March 25, 2022

Young Wang
Regulatory Consultant
Wanda Henry Co.
Representing: Sansure BioTech Inc.
4426 Prancing Deer Dr.
Ellicott City, MD 21043

Re: EUA200294/S004
Trade/Device Name: Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)
Dated: October 13, 2021
Received: October 14, 2021

Dear Mr. Wang:

This is to notify you that your request to; (1) update the Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) authorized labeling (the Instructions for Use (IFU) and Healthcare Provider Fact Sheet) in response to Condition of Authorization (1) in the Viral Mutation Revision Letter dated September 23, 2021, (2) minor edits to the Intended Use of the test, (3) revise the inclusivity data with results of an updated *in silico* analysis, and (4) minor updates and clarifications to the IFU, is granted. Upon review, we concur that the data and information submitted in EUA200294/S004 supports the requested updates for use with the Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing). FDA have updated the Fact Sheet for Healthcare Provider and Fact Sheet Patient to reflect 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 Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) issued on May 4, 2020, and the Viral Mutation Revision Letter issued on September 23, 2021.

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