

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2111714	(X3) Date Survey Completed 02/19/2020
Name of Provider or Supplier Smg Bridgewater Internal Medicine	Street Address, City, State 312 Bedford St, Whitman, MA	
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 CLIA recertification survey was conducted for the Steward Medical Group - Whitman Lab pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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. 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.</p> <p>This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with the Technical Consultant (TC) on 2/19/2020, the laboratory did not document and maintain a copy of all PT records as evidenced by the following: The surveyor reviewed American Proficiency Institute (API) PT records for calendar years 2018 and 2019 (16 total testing events). The review revealed that 14 out of 16 signed attestation statements provided by the PT program were not available for the following events: 1. API Chemistry Core 2018 Events 2 and 3. 2. API Hematology/Coagulation 2018 Events 2 and 3. 3. API Chemistry Miscellaneous 2018 Event 1 and 2. 4. API Chemistry Core 2019 Events 1, 2, and 3. 5. API Hematology/Coagulation 2019 Events 1, 2, and 3. 6.</p>

API Chemistry Miscellaneous 2019 Event 1 and 2. The TC confirmed in an interview on 2/19/2020 at 10:45 AM that not all attestation statements were signed by the analyst and the laboratory director.