



February 5, 2021

Dr. Meijie Tang
Chief Executive Officer
Nirmidas Biotech, Inc.
2458 Embarcadero Way
Palo Alto, CA 94303

Re: EUA202743/S002

Trade/Device Name: MidaSpot COVID-19 Antibody Combo Detection Kit

Dated: February 1, 2021

Received: February 1, 2021

EUA202743/S003

Trade/Device Name: MidaSpot COVID-19 Antibody Combo Detection Kit

Dated: February 2, 2021

Received: February 2, 2021

Dear Dr Tang:

This is to notify you that your request to add an additional authorized distributor of the MidaSpot COVID-19 Antibody Combo Detection Kit is granted. The contact information provided regarding the additional authorized distributor is complete and acceptable.

In addition, your request for extension of the MidaSpot COVID-19 Antibody Combo Detection Kit shelf-life stability to 5 months when stored at 4-25°C and maintaining an option of storing the kit for 9 months when stored at 2-8°C is granted. The real-time stability study report and line data provided in your supplement are acceptable and support the requested extension of the shelf-life stability to 5 months.

By submitting this information 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 MidaSpot COVID-19 Antibody Combo Detection Kit issued on December 31, 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