

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0091845	(X3) Date Survey Completed 10/16/2018
Name of Provider or Supplier Castleton Family Health Center	Street Address, City, State 275 Route 30 North, Bomoseen, VT	
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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the manufacturer's acceptable ranges of assayed hematology control materials in 2017 and 2018. Findings include: 1) Review on 10/16/2018 of complete blood count (CBC) control records from August 2018 revealed the laboratory used the manufacturer's acceptable ranges for three of three levels of CBC control materials. There was no documentation that the laboratory verified the acceptability of the current CBC control lot prior to putting it into use on 8/26/2018. Each CBC control lot is used for approximately 2 months for a total of six CBC control lots per year in 2017 and 2018. 2) Interview on 10/16/2018 at 11:15 a.m. with laboratory supervisor confirmed the above finding and revealed the laboratory has not verified the acceptability of any lot of CBC control materials used in 2017 and 2018.</p>
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the semi annual procedures for evaluation conducted in 2018 failed to include assessment of hematology test performance.

Findings include: 1) Review on 10/16/2018 of personnel records revealed four new testing personnel; one hired in December 2017 (Staff A), one in May 2018, and two in July 2018. Record review revealed that Staff A's personnel record semi annual competency evaluations conducted on 2/5/2018 and 7/25/2018 failed to include assessment of test performance for complete blood count (CBC) and microscopic analysis of urine sediment. 2) Interview on 10/16/2018 at 11:00 a.m. with the laboratory supervisor confirmed semi annual competency evaluations for Staff A did not include assessment of test performance for CBC and microscopic analysis of urine sediment.