

QUICK REFERENCE SUMMARY

Laboratory Services *Compliance Essentials*



Rural Health Clinics must provide the four basic laboratory services below and comply with applicable CLIA requirements. Authority: 42 CFR §§491.2 and 491.9(c)(2), and 42 CFR Part 493.

1

VERIFY REQUIRED LABORATORY SERVICES

Confirm your clinic provides, at minimum, the four basic lab services listed below.



Urine testing by stick
or tablet method
(including ketones)



Blood
Glucose Testing



Pregnancy
Testing



Primary culturing for
transmittal to a
certified laboratory

2

VERIFY STAFF COMPETENCIES

Maintain competency documentation for every staff member performing laboratory testing.

- Upon hire
- At least annually
- Before implementing a new test or method



SURVEY TIP: Confirm competency records are current and ready for review.

4

VERIFY WRITTEN LABORATORY POLICY

Your policy should address:

- Tests performed on-site and where other testing is referred
- Compliance with the manufacturer's Instructions for Use
- Staff competency requirements
- Required quality control, calibration, maintenance, temperature monitoring, proficiency testing, and documentation

3

VERIFY CLIA CERTIFICATE

Confirm your CLIA certificate:

- Is current and reflects the correct certificate type
- Covers the highest complexity of testing performed
- Lists the correct clinic name, location, and
- Is updated after changes in ownership, location,
- Laboratory Director, when applicable
- Laboratory Director, or testing complexity



HELPFUL RESOURCE:

Before adding a test, use the FDA CLIA Test Categorization Database to confirm its complexity is appropriate under your clinic's current CLIA certificate.



**FDA CLIA Test
Categorization Database**

HEALTH SERVICES ASSOCIATES

10 S Division Avenue Fremont, MI 49412 | 231.924.0241 | hsagroup.net