf -S

Uwe Scherf, M. Sc., PhD.
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