Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2176291	09/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Thomasville Regional Medical Center	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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the Hematology Quality Control (QC) records, Blood Bank (BB) QC records, and an interview with General Supervisor (GS), the laboratory utilized expired Hematology QC and BB reagent prior to patient testing. This was noted for 1 of the 30 days reviewed in June 2023 for the expired Hematology QC, 15 patients Complete Blood Count (CBC) were affected; Expired BB reagents were utilized for 4 of the 31 days in March of 2024, 3 patients were affected. The findings include: 1. A review of the Hematology QC logs revealed the laboratory performed CBC QC on 12-17-2023 using levels one (lot 123175130) and two (lot 133185130) with expiration date of 12-16-2023. A review of the patient records indicated 15 patients were affected. 2. A review of the BB QC logs revealed the laboratory utilized an anti-B on 06-29-2024 with expiration date of 06-25-2024. BB worksheet indicated one patient was affected. 3. Additional review of the BB QC logs revealed the laboratory utilized an anti-A on 03-19-2024, 03-22-2024 and 03-23-2024 with expiration date of 03-16-2024. BB worksheet indicated two patients were affected. 4. During the exit interview on 9/18/24 at 12:16 PM, the GS confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Sysmex CS 2500 analyzer maintenance records, Sysmex CS 2500 user manual, Opti-CCA analyzer maintenance records, Opti-CCA user manual, microscopes maintenance records, and an interview with the General Supervisor (GS), the laboratory failed to perform and document maintenance according to the manufacturer's established requirements and the laboratory's policy and procedures. This was noted for: a) The Sysmex CS 2500 Coagulation analyzer monthly maintenance was not performed for 5 out of 20 months reviewed in 2023 through 2024. b) The Opti-CCA Blood Gas analyzer weekly maintenance was not performed from the date of the last survey (10/5/2022) to the current survey (9/17/2024) c) The microscope maintenance was not performed from the date of the last survey (10/5 /2022) to the date of the current survey (9/17/2024). The findings include: 1. A review of the maintenance logs for the Sysmex CS 2500 Coagulation analyzer revealed no evidence of documented monthly filter maintenance performed for the following months: A) 2023: February, March, July, and November. B) 2024: May. 2. A further review of the Sysmex CS 2500 user manual revealed on page 12-3, "Monthly Maintenance: Clean the filters and document...." 3. A review of the maintenance logs for the Opti-CCA Blood Gas analyzer revealed no documentation of weekly maintenance performed per the manufacturer's established requirements from the date of the last survey (10/5/2022) to the current survey (9/17/2024). 4. A further review of the Opti-CCA user manual revealed on page 7-1, "7.2 Weekly Maintenance: Once a week, the Sample Measurement Chamber (SMC) must be cleaned." 5. A review of the lack of microscope maintenance revealed no evidence of documented maintenance for the microscope from the time of the previous survey (10/5/2022) to the date of the current survey (10/5/2022). 6. During an interview with the GS on 9/17/24 at 2:44 PM, the GS stated the last preventative maintenance was performed on 2/5/23, no other maintenance was performed or documented since then. 7. The GS confirmed the above findings during the exit interview on 9/18/24 at 12:16 PM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on a review of the Alere Triage D-Dimer Calibration Verification (CV) records, the policy and procedures, and an interview with the General Supervisor (GS), the laboratory failed to perform CV procedures on D-Dimer at least every six months as specified by laboratory's policy and procedure. This was noted for 1 of 4 possible CV's missed from 2022 through 2024. The findings include: 1. A review of the Alere Triage D-Dimer records revealed CV procedures were not performed according to the CLIA requirement for analytes calibrated with less than three calibrators for the following dates: a. The 1st CV was performed on 6/28/2022, 10 months later, b. The 2nd CV was performed on 4/20/2023, 9 months later, c. The 3rd CV was performed 1/4/2024, 8 months later, d. The 4th CV was performed on 9/4 /2024. 2. A further review of the D-Dimer Triage policy and procedure revealed, "Calibration verification studies: Perform semiannual calibration verification testing...." 3. During the exit interview on 9/18/2024 at 12:16 PM, the GS confirmed these findings.
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 a review of the D-Dimer Quality Control (QC) logs, D-Dimer Quality Assessment Plan, and an interview with the General Supervisor (GS), the laboratory failed to ensure two levels of monthly QC were performed and documented as stated in the procedure manual. The surveyor noted the missing QC on 2 of the 12 months reviewed in 2023. The finding include: 1. A review of the D-Dimer Quality Control (QC) logs revealed no evidence of documented QC performed in November 2022 and June 2023 on the Alere Triage analyzer. 2. A further review of the D-Dimer Quality Assessment Plan revealed, "5. Review quality control results, including QC..." 3. During an interview on 9/18/2024 at 10:48 AM, the GS confirmed these findings.