U.S. FOOD & DRUG ADMINISTRATION

June 17, 2020

Mary Smith
Sr. Manager, Regulatory Affairs
P23 Labs, LLC
500 S. University Ave., Suite 504
Little Rock, AR 72205-5306

Re: EUA200403/A001
Trade/Device Name: P23 Labs TaqPath SARS-CoV-2 Assay
Dated: June 1, 2020
Received: June 1, 2020

Dear Ms. Smith:

This is to notify you that your request to update the EUA Summary and laboratory Standard Operating Procedures that are part of the authorized labeling for the P23 Labs TaqPath SARS-CoV-2 Assay to; (1) update the Intended Use to include "*The P23 Labs TaqPath SARS-CoV-2 assay can be used with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit when determined to be appropriate by a healthcare provider"* along with some other minor edits or clarifications, (2) include the Everlywell COVID-19 Test Home Collection Kit as an authorized home collection kit for use with the test and associated supporting data, (3) add an RNase P RT-PCR assay that will be run on all Everlywell collected samples, prior to running the P23 Labs TaqPath SARS-CoV-2 Assay, to control for adequate human specimen collection, (4) add previously collected clinical data for nasopharyngeal swab performance, and (5) add minor edits and clarifications, is granted. Upon review, we concur that the data and information submitted in EUA200403/A001 supports the requested updates for use with the P23 Labs TaqPath SARS-CoV-2 Assay. By submitting this amendment 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 P23 Labs TaqPath SARS-CoV-2 Assay issued on May 21, 2020.

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

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