DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

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

Ref: S&C: 13-39-CLIA EXPIRED

DATE: November 04, 2025

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: **EXPIRED:** Guidance Regarding the Deployment of the Emergency Use Approval (EUA) Bird Flu Test (H7N9) to State Public Health Laboratories (PHLs) by the Centers for Disease Control and Prevention (CDC)

Memo Information:
Memo expiration date: 2025-11-04
Original release date: 2013-06-14

Memorandum Summary

- **Guidance for Regional Office (RO) Surveyors**—During routine biennial re-certification surveys of State PHLs, ROs must confirm that the H7N9 test was verified by each laboratory per the CDC protocol and the corresponding Clinical Laboratory Improvement Amendments (CLIA) policies and procedures are in place to ensure readiness and compliance in the event of an outbreak.
- **CDC Directions to State PHLs –** Upon receipt of the bird flu test system and corresponding instructions and information, State PHLs will verify the centrally developed test specifications in their laboratory per the CDCs guidance.
- **Food and Drug Administration (FDA) Link for H7N9:** http://www.fda.gov/medicaldevices/safety/emergencysituations/ucm161496.htm?source=govdelivery

Background

A new and virulent strain of bird flu, called H7N9, is sweeping through several areas of China and there is concern that it may eventually travel to the U.S. In its mode of prevention and preparedness, the CDC is collaborating with its Chinese counterpart and has developed a new test, modeled on previous flu strain tests, for State PHLs to check U.S. residents in the event of an outbreak in the U.S.

The CDC's H7N9 test recently received an EUA from the FDA and was deployed April 25, 2013. As a result, CMS is coordinating efforts with the CDC on test method specification establishment protocols, developed and tested by CDC, for subsequent verification on site at each of the PHLs. The CDC protocol considers the lack of U. S. patient samples and limited control materials available for validation of this test, In these circumstances, we encourage laboratories to further evaluate the test performance should more control or patient materials

become available or if the test usage increases.

For more information about the H7N9 flu and its EUA test, please visit the FDA web site at: http://www.fda.gov/medicaldevices/safety/emergencysituations/ucm161496.htm?govdelivery

Guidance for RO Surveyors

Surveys: To facilitate PHL preparedness in case of the H7N9 bird flu, ROs or the appropriate accrediting organizations (AO) must confirm during routine biennial re-certification surveys, using standard CLIA or AO policies and procedures, that each PHL has verified the CDC's test specifications, under CDC's guidance, and has established appropriate policies and procedures.

Data System: Use standard CLIA data entry protocols for survey kits.

Scope: This memo applies to only State PHLs.

If H7N9 comes to the U.S.: Further guidance to ROs and AOs will be forthcoming.

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.
Learn to:

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- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

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