

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0959517	(X3) Date Survey Completed 09/21/2022
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on September 21, 2022. 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:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Testing Personnel Competency and an interview with the Office Manager, the Technical Consultant(TC) failed to perform annual competencies for the Testing Personnel for the subspecialty Hematology. The Findings include: 1. An annual competency assessment was not performed for the following staff for Hematology 2020, 2021, and 2022 thus far for Testing Personnel #1 and Testing Personnel #8 (CMS-209), at the time of the survey. 2. An interview on September 21, 2022, with Testing Personnel#1 (CMS-209), at approximately 2:00 PM, confirmed that competencies were performed for Testing Personnel #1 or #8 for 2020, 2021, and thus far 2022.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when</p>

appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of the general laboratory standard operating procedure manual (SOP) and staff interview, the laboratory failed to establish written instructions for sending specimens to an outside reference laboratory for testing. The findings include: 1. A review of the SOP confirmed that a written policy and procedure (to include collection, preservation, storage, transport, testing schedule times, or how to obtain additional assistance) was not available for staff to follow when sending specimens to reference laboratory (Quest Diagnostics). 2. During an interview on September 21, 2022 at 1:10 PM with the Office Manager in the breakroom, confirmed that the laboratory did not have a written policy and procedure for staff to follow when sending specimens to reference laboratories.

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 the laboratory's testing personnel competency assessment records and an interview with the Office Manager, the Technical Consultant (TC) failed to ensure the competency assessment was performed for all Testing Personnel. The Findings include: 1. Annual competency records revealed that the TC did not perform competency for the following Testing Personnel for 2020, 2021, and thus far 2022: Testing Personnel #1- Testing Personnel #8(CMS-209), at the time of the survey. 2. During an interview with Testing Personnel#1(CSM-209) on September 21, 2022 at approximately 2:30 PM, confirmed that the Technical Consultant did not perform competencies for all Testing Personnel.