Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0021448	04/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mountain Lakes Medical Center	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	On May 26, 2022 an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of Proficiency Testing (PT) records and interviews with the Technical Consultant(TS) (TP#2 CMS 209), the laboratory director failed to review and attest that PT samples were tested in the same manner as patient specimens. Findings include: 1. Review of the American Proficiency Institute (API) PT records revealed the laboratory failed to provide or retain the signed attestation forms for API events: API 1st Events of Chemistry, Hematology/ Coagulation, Immunology and ImmunoHematology and Microbiology in 2021. 2nd Event of Hematology/ Coagulation in 2021. 2. An interview with the TS (TP#2 CMS 209) on 04/26/2022 at approximately 1:15 pm in the review room confirmed the PT documents were not reviewed and signed by the laboratory director in 2021.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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 review of personnel records and interview with the Technical Supervisor (TS), the laboratory did not have a competency assessment policy meeting the Clinical Laboratory Improvement Amendment (CLIA) six standards Criteria for testing personnel. Findings include: 1. Testing Personnel (TP) records review revealed that competency assessment was performed in 2020 and 2021; however, the assessment did not contain explicitly the six CLIA Standard Criteria for personnel competency assessments. 2. An interview with the (TS) (TP#2 CMS 209) on 04/26 /2022, at approximately 12:30 pm in the review room confirmed that the laboratory competency assessment policy does not contain all the CLIA competency six standard criteria in 2021 and 2022.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on Proficiency Testing(PT) document review and staff interview, the laboratory director (LD) failed to ensure all PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance to identify any problems that require corrective action. Findings include: 1. PT document review revealed that the LD failed to ensure all PT reports were reviewed in 2020 and 2021. Evaluation reports for 2021 Hematology/ Coagulation 2nd Event and Immunology/ Immunohematology 3rd Event 2020 were not signed by designee or Lab director. 2. During the interview with the laboratory's TS (TP#2 CMS 209) on 04/26/2022, at approximately 1:20 pm in the review room, it was confirmed the LD did not evaluate all PT results in 2020 and 2021.