

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0904146	(X3) Date Survey Completed 02/16/2018
Name of Provider or Supplier Bledsoe County Primary Care Center	Street Address, City, State 3625 Main Street, Pikeville, TN	
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 review of the proficiency testing (PT) records in 2016-17 and an interview with the quality manager determined the laboratory director failed to ensure that all PT attestation statements were signed during 2017. The findings include: 1. Review of the 2017-C event PT records for analytes of complete blood count (CBC) in the specialty of hematology revealed the laboratory director did not sign the attestation statement for testing persons during the final 2017-C event. 2. Interview with the quality manager on February 16, 2018, at approximately 10:50 AM confirmed that the director failed to attest/sign attestation statements for the 2017-C PT event for analytes of complete blood count (CBC) in the specialty of hematology. 2nd citation: Based on review of the Laboratory Personnel Report (CMS 209), PT attestation and result records in 2016-17 and an interview with the quality manager determined the laboratory failed to ensure PT samples were tested in the same manner as patient specimens for 2016. The findings include: 1. Review of the Laboratory Personnel Report (CMS 209) revealed three testing person (TP) analysts rotating PT events for analytes of CBCs in 2016-2017. 2. Review of the 2016-B event PT attestation records</p>

for analytes of complete blood count (CBC) in the specialty of hematology revealed TP #2 signed as the PT analyst during the final 2016-B event. 3. Review of the 2016-B event PT result records for analytes of complete blood count (CBC) in the specialty of hematology revealed TP #3 as the operator ID for all 5 specimens and PT analyst during the 2016-B event. 4. Interview with the quality manager on February 16, 2018, at approximately 11:00 AM confirmed that the laboratory failed to ensure the PT samples were tested in the same manner for the 2016-B PT event for analytes of complete blood count (CBC) in the specialty of hematology.