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: QSO-25-18-CLIA

DATE: May 30, 2025
TO: State Survey Agency Directors

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

SUBJECT: **REVISED**: Clinical Laboratory Improvement Amendments of 1988 (CLIA)- CLIA Applicability for Laboratory Testing Associated with Blood, Cells/Tissue, and Organs

Memo Revision Information:
Revisions to: *S&C-11-08-CLIA* ***Original release date:*** *January 7, 2011*

Memorandum Summary

- **CLIA Applicability Clarified:** This memorandum provides guidance on the applicability of CLIA regulations to testing associated with blood, cells/tissue, and organs for transfusion, implantation, infusion, or transplantation. *CLIA Applicability Table-Organs Intended for Transplantation has been revised to reflect the applicability of testing performed on a potential donor (Brain or Circulatory Death) for determining donor suitability and testing performed for the assessment of isolated in-vivo or ex-vivo perfusion of organ for transplant. Testing on a potential donor (brain or circulatory death) is subject to CLIA regulations, while testing perfusates from isolated in-vivo or ex-vivo organs for transplant is not subject to CLIA regulations.*
- **Based on CLIA Definition of Laboratory**: The basis for determining CLIA applicability is the definition of a laboratory in the CLIA regulations.

Background:
Individuals sometimes find it difficult to determine whether the CLIA regulations apply to particular classes of laboratory testing. For example, the Centers for Medicare & Medicaid Services (CMS) is aware of confusion related to blood, cellular products, tissue, *perfusate specimens*, and organ transplantation. As new therapies are developed and incorporated into clinical practice, particularly in the area of cellular therapies, questions about CLIA applicability are frequently encountered. The purpose of this memorandum is to clarify our current policies on CLIA applicability in these areas, and to consolidate CLIA applicability information for ease of reference.

Definitions

Blood refers to whole blood and blood components intended for transfusion.

Cells/Tissue refers to human cell, tissue, and cellular and tissue-based products manufactured for implantation, transplantation, or infusion. Examples include bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen.

Laboratory refers to a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. (42 CFR §493.2)

Organ refers to vascularized human organs for transplantation such as kidney, liver, heart, lung or pancreas.

CLIA Applicability

CLIA applicability is keyed to the definition of a "laboratory" in the CLIA regulations. If the entity conducting the testing in question qualifies as a laboratory under the CLIA definition at the time the testing in question is being conducted, the testing is subject to CLIA.

As we developed this document, we considered the various types of testing commonly performed on blood, cells/tissue, and organ donations in light of the definition of a laboratory. As much as possible, we strived to maintain consistency with prior decisions and to treat similar testing in a uniform manner, while also considering the unique aspects of each type of donation. A listing of the applicability determinations is contained in the attached tables. If an existing policy is changed due to the acquisition of new or better information, it is so noted in the chart.

We note that testing on a potential donor (brain or circulatory death) is subject to the CLIA regulations. Furthermore, perfusate specimens from isolated in-vivo or ex-vivo organs for transplant are not considered a specimen derived from the human body and therefore testing on such specimens is not subject to the CLIA regulations at this time.

Please note that this document does not address testing performed on ~~patients or~~ recipients of these donation types. Pre-transfusion or pre-transplantation testing of patients is subject to CLIA regulation. The scope of this document is limited to testing associated with blood, cells/tissue, and organs for transfusion, implantation, transplantation, or infusion.

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

Attachments- CLIA Applicability Tables:
1. Blood and Blood Components Intended for Transfusion
2. Cells/Tissue Manufactured for Implantation, Transplantation or Infusion
3. Organs Intended for Transplantation

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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CLIA Applicability Table		
Blood and Blood Components Intended for Transfusion		
Test	**CLIA Applicability**	**Comments**
Immunohematology Testing (ABO/Rh, antibody screen, antibody identification, antigen typing)	Yes	CLIA applies to antigen typing for phenotype (serologic methods) and genotype (molecular methods).
FDA-required testing for communicable diseases, e.g., HIV, hepatitis	Yes	
Additional testing for emerging infectious diseases	Yes	New tests may be implemented by the blood banking industry before FDA requires such testing.
CMV, Hemoglobin S	Yes	~~**CHANGE IN CURRENT POLICY**~~
Sterility testing	Yes	
Purity and potency tests, e.g., cell counts, pH, factor assays	No	
HLA testing	Yes	

CLIA Applicability Table		
Cells/Tissue Manufactured for Implantation, Transplantation or Infusion		
Test	**CLIA Applicability**	**Comments**
Identity testing (ABO/Rh, HLA)	No	
FDA-required testing for communicable diseases (HIV types 1 and 2, Hepatitis B, Hepatitis C, Treponema pallidum, HTLV types I and II, Chlamydia trachomatis and Neisseria gonorrhoeae)	Yes	
FDA-required testing for emerging infectious diseases	Yes	
Sterility testing (without donor notification, e.g., tissue)	No	
Sterility testing (donor notification policies are followed, e.g., stem cells)	Yes	
Purity and potency tests, e.g., TNC, CD 34 and other cell phenotype assays, cell viability	No	
Slit lamp biomicroscopy, specular microscopy	No	

CLIA Applicability Table		
Organs Intended for Transplantation		
Test	**CLIA Applicability**	**Comments**
Histocompatibility Testing (tissue typing)	Yes	*See §486.346(a)*
Testing for infectious disease	Yes	*See §486.344(c)(1)*

~~Testing a brain dead organ donor for the purpose of monitoring the viability of or maintaining the organ~~	~~Yes~~	
Testing performed on a potential donor (Brain or Circulatory Death) for determining donor suitability	*Yes*	*See §486.344(c)(2)*
Testing performed for the assessment of isolated in-vivo or ex-vivo perfusion of organ for transplant	*No*	