U.S. FOOD & DRUG ADMINISTRATION

February 01, 2022

Daniel Simpson
o/b/o GenScript USA Inc.
Corgenix Inc.
11575 Main Street
Broomfield, CO 80020

Re: EUA201427/S004
Trade/Device Name: cPass SARS-CoV-2 Neutralization Antibody Detection Kit
Dated: January 14, 2022
Received: January 14, 2022

Dear Mr. Simpson:

This is to notify you that your request to update the Instructions for Use of the cPass SARS-CoV-2 Neutralization Antibody Detection Kit to correct technical, and grammatical errors, and clarify result calculation instructions is granted. Upon review, we concur that the information submitted in EUA201427/S004 supports the requested edits to the cPass SARS-CoV-2 Neutralization Antibody Detection Kit Instructions for Use. By submitting this supplement 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 cPass SARS-CoV-2 Neutralization Antibody Detection Kit issued on December 16, 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

CC: Michael Lau, Director of Corporate Strategy, GenScript USA Inc.

U.S. Food & Drug Administration
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