



Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Ref: QSO 20-10-CLIA

DATE: February 6, 2020

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Notification to Surveyors of the Authorization for Emergency Use of the **CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel** Assay and Guidance for use in CDC Qualified Laboratories

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) is providing guidance to surveyors in regards to the authorization for emergency use of the Centers for Disease Control (CDC)'s 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel assay and the deployment into CDC qualified, and, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests).
- Assays that have been issued an Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) remain subject CLIA regulations.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and the corresponding protocols have been developed by the CDC for use by CDC qualified laboratories and the assay has been issued an EUA from the FDA.
- Upon receipt of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel assay and corresponding Manufacturer's Instructions (MI), CDC qualified laboratories will verify assay performance specifications in their laboratory per the manufacturer's instructions.
- CMS is also providing guidance for surveyors to notify their CMS Location if they discover a laboratory using an assay without an EUA that is testing for the same agent for which the emergency has been declared, or a modified EUA assay. The CMS Location will notify CMS Baltimore.

Background

The FDA Emergency Use Authorization (EUA) of Medical Products and Related Authorities Guidance for Industry and Other Stakeholders document describes key legal authorities to sustain and strengthen national preparedness for public health, military, and domestic emergencies involving chemical, biological, radiological, and nuclear (CBRN) agents,

including emerging infectious disease threats. The rapid development and deployment of emergency assays is afforded through the EUA authority under Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3). This permits the FDA Commissioner to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances, if certain criteria are met, after there is a determination and the Secretary of Health and Human Services (HHS) issues a declaration that circumstances exist justifying the authorization of emergency use of the medical product. The EUA remains in effect until the emergency declaration is terminated or until the FDA revokes the authorization. The emergency use of an assay under an EUA must be consistent with the terms of the Letter of Authorization, including the Scope and Conditions of Authorization.

As of December 31, 2019, active 2019-Novel Coronavirus (2019-nCoV) transmission has occurred in Wuhan City, Hubei Province, China. At that time, there were no FDA approved/cleared tests available that could detect and/or diagnose 2019-nCoV in clinical specimens in the United States. CDC recently developed a test for the detection of 2019-nCoV infections in humans and was authorized for emergency under an EUA by FDA on February 4, 2020.

Discussion

The CDC 2019-nCoV Real-Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR) assay is a molecular in vitro diagnostic test that aids in the detection of 2019-nCoV and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers and dual-labeled hydrolysis probes and control material used in rRT-PCR for the in vitro presumptive qualitative detection of 2019-nCoV RNA in upper and lower respiratory specimens.

CMS has coordinated with the CDC to ensure the establishment of performance verification specifications for assays developed and tested by CDC. Subsequent assay performance verification on site at each CDC qualified laboratory is required. Inclusion as a CDC qualified laboratory, as defined in the assay's Manufacturer's Instructions (MI) for use, is not automatic, and members must demonstrate certain capabilities and capacities, and meet established agent-specific performance standards. The CDC assay's manufacturer instructions requires at least one set of assay verification results from each laboratory. CMS encourages laboratories to further evaluate assay performance while testing continues and more patient samples with known results become available.

Assays that have been authorized for emergency use by the FDA remain subject to the CLIA regulations.

Laboratories must follow any and all manufacturer's instructions.

Verification of Performance Specifications

Upon receipt of the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel and corresponding Manufacturer's Instructions for Use (MI), CDC qualified laboratories will verify the assay performance specifications as per the Manufacturer's Instructions.

Resources

For guidance regarding the verification of performance specifications for EUA assays, please refer to [QSO 18-19-CLIA](#).

For a complete list of all assays authorized for use under EUA, please refer to the FDA link <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Laboratory Use of Assays Without FDA Emergency Use Authorization

Surveyors should determine if the laboratory is using an assay that has been authorized for emergency use by the FDA. Surveyors should notify their CMS Location if they discover a laboratory using an assay without an EUA that is testing for the same agent for which an emergency has been declared, or a modified EUA assay. The CMS Location will notify CMS Baltimore.

Contact: Questions related to this policy memorandum may be submitted to: LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/CMS Locations training coordinators within 30 days of this memorandum.

/s/
David R.
Wright Director

cc: Survey & Certifications Group Management