

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0959517	<b>(X3) Date Survey Completed</b>  09/23/2020
<b>Name of Provider or Supplier</b>  Reagan Medical Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 23, 2020. 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:
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and staff interview, the testing personnel (TP) and laboratory director (LD) failed to attest to the routine integration of PT samples into the patient workload as required. Finding include: 1. API (American Proficiency Institute) PT document review revealed the LD and TP failed to sign the following attestation statements: 2019 Hematology/Coagulation (Event 1); 2020 Chemistry (Event 2). 2. API (American Proficiency Institute) PT document review revealed the LD failed to sign the attestation statement: for 2020 Hematology /Coagulation (Event One). 3. An interview with TP #8 (CMS 209 Form) on 9/23/2020 at approximately 1:30 PM in the breakroom confirmed the aforementioned PT attestation forms were not signed.</p>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples.</p>

The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:  
Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the lack of an attestation statement for 2020 PT Chemistry (Event 1) at the time of survey. 2. An interview with Testing Personnel #8 (CMS209) on 9/23/2020 in the breakroom at approximately 2:00 p.m. confirmed the lack of the aforementioned PT attestation statement at the time of survey.

**D5293**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

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 as required. Findings include: 1. Laboratory QA checklist review revealed the lack of QA checklist documentation for 2020 (January - September thus far). 2. An interview with Staff #9 (CMS 209) in the breakroom on 9/23/2020 at approximately 2:00 p.m. confirmed the lack of QA checklist documentation for the aforementioned dates.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on quality control (QC) document review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problem for each specialty of testing performed as required. Findings include: For details refer to D5783.

**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 quality control (QC) document review and staff interview, the laboratory failed to perform corrective action to ensure the laboratory results were accurate and reliable as required. Findings include: 1. Review of Coulter Act Diff (Hematology Analyzer) QC revealed 2020 QC (Low #069900) was out of range for the following months with no corrective action: March -- 9 of 18 days; 1 of 6 days; July -- 20 of 26 days. 2. Review of Coulter Act Diff (Hematology Analyzer) QC revealed 2020 QC (Normal #079900) was out of range for the following months with no corrective action: March -- 2 of 18 days; July -- 2 of 27 days. 3. Review of Coulter Act Diff (Hematology Analyzer) QC revealed 2020 QC (High #089900) was out of range for the following months with no corrective action: March -- 10 of 18 days; April -- 3 of 29 days. 4. Review of Coulter Act Diff (Hematology Analyzer) QC data revealed two of three controls were out of range with no corrective action for the following 2020 dates: March 24 (Low and High); April 3 (Low and High), July 16 (Low and Normal). Patient specimens were processed on the Coulter AcT Diff and resulted on these three dates of testing. 5. A phone interview with the lead certified medical assistant on 10/2 /2020 at approximately 1:45 p.m. confirmed patients were processed and resulted for the Coulter AcT Diff on March 24, 2020, April 3, 2020, and July 16, 2020.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on quality control (QC) document review and staff interview, the laboratory failed to provide overall management and direction of the laboratory as required. For details refer to D5293 and D5783.

**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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure PT reports were reviewed as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed the following PT reports were not reviewed : 2019 Hematology/Coagulation PT (Event One); 2020 Hematology/Coagulation Self-Assessment (Event One); 2020 Chemistry ( Event One). 2. An interview with Testing Personnel #8 (CMS 209) in the breakroom on 9/23 /2020 at approximately 1:45 p.m. confirmed the lack of required PT report review for the aforementioned PT events.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on quality control (QC) review and staff interview, the technical consultant failed to provide technical oversight over the laboratory as required. Findings include: For details refer to D5293 and D5783

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) document review and staff interview the laboratory failed to employ qualified TP to perform laboratory testing as required. Findings include: 1. TP document review revealed education documentation for TP #8 (CMS 209) was not available at the time of survey. 2. An interview with TP #8 (CMS 209) in the break room on 9/23/2020 at approximately 1:40 PM, confirmed the aforementioned lack of education documentation at the time of survey.