



April 14, 2026

Maria Sur
Senior Director, Regulatory Affairs
Laboratory Corporation of America
8790 Devon Ridge Court
Sunbury, OH 43074

Re: EUA230044/S002
Trade/Device Name: Labcorp Monkeypox PCR Test Home Collection Kit
Dated: March 16, 2026
Received: March 16, 2026

Dear Maria Sur:

This is to notify you that your request to update the Labcorp Monkeypox PCR Test Home Collection Kit with data evaluating additional clinical specimens with the product to fulfill Condition of Authorization S of the July 18, 2024, Letter of Authorization, is granted. Upon review, we concur that the data and information submitted in EUA230044/S002 supports the requested update for the Labcorp Monkeypox PCR Test Home Collection Kit and fulfills Condition of Authorization S of the July 18, 2024, Letter. 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 Labcorp Monkeypox PCR Test Home Collection Kit reissued on July 18, 2024.

Sincerely yours,

Noel J. Gerald, Ph.D.
Deputy Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health