

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0698561	(X3) Date Survey Completed 06/25/2019
Name of Provider or Supplier Isbell Medical Group Pc	Street Address, City, State 550 Medical Center Drive Sw, Fort Payne, AL	
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
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 a review of the API (American Proficiency Institute) Proficiency Testing records and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to retain program report forms and signed attestation statements for six of seven surveys reviewed. The findings include: 1. A review of the poorly organized 2017-2019 API Microbiology Proficiency Testing records revealed the following missing documentation or signatures for the surveys: A) 2017-Event #2: no signatures of the Laboratory Director or the testing personnel on the attestation statements (the names were written in by TP #1) B) 2017-Event #3, 2018-Event #1 and 2019-Event #1: no signatures of the Laboratory Director or the testing personnel on the attestation statements (forms were blank) C) 2018-Events #2 and #3: Missing program forms and attestation statements 2. In an interview on 6/25/2019 at 1:10 PM, the above noted findings were reviewed and confirmed with TP #1. SURVEYOR ID#32558 Licensure and Certification Surveyor</p>