Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0196363	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Feasterville Family Health Care Center	**Street Address, City, State** 1665 Bustleton Pike, Feasterville, PA	

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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based upon a review of proficiency testing records and interview of Laboratory Testing Personnel 1, the laboratory failed to document the Laboratory Director's signature for attestation statements 5 of 5 MLE proficiency testing events from (02/14 /2017) through the date of the survey (06/05/2018). Findings: 1. At the time of the survey, (09:30 06/05/2018), 5 of 5 MLE testing event attestation statements reviewed, did not have the Laboratory Director's signature. 2. Testing events reviewed include: MLE 2017 1st event, MLE 2017 2nd event, MLE 3rd event, MLE 2018 1st event, and MLE 2018 2nd event. 3. During the survey, Laboratory Testing Personnel 1 confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials

	for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon Hematology quality control record review and interview of Testing Personnel 1, the laboratory failed to document all control procedures performed, from 01/16/2018 through the date of the survey (06/05/2018). Findings include: 1. The laboratory was performing manual blood cell differential staining but quality control documentation was not performed each day of use, from 01/16/2018 through the date of the survey (06/05/2018). 2. During the survey, Laboratory Testing Personnel 1 confirmed the above finding.