Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1058704	07/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Reagan Medical Center Of Hamilton Mill	3685 Braselton Highway Suite 100, Dacula, 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 July 27, 2023. 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:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the laboratory tour and staff interview, the laboratory failed to ensure two identifiers were present on 3 out of 3 urine specimen's, during the time of the survey. The Findings include: 1. During the laboratory tour and observation, it was revealed that there were 3 out of 3 urine specimens with one identifer on the specimen urine cups. 2. During an interview with Testing Personnel #1(CMS-209) on July 27, 2023 at 12:35 PM, in the laboratory, confirmed there were 3 out of 3 specimens with one identifier on the specimen cups.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	Based on review of the American Proficiency Institute(API) proficiency test (PT) records and interview with the staff, the laboratory testing personnel and lab director failed to attest to performing the proficiency testing for hematology. The Findings include: 1. API(PT) document review revealed that the Testing Personnel and the Laboratory Director failed to sign the attestation statement document for hematology 2022 (2nd Event). 2. During an inteview with Testing Personnel #1 (CMS-209), on July 27, 2023, at approximately 11:25 AM, in the breakroom, confirmed that the laboratory failed to sign the attestation statement document for hematology 2022 (2nd Event).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 review of the American Proficiency Institute(API) proficiency test (PT) records and interview with the staff, the laboratory failed to evaluate, review, and attest the proficiency test for hematology in 2022 with the 2nd event. The Findings include: 1. Review of the API-PT records revealed the Laboratory Director(LD) and Testing Personnel (TP) failed to sign the attestation statement document for hematology in 2022-2nd Event. 2. Review of the APT-PT records revealed the Laboratory Director(LD) did not evaluate, review, or attest the proficiency test for hematology in 2022-2nd Event. 2. During an inteview with Testing Personnel #1 (CMS-209) on July 27, 2023 at approximately 11:25 AM, in the breakroom, confirmed that the Laboratory Director(LD) and Testing Personnel(TP) failed to sign the attestation statement document for hematology 2022-2nd Event.