GUIDANCE DOCUMENT

Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency

Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff

MARCH 2020

Final

Docket Number:

FDA-2020-D-0987 (https://www.regulations.gov/docket?D=FDA-2020-D-0987)

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Office of Medical Products and Tobacco, Center for Devices and Radiological Health

The Food and Drug Administration (FDA or Agency) is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) diagnostic tests developed by laboratories and commercial manufacturers during the public health emergency.

On February 4, 2020, the Secretary of Health and Human Services (HHS) determined that there is a public health emergency (/media/135010/download) and that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV). Rapid detection of COVID-19 cases in the United States requires wide availability of diagnostic testing to control the emergence of this rapidly spreading, severe illness. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the United States.

In light of this public health emergency, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

Submit Comments

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