Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0959517	**(X3) Date Survey Completed** 07/30/2024
Name of Provider or Supplier Reagan Medical Center	**Street Address, City, State** 2878 Five Forks Trickum Rd Ste 2-A, Lawrenceville, 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 September 11, 2024 an off site follow-up review was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP) and staff interviews, the laboratory director (LD) failed to review, date or approve all current procedures in the laboratory from July 2022 thru the date of inspection, July 30, 2024. Findings: 1.) Hematology procedure manual review revealed analyzer (Sysmex PocH 100 i) operating manuals were used in lieu of a procedure manual. The use of the operating manuals were not authorized, signed, or dated by the laboratory director, prior to use. 2.) This findings were confirmed by the office manager, on 07/30/2024, in the review room, at approximately 2:05 PM.
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 patients final reports on Sysmex Poch 100 i hematology analyzer's screen results, it was determined that the laboratory director and technical consultant (TC) failed to give accurate patient results starting in February 2024 through day of survey 07/30/24. Findings, 1.: A comparison review of the in-house CBC patient reports with in-house CBC report from Sysmex Poch 100 i revelead patient results were released using the established normal ranges for the old Beckman Coulter AcT Diff 2 analyzer rather than the new instrument. 2. A review of the current normal ranges within the sysmex analyzer with TP#3 CMS 209 revealed the normal ranges in use were different from the normal ranges on the patient's final reports from February 2024 thru the day of survey, 07/30/2024. 3. Inteviews with staff and office manager in the review room on 07/30/2024 at approximately 2:00 PM confirmed the above findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly basis as stated in their QA policy manual in 2022 thru the date of survey, July 30, 2024. Findings: 1. A review of the laboratory QA documents revealed the Technical Consultant (TC) did not review and sign monthly quality activities (QC, equipment maintenance, room temperature logs, humidity, eye wash, refrigerator and freezer logs) from July 2022 thru day of survey 07/30/2024 in the Specialty of Hematology and Chemistry. 3. Exit interviews with staff and (TP#3 CMS 209) office manager on 07/30/2024, at approximately 1:45 PM in the review room confirmed the above laboratory logs and QA activities were not reviewed and signed by the TC or LD from July 2022 thru day of survey 07/30/2024.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on documents review and interview with the office manager, the Lab Director (LD) failed to ensure that ALL pre analytic, analytic and post analytic Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory from 2022 thru the date of survey, as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. QA documents review revealed the Lab Director and the Technical Consultant (TC), did not have a monthly QA checklist for Pre analytic, Analytic and Post analytic phases of testing from 2022 thru the date

	of survey. 2. There was no evidence of QC records review by the Labortatory Director or Technical Consultant (TC) from 2022 thru the date of survey. 3. An interview with the laboratory's office manager (TP# 3 CMS 209) in the review room on 07/30/2024 at approximately 1:40 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory from 2022 thru the date of survey.
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 record review and interview with the office manager, the laboratory failed to ensure that training, semi-annual and annual competency assessments for testing personnel (TPs) performing moderate complexity testing in 2022 thru the date of survey, were performed by the Technical Consultant or Laboratory Director. Findings: 1. A review of laboratory training and competency assessment records revealed that initial trainings, semi annual and annual competencies for (TPs #s 3 - 6 CMS 209) in 2022 thru the date of survey, July 30, 2024, were performed by an unqualified personnel (TP #3 CMS 209), instead of the Technical Consultant or Laboratory Director. 3. An interview with the office manager, in the review room, at approximately 1:00 PM, on 07/30/2024 confirmed competencies and personnel trainings were completed by unqualified staff (TPs # 3 CMS 209) in 2022 thru the date of survey.