

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1058704	(X3) Date Survey Completed 04/29/2019
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 April 29, 2019. 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:
D6017	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2019 API (American Proficiency Institute) Proficiency Testing (PT) documents and an interview with the laboratory manager, the laboratory director failed to ensure Proficiency Testing results were submitted within the timeframes established by the PT program. Findings include: 1.) A review of the 2019 API (PT) records revealed Event #1 of the Hematology survey received a score of 0% "Failure to Participate" because results were not submitted to API on a timely basis. 2.) An interview with the laboratory manager, at approximately 12:15 pm on April 29, 2019 in the review room confirmed the laboratory failed to submit PT results(1st Event 2019) before the cut off date.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the</p>

performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) competency reviews and interview with the laboratory manager, the technical consultant (TC) who is also the laboratory director failed to perform TP annual competencies as required in 2018. Findings include: 1. TP competency document review revealed the TC did not perform 2018 annual competencies for the following Staff #s 1, 2, 3, 4, 5 and 6 on (CMS 209). 2. An interview with the laboratory manager on April 29, 2019 in the review room at approximately 12:30 p.m. confirmed the 2019 annual competencies for the aforementioned Testing Personnel were not performed by the TC in 2018.