



April 12, 2021

Meijie Tang, Ph.D.  
Chief Executive Officer & President  
Nirmidas Biotech, Inc.  
2458 Embarcadero Way  
Palo Alto, CA 94303

Re: EUA202743/S004 and EUA 202743/S005  
Trade/Device Name: MidaSpot COVID-19 Antibody Combo Detection Kit  
Dated: March 4, 2021  
Received: March 4, 2021

Dear Dr Tang:

This is to notify you that your request to (1) add an additional authorized distributor of the MidaSpot COVID-19 Antibody Combo Detection Kit, and (2) update the Instructions for Use (IFU) to extend the MidaSpot COVID-19 Antibody Combo Detection Kit shelf-life stability to six 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. Upon review, we concur that the data and information submitted in EUA202743/S004 and EUA202743/S005 support the requested updates for use with the MidaSpot COVID-19 Antibody Combo Detection Kit. FDA requested updates to the IFU to include additional limitations related to performance for vaccinated individuals and performance with circulating variants and has updated the Healthcare Provider and Patient Fact Sheets for the MidaSpot COVID-19 Antibody Combo Detection Kit to reflect more recent authorizations. 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,

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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