

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2176291	(X3) Date Survey Completed 10/05/2022
Name of Provider or Supplier Thomasville Regional Medical Center	Street Address, City, State 300 Medical Park Drive, Thomasville, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Beckman Coulter DxH 600 calibration records and an interview with the General Supervisor, the laboratory failed to ensure calibration results were within the manufacturer's acceptable limits for one of four calibration procedures performed in 2021-2022. The findings include: 1. A review of calibration records for the Beckman Coulter DxH 600 Hematology analyzer revealed failures on the 7/29/2022 calibration for White Blood Cells (WBC) and Red Blood Cells (RBC). However, there was no documentation the unacceptable calibration was repeated. 2. During an interview on 10/5/2022 at 1:15 PM, the General Supervisor confirmed the above findings.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification</p>

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.

This STANDARD is not met as evidenced by:
Based on a review of Beckman Coulter DxC AU 700 calibration verification records and interviews with the General Supervisor, the laboratory failed to perform and document calibration verification procedures at least once every six months as specified by CLIA requirements. The surveyor noted the laboratory failed to perform and document one out of two calibration verifications due in 2021 on the Beckman Coulter DxC AU 700 chemistry analyzer. The findings include: 1. A review of Beckman Coulter DxC AU 700 chemistry analyzer records revealed calibration verifications were performed on 12/10/2020, 5/12/2021, and 7/19/2022. There was no documentation of a calibration verification performed the second half of 2021. 2. During an interview on 10/5/2022 at 10:30 AM, the General Supervisor explained the missing calibration verification occurred under a previous Laboratory Manager. 3. During an interview on 10/18/2022 at 4:30 PM, the General Supervisor confirmed only one calibrator was used to calibrate each analyte run on the DxC AU 700. The surveyor explained any analyte calibrated with less than three calibrators must have a semi-annual calibration verification.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on reviews of Serum Infectious Mononucleosis (Mono) Quality Control (QC) logs, the Policy and Procedure Manual and an interview with the General Supervisor, the laboratory failed to ensure two levels of QC were performed and documented each

day of patient testing in the absence of a valid Individualized Quality Control Plan (IQCP). The surveyor noted 33 patient tests were performed from January 2021 to October 5, 2022. The findings include: 1. A review of kit test logs revealed QC for Serum Mono was only performed with each new kit lot number. A review of logs from January 2021 to October 5, 2022 revealed the laboratory performed 33 patient Mono tests. 2. During an interview on 10/4/2022 at 2:00 PM, the General Supervisor confirmed QC for Serum Mono was performed each time a new kit was first opened. 3. A review of the Policy and Procedure Manual revealed a Risk Assessment for Serum Mono had been performed, however, the laboratory failed to implement a Quality Control Plan and a Quality Assessment Plan as required for a complete IQCP to allow for decreased QC frequency. Per CLIA regulations a valid IQCP must be implemented, or the laboratory must perform QC each day of patient testing. 4. During an interview on 10/5/2022 at 11:50 AM, the General Supervisor confirmed the laboratory did not have a Quality Control Plan or Quality Assessment in the IQCP available for the surveyor's review.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on a review of personnel evaluation records and an interview with the General Supervisor, the Technical Consultant failed to ensure testing personnel had documentation of training before performing patient tests. This was noted for three out of eight Testing Personnel listed on the Form CMS-209 (Laboratory Personnel Report) from the date of the last survey (9/2/2020) to the date of the current survey (10/5/2022). The findings include: 1. A review of personnel evaluation records revealed the following: a) Initial training was not performed and documented for Testing Personnel #3 and Testing Personnel #6. b) Initial training for Testing Personnel #1 was performed by Testing Personnel #3 instead of the Technical Consultant. 2. During an interview on 10/5/2022 at 2:30 PM, the General Supervisor confirmed the above findings.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of personnel evaluation records and an interview with the General Supervisor, the Technical Consultant failed to evaluate and document the performance of individuals responsible for moderate complex testing at least semi annually during the first year of patient testing. This was noted for one out of eight Testing Personnel from the date of the last survey (9/2/2020) to the date of the current survey (10/5/2022). The findings include: 1. A review of personnel records revealed the Technical

Consultant failed to perform and document the semi-annual competency evaluation (due February 2022) for all moderate complexity testing for Testing Personnel #6. 2. During an interview on 10/5/2022 at 2:30 PM, the General Supervisor confirmed the above findings.