



# CLIA Updates

Summer 2021

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## COVID-19 RELATED TESTING NOTICE

**Stop Using** Innova SARS-CoV-2 Antigen Rapid Qualitative Test - FDA Safety Communication

**Stop Using** Lepu Medical Technology SARS-CoV-2 Antigen and Leccurate Antibody Tests - FDA Safety Communication

To view current FDA 2021 Safety Communications please click the link: [2021 Safety Communications | FDA](#)

## TEST RECALL

**TOPIC:** LeadCare II, LeadCare Plus, and LeadCare Ultra Blood Lead Tests by Magellan Diagnostics:

**Class I Recall** - Due to Risk of Falsely Low Results

## Abbott i-STAT CHEM8+ and CG4+ Update

The CHEM8+ (BLUE) and the CG4+ (BLUE) cartridges were cleared by the FDA and **categorized as moderate complexity for arterial or venous whole blood** as of 2/28/2020 and 4/9/2020, respectively. With respect to the G3+ (BLUE) test cartridge, CMS is exercising enforcement discretion (as of 3/27/2020) to allow laboratories with a Certificate of Registration that applied for a Certificate of Compliance, or laboratories with a Certificate of Compliance, that have the i-STAT system, to use the G3+ (BLUE) test cartridge as a moderate complexity test. (APOC2020-001B and APOC2020-002A). Enforcement discretion will continue for the duration of the declared COVID-19 public health emergency or until the FDA has cleared/approved this test cartridge, whichever comes first. Laboratories need to follow all CLIA regulations that apply to moderate complexity testing. CMS based this decision on the FDA's determination to exercise enforcement discretion for the G3+ (BLUE) test cartridge. (APOC2020-001B and APOC2020-002A)

Link to the CMS document regarding Abbott i-STAT: [Frequently Asked Questions FAQs Abbott i-STAT \(cms.gov\)](#)

## Expired Certificates of Compliance

All active laboratories with a CLIA Certificate of Compliance or Certificate of Registration whose certificate expiration date falls on or before 09/29/2021 will be **extended to 09/30/2021**.

## FREQUENTLY ASKED QUESTIONS

**QUESTION.** What are the recommended centrifuge speed and time for sodium citrate tubes?

**ANSWER:** Follow the manufacturer's instructions or product inserts.

For BD Vacutainer sodium citrate tubes, the product insert includes the recommendation from Clinical and Laboratory Standards Institute (CLSI) to spin sodium citrate tubes at 1500 RFC for 15 minutes to achieve platelet poor plasma (platelet count < 10,000) and accurate coagulation test results.

Link to: [BD Vacutainer® Sodium Citrate Tubes FAQ - BD](#)

**QUESTION.** What are Montana's requirements for testing personnel?

**ANSWER:** CLIA requires the qualifications of testing personnel to meet the following standards with 42 CFR 493:

**High Complexity Laboratories:** §493.1489 Standard; Testing personnel qualifications.

Cytology: §493.1483 Standard; Cytotechnologist qualifications.

**Moderate Complexity Laboratories:** §493.1423 Standard; Testing personnel qualifications.

Waived tests have no personnel qualification requirements.

Link to CLIA Regulation: [CLIA Code of Federal Regulations](#)

**Montana requires licensure for testing personnel.**

Refer to the following Montana Licensing Boards for specifics:

Link to Montana Clinical Laboratory Science Practitioners: [Clinical Laboratory Science Practitioners \(mt.gov\)](#)

Link to Montana Board of Nursing: [Board of Nursing \(mt.gov\)](#)

Link to Montana Board of Medical Examiners: [Board of Medical Examiners \(mt.gov\)](#)

Link to Montana Board of Respiratory Care Practitioner: [Respiratory Care Practitioner \(mt.gov\)](#)

## Common Deficiencies (Non-Waived)

### **D5403**

**§493.1251 Standard: Procedure manual.**

The procedure manual must include the following when applicable to the test procedure:

- (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242.
- (2) Microscopic examination, including the detection of inadequately prepared slides.
- (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.
- (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
- (5) Calibration and calibration verification procedures.
- (6) The reportable range for test results for the test system as established or verified in §493.1253.
- (7) Control procedures.
- (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
- (9) Limitations in the test methodology, including interfering substances.

(10) Reference intervals (normal values).

(11) Imminently life-threatening test results, or panic or alert values.

(12) Pertinent literature references.

(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

**HINT: Does your reference ranges listed in the patient's result report match your procedure, instrument manual, or insert?**

## D5439

### §493.1255 Standard: Calibration and calibration verification procedures.

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following Perform and document calibration verification procedure -

(b)(1) Following the manufacturer's calibration verification instructions.

(b)(2) Using the criteria verified or established by the laboratory under §493.1253(b)(3)--

(b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

**(b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and**

**(b)(3) At least once every 6 months and whenever any of the following occur:**

(b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

**HINT: Check your chemistry electrolytes (Na, K and Cl) and start to include the i-STAT Chem 8+. CG4+ and G3+.**

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Questions about the information discussed in this CLIA Update?

The Montana CLIA Program would love to answer them. Contact us at:

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If you would like to be added to the emailing list for future correspondence from the Montana CLIA program, please send an email to Michelle Griffin at [Michelle.Griffin@mt.gov](mailto:Michelle.Griffin@mt.gov)

References:

[CLIA \(mt.gov\)](http://CLIA.mt.gov)

[Clinical Laboratory Improvement](#)

[Amendments \(CLIA\) | CMS](#)

[CMS CLIA Federal Regulations 42 CFR 493](#)