DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: S&C: 15-08-CLIA EXPIRED

DATE: November 04, 2025

TO: State Survey Agency Directors

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

SUBJECT: **EXPIRED:** Information for Clinical Laboratories Concerning Possible Ebola Virus Disease

Memo Information:
Memo expiration date: **2025-11-04**
Original release date: **2014-11-07**

Memorandum Summary

- ***Testing of Persons under Investigation for Possible Ebola Virus Disease:*** The U.S. Centers for Disease Control and Prevention (CDC) has issued Interim Guidance for Specimen Collection, Transport, Testing and Submission for persons under investigation for Ebola virus disease in the United States. **Before collecting any specimens, coordinate with the State Public Health Laboratory (PHL)/CDC.**
- ***Guidance on Personal Protective Equipment (PPE) to be used by Healthcare Workers:*** Included is current CDC Guidance on PPE to be used by Healthcare Workers during Management of Patients with Ebola Virus Disease in U.S. Hospitals including Procedures for Putting On (Donning) and Removing (Doffing).
- ***Occupational Safety & Health Administration (OSHA) also provides Valuable Ebola Information.***
- ***Links to these documents, other Ebola information and a 24/7 CDC contact number are provided.***
- ***Effective Training and Communication are Essential to Safety.*** Laboratorians and other healthcare personnel handling specimens for Ebola testing are strongly urged to review and fully adopt and implement this guidance.
- ***Food and Drug Administration (FDA) Test System Information for Hospitals and Laboratories is Provided.*** This includes test manufacturer, methodology, quality control (QC) and test validation.
- ***Surveyors are to assess compliance for only CLIA. All regulations remain in effect.***

Background:

The U.S. Centers for Disease Control and Prevention (CDC) has issued interim guidance to laboratories for specimen collection, transport, testing and submission of samples and the proper use of PPE for persons under investigation for Ebola virus disease. This guidance should be used to explain to laboratorians and other healthcare personnel the biosafety requirements for collecting and performing routine testing of specimens for patients suspected of having Ebola disease and if necessary, use of PPE. **Before collecting any specimens, coordinate with the State Public Health Laboratory (PHL)/CDC.**

Topics in CDC Specimen Guidance

- Infection Control When Collecting and Handling Specimens
- Specimen Handling for Routine Laboratory Testing
- Environmental Cleaning and Disinfection
- Management of Laboratory Waste
- CDC Division of Selected Agents and Toxins Considerations
- Transporting Specimens Within the Hospital /Institution
- When Specimens Should Be Collected for Ebola Testing at CDC
- Diagnostic Testing for Ebola Performed at CDC
- Packaging and Shipping Clinical Specimens to CDC When to Contact CDC

Key Points in CDC Specimen Guidance:

- U.S. clinical laboratories can safely handle specimens from these potential patients by taking all required precautions and practices in the laboratory specifically designed for pathogens spread in the blood.
- Risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible person to determine the potential for sprays, splashes, or aerosol generated during laboratory procedures.
- Any person collecting specimens from a patient with suspected Ebola virus disease should wear appropriate PPE.
- Anyone collecting specimens from a patient should follow the procedures listed in the guidance for transporting them through the healthcare facility, clean-up of spills, storing, packaging and shipping to CDC for testing.

Effective and Ongoing Trainings and Communication using these Resources are Essential to Staff, Patient, and Surveyor Safety. If it is determined that a survey must be conducted, surveyors are expected to assess compliance with only CLIA. The laboratory director is ultimately responsible for the physical plant and environmental conditions under which the testing is performed. All CLIA regulations remain in effect and all individual State protocols must be met. Specific questions about device decontamination should be directed to specific manufacturers and CDC.

Resources and Questions

The CDC guidance for specimens and PPE, including a printable Fact Sheet, can be found at:

http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

CDC Ebola Virus Disease information and updates are available at: http://www.cdc.gov/vhf/ebola/index.html.

Occupational Safety and Health Administration (OSHA) Ebola Guidelines are available at: http://www.osha.gov/SLTC/ebola/

FDA Test System information is at: http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/UCM410 308.htm

Questions about this memorandum should be addressed to Judith Yost (judith.yost@cms.hhs.gov), Karen Dyer (karen.dyer@cms.hhs.gov) or Kathy Todd (kathleen.todd@cms.hhs.gov). Additionally, questions and concerns should also be carbon copied (cc'ed) using the SCG Emergency Preparedness Mailbox (SCGEmergencyPrep@cms.hhs.gov). Questions about the potential Ebola Virus Disease guidance/screening criteria should be addressed to the CDC. There is 24/7 CDC Ebola phone coverage at: 770-488-7100.

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

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:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

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