

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2034612	(X3) Date Survey Completed 01/11/2023
Name of Provider or Supplier Square Medical Group	Street Address, City, State 884 Washington St, 2nd Fl, Weymouth, 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 Square Medical Group laboratory 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 Technical Supervisor (TS) and General Supervisor (GS) on 01/11/2023, 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 2021 and 2022 (four (4) testing events). The review revealed that signed attestation statements provided by the PT program were not available for the following events: Two (2) out of four (4) attestation statements were not signed by the analyst: API Chemistry Miscellaneous 2021 Events 1 and 2. One (1) out of four (4) attestation statements was not signed by the laboratory director: API Chemistry Miscellaneous</p>

2021 Event 2. The TS and GS confirmed in an interview on 01/11/2023 at 9:53 AM that not all attestation statements were signed by the analyst and laboratory director. The laboratory performs 39,240 toxicology tests annually.