

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1058704	(X3) Date Survey Completed 11/22/2021
Name of Provider or Supplier Reagan Medical Center Of Hamilton Mill	Street Address, City, State 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 November 22, 2021. 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:
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the review of Proficiency Testing (PT) documents and an interview with the office manager, the laboratory failed to enroll in a CMS approved PT program for Cardiac Enzyme testing in the specialty of Chemistry. Findings include; 1.) PT documents review revealed no enrollment or participation in 2020 American Proficiency Institute (API) Events #1 and #2, while doing patient testing. 2.) An interview with the office manager on 11/22/2021 in the break room at approximately 12:30 PM confirmed no Proficiency Testing for cardiac enzyme testing in the 1st and 2nd quarter of 2020.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual (SOP) and staff interview, the laboratory director (LD) failed to approve a Standard Operating Procedure (SOP) specific to Alere-Triage Meterpro Chemistry analyzer. Findings include: 1.) Review of current SOP revealed no signature and date from the laboratory director as to when it was approved and put into effect. 2.) No normal ranges and panic values were found in the (SOP) at the time of survey. 3.) Interview with the laboratory manager at approximately 12:00 PM on 11/22/2021 in the break room confirmed the above findings.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(ii)

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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on the review of Proficiency Testing (PT) documents and an interview with the office manager, the laboratory failed to participate in the 2020 1st quarter of the American Proficiency Institute(API) Proficiency Testing(PT) in Hematology. Findings include; 1.) PT documents review revealed the laboratory did not submit API results in time during 2020 American Proficiency Institute (API) Events #1 resulting in "failure to participate" in CBC Hematology testing. 2.) An interview with the office manager on 11/22/2021 in the break room at approximately 12:45 PM confirmed failure to participate in Event #1 of 2020.