Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483535	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lakeland Medical Associates	117 Medical Circle, Athens, TX	

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
D0000	The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, corrective actions, and interview with facility personnel, the laboratory failed to take remedial action for unsatisfactory low-density lipoprotein (LDL)scores from the second event of 2021 (1 of 3 events per year). The findings included: 1. Based on review of the American Proficiency Institute (API) testing scores, the laboratory received the following scores: 2nd event 2021 low-density lipoprotein (LDL)- 20 percent Scores less than 80 percent constitute unsatisfactory analyte performance. 2. Laboratory submitted results and acceptable ranges are as follows: Low-density lipoprotein (LDL) Lab value Acceptable range Performance 24 17-23 unacceptable - high 37 25-34 unacceptable - high 51 38-50 unacceptable - high 45 33-45 acceptable 60 44-59 unacceptable - high 3. The laboratory's corrective action documentation included the following comments: Could patient results have been affected? If so, explain course of action: The laboratory wrote "Patients should not be affected, delta checks are pretty consistent." Under Corrective Action, the laboratory wrote: "Reran API samples and they passed.

	Quarterly and monthly maintenance have recently been performed and that may have contributed to it." 4. In an interview in the conference room on 09/21/2021 at 11:58 hours, the laboratory manager stated they had not evaluated any patient results that may have been affected prior to the maintenance procedures that may have brought the repeated API samples into acceptable ranges.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 surveyor observations, review of laboratory quality control records, and interview with facility personnel, the laboratory failed to ensure Freezer 1 temperatures were acceptable for storage of quality control materials for 31 days between January 2021 and June 2021. The findings included: 1. At 15:47 hours on 9 /21/2021 in the laboratory, the surveyor observed the following quality control materials stored in Freezer #1: Bio-Rad Liquid Assayed Multiqual - Lot 45871 and Lot 45873 - 4 boxes total. Storage: -20 degrees Celsius to -70 degrees Celsius. 2. Based on review of the laboratory's log "Temp-Chex Temperature Record", the following temperatures were outside of acceptable limits for storage of the Bio-Rad Liquid Assayed Multiqual control materials: 1/6/2021 -15C 1/8/2021 -19C 1/25/2021 -18C 2/4/2021 -18C 2/5/2021 -19C 2/8/2021 -19C 2/9/2021 -18C 2/10/2021 -18C 2/11 /2021 -19C 3/11/2021 -19C 3/19/2021 -18C 3/22/2021 -19C 3/23/2021 -19C 3/24 /2021 -19C 3/25/2021 -19C 3/26/2021 -15C 3/29/2021 -18C 3/30/2021 -18C 4/2/2021 -19C 4/5/2021 -19C 4/20/2021 -19C 4/21/2021 -19C 5/11/2021 -19C 5/17/2021 -18C 5/18/2021 -18C 5/21/2021 -19C 5/28/2021 -16C 6/7/2021 -15C 6/8/2021 -15C 6/9 /2021 -19C 6/15/2021 -19C 3. In an interview in the laboratory at 15:47 hours on 9/21 /2021, the Laboratory Manager stated she thought the low readings were not accurate and testing personnel may not be reading the thermometer accurately.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, and interview with facility personnel, the laboratory failed to monitor the accuracy and precision over time of the Accu-Sed Plus quality control materials for 9 of 9 months reviewed between December 2019 and August 2021. The findings included: 1. Based on review of the laboratory procedure "Lakeland Medical Associates Excyte mini ESR analyzer Sedimentation Rate Quality Control", under Procedure, the document stated "QC results must be within appropriate QC ranges that are provided in the QC package insert. Any results that are not within range must be repeated." 2. Based on review of forms titled "Sedimentation Rate QC" between December 2020 and August 2021, quality control was run daily and evaluated for acceptability, but no measure of accuracy and precision over time were evaluated and documented. 3. In an interview at 11:24 hours on 9/21/2021 in the conference room, the laboratory manager stated the laboratory had not evaluated the accuracy and precision over time for the Accu-Sed Plus quality control materials.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor observations, review of quality control records, and interview with facility personnel, the laboratory failed to set acceptability ranges for 2 of 3 quality control materials for 4 of 4 weeks between 8/21/2021 and 9/22/2021. The findings included: 1. Based on surveyor observations at 11:20 hours on 9/22/2021 in the laboratory, the surveyor observed the quality control acceptability limits for 2 of 3 levels of quality control the Sysmex-1000i hematology analyzer were set to 100%. Examples: Control Level 1 -QC-12080804 - Red Blood Cell count (RBC) Target: 2.28 Lower limit: 0.0 Upper limit: 4.56 (100% of the target 2.28) Control Level 1 - QC-12080804 Platelet count Target: 58 Lower limit: 0.0 Upper limit: 116 (100% of the target 58) Control Level 3 - QC-12080806 Red Blood Cell count (RBC) Target: 5.14 Lower limit: 0.0 Upper limit: 10.28 (100% of the target 5.14) Control Level 3 - QC-12080806 Platelet count Target: 529 Lower limit: 0.0 Upper limit: 1058 (100% of the target 529) 2. Based on review of the quality control records, the quality control lots Control Level 1 -QC-12080804 and Control Level 3 - QC-12080806 were in use between 8/21/2021 and the date of the observation 9/22/2021 with percent limits set to 100 percent for 2 of 3 quality levels. 3. In an interview at 11:20 hours on 9/22/2021 in the laboratory, the laboratory manager confirmed the percent limits for analytes on Level 1 -QC-12080804 and Control Level 3 - QC-12080806 were in use between 8/21 /2021 and the date of the observation 9/22/2021 and were set to 100 percent, resulting

	in every lower limit being 0.0 and every upper limit being 100 percent of the target value.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory quality control records, corrective action records, and interview with facility personnel, the laboratory failed to evaluate all patients tested back to the last acceptable control for 23 patients tested for analyte Cholesterol on 8/6 /2021 and 29 patients tested for Albumin on 9/10/2021. The findings included: 1. Based on review of corrective action documentation for the Beckman AU chemistry analyzer, the laboratory documented corrective action steps when quality control was outside of acceptable limits. The laboratory did not have documentation of evaluating patients back to the last acceptable control. On 8/9/2021, analyte Cholesterol quality control level two was outside of acceptable limits. The testing personnel repeated Cholesterol with a fresh control and the values remained outside of laboratory acceptability ranges. The analyte Cholesterol was recalibrated. Following recalibration, all quality control was within limits. There was no documentation of evaluating patients back to the last acceptable control after recalibrations and repeating quality control. The last acceptable set of Cholesterol controls were on 8/6 /2021 and 23 patients were tested for the analyte Cholesterol. On 9/13/2021, the analyte Albumin quality control level two was outside of acceptable limits. Albumin was recalibrated. Following the recalibration, Albumin quality control was still outside of laboratory established limits. The testing personnel then replaced the on-board reagent, recalibrated, and repeated quality control, which fell within established limits. There was no documentation of evaluating patients back to the last acceptable control after recalibrations, replacing reagents, recalibrating the new reagent, and repeating quality control. The last acceptable set of Albumin controls were on 9/10 /2021 and 29 patients were tested for the analyte Albumin. 2. In an interview at 15:27 hours on 9/21/2021, the laboratory manager confirmed the laboratory did not assess patients back to the last acceptable control when documenting corrective actions for quality control values that are outside of acceptable limits.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of policies and procedures, patient final reports, and interview with

	facility personnel, the laboratory failed to ensure pertinent reference intervals or normal values were available on the final patient test reports for five of five patient test reports reviewed. The findings included: 1. Based on review of the laboratory policy "Lakeland Medical Associates Urine Microscopic", the procedure stated the following: "Reporting Results White blood cells (WBC), Red blood cells (RBC), and bacteria should be reported as number per high power field. Epithelial cells and casts should be reported as number per low power field, using a 10-15 field average. Bacteria should be reported as none, few, I+, 2+, 3+, 4+. Crystals are reported I+, 2+, 3+ and type. Enter results in LabDaq and deliver report to ordering doctor either immediately, if ordered as STAT or patient waiting or put in folder for later delivery. " 2. Based on review of five of five patient final reports for urine microscopic examinations, results for various microscopic findings were recorded, but pertinent reference values were not included on the report. 3. In an interview at 10:26 hours on 9 /22/2021 the conference room, the laboratory manager confirmed the final patient reports for urine microscopic examinations did not include pertinent patient normal ranges/values.