May 28, 2021

Robert J. Rae
CEO
Pro-Lab Diagnostics
21 Cypress Blvd. Suite 1155
Round Rock, TX 78665

Re: EUA202230/S002
Trade/Device Name: Pro-AmpRT SARS-CoV-2 Test
Dated: May 13, 2021
Received: May 21, 2021

Dear Mr. Rae:

This is to notify you that your request to update the Instructions for Use (IFU) of the Pro-AmpRT SARS-CoV-2 Test to; (1) remove the claim for the use of non-extracted samples (direct method), and (2) update the EUA Summary and IFU to reflect this change, is granted. Upon review, we concur that the data and information submitted in EUA202230/S002 supports the requested updates for use with the Pro-AmpRT SARS-CoV-2 Test. FDA has updated the intended use and the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations. 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 Pro-AmpRT SARS-CoV-2 Test issued on August 13, 2020.

Sincerely yours,

_____

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