

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0021448	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Mountain Lakes Medical Center	Street Address, City, State 162 Legacy Point, Clayton, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 06, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the inspection of the reagents in the main refrigerator during the laboratory tour and staff interview, the laboratory's Testing Personnel (TP) did not label in-use control material appropriately at the time of survey on 03/06/2024. Findings; 1.) Observation of the reagents in the reagent refrigerator revealed that the (TP) did not place an open and/ or expiration date on the Chemistry Multi Qual Control vials (Levels 1 & 2) in- use, on day of survey , 03/06/2024.. 2.) Testing Personnel (TP) poured Hemoglobin (HgbA1C) Controls levels 1 & 2 into unlabeled insert cups without proper labelling to identify the contents of the insert cups on day of survey, 03 /06/2024. 3.) Interviews with staff and laboratory manager, at approximately 10:45 am, in the lab, confirmed the findings on the day of survey, 03/06/2024.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

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:

Observation during the laboratory tour, maintenance documents review and staff interviews, revealed the laboratory failed to perform annual calibrations for its pipettes as required by the Standard Operating Procedures (SOP) in 2023. Findings: A review of maintenance and equipment calibration records, on the day of survey, 03/06/2024, revealed the following: 1.) MLA pipettes (10ul, 25ul, 50ul, 100ul, 700ul, 1000ul) had the calibration expiration date of 03/31/2023. 2.) ID TIP Master brand pipettes (25ul, 50ul, 125ul) had the calibration expiration date of 03/31/2023. 3.) Interviews with staff and laboratory manager (TP# 7 CMS 209) in the conference room, on 03/06/2024, at approximately 3:00 PM confirmed the above findings.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's 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:

A review of the Chemistry daily Quality Control (QC) and maintenance records confirmed that the laboratory released patient results for two (2) out of nineteen (19) patients without evidence of (QC) being performed in 2024. Findings: 1.) A review of the daily chemistry (QC) from Dimensions EXL analyzer review revealed, control records and patient testing records for the analyte FT4 from 01/01/2024 through 03/05/2024 confirmed two (2) out of nineteen (19) patients tested were resulted without evidence of (QC) being performed on the day of testing. Patients affected were MR*77604, resulted on 02/02/2024, and MR*59932, resulted on 03/04/2024. 2.) An interview with the laboratory manager (TP#7CMS 209), in the conference room, at approximately 3:00 PM, on March 06, 2024 confirmed the above findings in 2024..

D6075

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(6)

Each individual performing moderate complexity testing must document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:

A review of Chemistry maintenance records review and staff interview confirmed the laboratory failed to perform and document corrective action for out of range cuvette testing temperatures for the Dimensions EXL 200 Chemistry analyzers from 2022 to 2024. Findings: 1.) A review of maintenance records and manufacturer's guidelines revealed that the cuvette operation temperatures should be between 36.8 to 37.2 degrees Fahrenheit for the Dimensions EXL Chemistry analyzers. The cuvette temperatures for EXL 200 analyzer, serial #275204, put into use in September 2022, revealed that the cuvette testing temperatures were consistently above 37.5 thru March 2024. 2. A review of the additional EXL 200 analyzer, #DR275246, put into use on 01

/17/ 2024, revealed that the cuvette testing temperatures were consistently above >37.4 thru March 2024. 2.) Interview with the lab manager (TP # & CMS 209) in the conference room, on 03/06/2024, at approximately 03:30 PM confirmed the above findings for years 2022 to 2024.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for 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; (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:
A review of the Quality Control maintenance documents and staff interviews revealed that the Lab Director, who is also the Technical Supervisor(TS), failed to ensure proper Quality Assurance (QA) procedurew weere followed. These procedures include the routine review of instrument (QC) and maintenance data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA) forthe years 2022- 2024. Findings include: 1. A review of (QC) and (QA) documents revealed the Laboratory Director who is also the (TS) did not implement a QA monitor program to identify and correct problems in the laboratory as required in years 2022 - 2024. 2. An interview with the Lab Manager (TP#7 CMS209), in the conference room, on 03/06/2024, at approximately 4:00 PM, confirmed the Technical Supervisor (TS) and Lab Director did not implement adequate (QA) monitoring in years 2022 thru 2024.