

TOWN HALL

Virtual Town Hall - Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency

MARCH 6, 2020

On This Page

- Meeting Information
 - Event Materials
-

Date:

March 6, 2020

Time:

1:00 PM - 2:00 PM ET

Organized By:

Medical Devices (/advisory-committees/committees-and-meeting-materials/medical-devices)

Meeting Materials:

- Transcript (/media/136703/download)

Summary:

On March 6, 2020, the U.S. Food and Drug Administration (FDA) will host a virtual Town Hall for laboratories certified to perform high-complexity testing under the Clinical Laboratory Improvement Amendments (CLIA) that are developing or have developed molecular diagnostic tests for SARS-CoV-2. The purpose of the Town Hall is to help answer technical questions about development and validation of molecular tests for SARS-CoV-2 and the recently-issued guidance.

Background:

On February 29, 2020, the FDA issued the immediately in effect guidance, Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency.

Event Materials

Title ▲	File Type/Size ▼
Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing - Transcript (/media/136703/download)	pdf (99.94 KB)

Showing 1 to 1 of 1 entries

[🔗 More Meetings, Conferences, and Workshops \(/news-events/fda-meetings-conferences-and-workshops\)](#)