

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2124233	(X3) Date Survey Completed 09/23/2019
Name of Provider or Supplier Medical Associates Plus	Street Address, City, State 2508 University Dirve, Thomson, 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 23, 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:
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(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;</p> <p>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 all PT reports received were reviewed as required. Findings include: 1. API (American Proficiency Institute) PT document review revealed the LD failed to review the following PT reports: 2018 Hematology /Coagulation (Event Two); 2019 -- Core Chemistry (Event One) and Hematology /Coagulation (Event One). 2. API (American Proficiency Institute) PT document review revealed there were no PT review documents available at the time of survey for the following 2018 PT events: Hematology/Coagulation (Event Three), Core Chemistry (Event One), and Miscellaneous Chemistry (Event One). 3. An interview with Staff #2 (CMS 209) in a doctor's office at approximately 5 p.m. confirmed the aforementioned lack of LD PT report review and missing PT review documents.</p>
D6071	TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(2)

Each individual performing moderate complexity testing must maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples.

This STANDARD is not met as evidenced by:

Based on review of proficiency test (PT) documents and staff interview, the laboratory failed to maintain records that demonstrate PT samples are tested in the same manner as patient samples as required. Findings include: 1. API (American Proficiency Institute) PT document review revealed there were no attestation statements at the time of survey for the following PT events: 2018 Chemistry (Event Two) and 2019 Hematology (Event Two). 2. An interview with Staff #2 (CMS 209) in a doctor's office on 9/23/2019 at approximately 5 p.m. confirmed the aforementioned missing PT attestation statements.