Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641802	07/02/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lake Martin Community Hospital	201 Mariarden Road, Dadeville, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on a review of the Alere Triage Quality Control records for D-Dimer testing and an interview with the Technical Supervisor (TS), it was determined the laboratory failed to retain the manufacturer's QC assay information sheets (package inserts) for all but the current lot numbers in use from the date of the last survey, 05-19-2023, to the date of the current survey 07-02-2025. The findings include: 1. A review of D-Dimer QC records revealed no retention of the manufacturer's assay information sheets (package inserts) except the sheets for the current lot number of controls in use which were posted on the wall where the Alere Triage analyzer was located. 2. During Day 2 exit conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM, the TS confirmed the above findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on the review of the American Proficiency Institute (API) Proficiency Testing (PT) records, the laboratory failed to ensure: A) Submission of PT results before the postdate (Refer to D5215). B) Failed to implement effective corrective actions for unsuccessful PT events (Refer to D5217).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, corrective action documentation, and an interview with the Technical Supervisor (TS), the laboratory failed to ensure PT results were submitted before the postmark due date. This was noted for 1 of 34 events reviewed in 2023-2025. The findings include: 1. A review of the API PT records revealed a score of 0 percent and "Failure to participate" on 2025 Microbiology 1st Event for with a deadline date of 02-26-2025. 2. During Day 2 exit conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM, the TS confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Technical Supervisor (TS), the laboratory failed to implement an effective corrective action for the recurring unsuccessful PT scores on the Erythrocyte Sedimentation Rate (ESR), a non-regulated analyte performed on the Diesse MINI-CUBE. The surveyor noted the PT evaluation failures occurred in three of the seven Hematology events from 2023-2025. The findings include: 1. A review of the API PT records revealed the ESR PT evaluation scores for the following events: A) 2023 Hematology Second Event, ESR 0 percent B) 2024 Hematology First Event, ESR 50 percent C) 2024 Hematology Third Event, ESR 50 percent 2. During Day 2 exit conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM, the TS confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic

	systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation during the laboratory tour, reviews of the Sysmex XN-550 Hematology analyzer, the Siemens CA-600 Coagulation analyzer, Dimension EXL-200 Chemistry analyzer, Opti CCA-TS2 analyzer records, Calibration-Verification (C-V) records, Triglycerides Quality Control (QC) records, environmental logs and interviews with the Technical Supervisor, the laboratory failed to ensure: 1. Thermometers for the refrigerator and freezer where the reagents and Quality Control (QC) materials were stored have not exceeded the due date indicated by the manufacturer. (Refer to 5417) 2. Manufacturer's maintenance requirements were performed and documented on the Sysmex XN-550 Hematology analyzer, Siemens CA-600 Coagulation analyzer, and Dimension EXL-200 Chemistry analyzer. (Refer to 5429) 3. C-V were performed and documented semi-annually on the Siemens Dimension EXL-200 and the Opti CCA-TS2. (Refer to D5439) 4. QC for the Triglycerides were performed and documented prior to patient testing. (Refer to D5481) 5. Laboratory's temperatures and humidity logs from June 2023-December 2023 were available for review. (Refer to 5413)
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on reviews of the environmental logs and an interview with the Technical Consultant (TC) and Testing Personnel 5 (TP5), the laboratory failed to provide records of the Room Temperatures (RT), Humidity, and temperatures for the refrigerators, freezers, and Blood Bank (BB) Dry Bath. The surveyor noted there were no temperature and humidity documentation available for review upon request from June 2023 through December 2023. The findings include: 1. A review of the environmental logs revealed the laboratory failed to provide documentation of the following for seven months in 2023: A) RT and Humidity B) Freezer C) BB Dry Bath D) Chemistry and Arterial Blood Gases Refrigerators E) BB Refrigerator 2. During Day 2 exit conference with the CEO, Hospital Administrator, TS, and Testing Personnel #5 on 07-02-2025 at 4:00 PM, TS confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	(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 direct observation during the laboratory tour and an interview with the Technical Supervisor (TS), the laboratory utilized two thermometers after expiry from the date of the last survey on 05-19-2023 through the date of the current survey on 07-02-2025. The findings include: 1. During the laboratory tour with the TS on 07-01-2025, at approximately 8:12 AM, the surveyor observed the temperature of the refrigerator where the Hematology and Coagulation Quality Control (QC) materials was one degree Celsius. The surveyor noted on the box for the QC materials, the manufacturer listed the temperature requirement to be two to eight degrees Celsius. When the surveyor checked the Fisherbrand thermometer's due date, the attached label indicated, November 2022. 2. Based direct observation, the freezer Excursion Trac thermometer where the Chemistry and Coagulation QC materials were stored had a due date of March 2024. 2. The TS confirmed the above findings during Day 2 exit conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 reviews of the Hematology, Coagulation and Chemistry maintenance logs, the manufacturers' user manual, and an interview with the Technical Supervisor (TS), the laboratory failed to perform and document weekly, monthly, and quarterly maintenance for the three analyzers. This was noted from 2023 to 2025. The findings include: 1. A review of the 2023-2025 maintenance logs revealed no documentation of maintenance for the following analyzers. A) Hematology Sysmex XN-550; missing weekly maintenance from March to May 2025. B) Coagulation Siemens CA-600; missing daily, weekly, and quarterly maintenance from May to December 2023. C) Chemistry Siemens Dimension EXL; missing weekly and monthly maintenance from March to May 2025 2. A review of the manufacturers' user manuals revealed the following requirements on maintenance. A) Sysmex XN-550 Quick Guide page 12, "Weekly Maintenance-Routine Cleaning" B) Siemens CA-600 Quick Reference Guide, page 8, "Daily maintenance 1. Turn power off, wait 15 seconds, and turn on..." page 9, "Weekly maintenance, Clean instrument exterior..." "Clean instrument interior..." page 10, "Quarterly maintenance, LED calibration, "Cleaning the rinse container..." C) Siemens Dimension EXL Resource Guide, weekly and monthly maintenance, pages 32-33, "HM Weekly Maintenance, Clean HM Wash Probes..." pages 34-44, "HM Monthly Maintenance, Stylet HM Wash Probes..." 3. During Day 2 exit conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM, TS confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	(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 reviews of the Chemistry and Blood Gases Calibration-Verification (C-V) records, and an interview with the Technical Supervisor (TS), the laboratory failed to perform and document C-V procedures at least every six months as required by CLIA regulations. The surveyor noted no documentation for one of the two Electrolytes and Blood Gases C-Vs in 2024 after the previous survey of 05-19-2023. The findings include: 1. A review of the calibration records for the Electrolytes on Dimension EXL and Blood Gases on Opti-CCA-TS2 analytes were calibrated with less than three calibrators. As per CLIA regulatory requirements, these analytes must have a semi-annual C-V. 2. A review of the C-V records revealed the following C-V performed and documented: A) Electrolytes C-V, 09-22-2023; 06-17-2024; 02-25-2025, one missing in 2024 B) Blood Gases C-V, 08-31-2023; 06-18-2024; 03-10-2025, one missing in 2024 3. During Day 2 exit conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM, TS confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Siemens Dimension EXL Quality Control (QC) logs provided during the survey, and an interview with the Technical Supervisor (TS), the laboratory failed to ensure two levels of Triglycerides QC were performed and documented each day of patient testing. The surveyor noted no QC was performed for 9 out of the 31 days in October 2024. The findings include: 1. A review of the Siemens Dimension EXL QC logs revealed the laboratory failed to perform the required two levels of Triglycerides QC prior to patient testing for the following days in October 20-22, 2024, October 24-26, 2024, and October 28-30, 2024. The number of patients performed when QC was not performed and documented was not provided by the TS or TP5 when requested by the surveyor during the survey. 2. During the Day 2 exit

	conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM, TS confirmed the above findings.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (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; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the Technical Supervisor (TS), the TS failed to evaluate and document the semi-annual and annual competency assessments for Testing Personnel (TP) responsible for the moderate and high complexity testing in the laboratory. The surveyor noted four of the eight TP had no documentation of competency assessments from the date of the last survey, 05-19-2023 to the date of the current survey, 07-02-2025. The findings include: 1. A review of personnel records for TP listed on the CMS-209 Form (Laboratory Personnel Report) revealed the TS failed to perform and document the semi-annual and annual competency assessments for TP2, TP4, TP7, TP8 from 2023-2025. Semi-annual and annual competencies for these TPs were performed by TP5. 2. During Day 2 exit conference with the CEO, Hospital Administrator, TS and Testing Personnel #5 on 07-02-2025 at 4:00 PM, the TS confirmed the above findings.