

Jill Taylor, Ph.D.
Director
Wadsworth Center, NYSDOH

Dear Jill,

On March 11, 2020, the Wadsworth Center of the New York State Department of Health (“Wadsworth”) requested that, in light of the urgent public health need for additional testing capacity, FDA exercise enforcement discretion and not object to Wadsworth authorizing certain laboratories in New York State to develop and perform COVID-19 tests without an Emergency Use Authorization (EUA) or other marketing authorization under the Federal Food, Drug, and Cosmetic Act. You explained that New York has approximately 28 laboratories that currently hold a New York State Department of Health (Department) clinical laboratory permit with experience in molecular-based virology testing. These laboratories also have experience in the development and validation of laboratory developed tests. You also explained that these laboratories would be required to notify Wadsworth that they have validated a test for COVID-19 and could begin testing if they submit validation studies within 15 business days. Wadsworth would require the submission of the validation data and, if Wadsworth’s review identifies any concerns, you would require the laboratory to stop testing until the concerns were addressed.

FDA understands that Wadsworth Center has a long-established framework in place for oversight of laboratory developed tests. FDA also notes that we have previously accredited Wadsworth as a third party reviewer for molecular assays under the Federal Food, Drug, and Cosmetic Act. Based on the urgent public health need for additional testing capacity, Wadsworth’s existing framework for oversight of laboratory developed tests, and FDA’s past experience working with Wadsworth in review of molecular tests, FDA does not intend to object if a laboratory that is authorized by the New York State Department of Health under its established framework and as described above does not submit an EUA for a laboratory developed test for detection of SARS-CoV-2 during the period of the public health emergency.

Sincerely yours,
Ellen

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