

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2055268	(X3) Date Survey Completed 09/26/2019
Name of Provider or Supplier Immediate Care Foley	Street Address, City, State 1265 South Mckenzie Street, Foley, 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 MLE (Medical Laboratory Evaluation) proficiency testing records for Hematology and Chemistry, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the Laboratory Director (or qualified delegee) signed the attestation statements for testing events; 2018 MLE M3 and 2019 MLE M2. This affected two of six testing events reviewed by the surveyor. The findings include: 1. A review of the MLE proficiency testing records revealed the Laboratory Director [or qualified delegee (technical consultant)] had not signed the attestation statements for Event 2018 MLE M3 and Event 2019 MLE M2. 2. In an interview on October 3, 2019 at 12:30 PM, the surveyor asked TP #1 to review the proficiency testing manuals for the attestation statements for Event M3 of 2018 and M2 of 2019. TP #1 reviewed the attestation statements (manuals), and confirmed the Laboratory Director (nor a qualified delegee) had signed. TP #1 stated there's usually a copy, since she has to sent the statements to another location for the director to sign. However, signed attestation statements (by the Laboratory Director) for the above mentioned events were not found during the survey review.</p>