Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D1077351	03/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Upper Valley Community Health Services	335 East Main, Saint Anthony, ID	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and proficiency testing (PT) record review, the laboratory testing personnel failed to test the PT samples for complete blood counts (CBCs) from the American Academy of Family Physicians (AAFP) in the same number of times that it tests patient specimens since the last survey on July 17, 2016. Findings: 1. A PT record review from AAFP for CBCs performed on the Medonic test system revealed the testing personnel tested the PT samples three to five times before submitting the results. 2. An interview on March 14, 2018, at 9:10 AM, with the laboratory manager, confirmed the laboratory failed to test the CBC PT samples in the same manner as patient specimens.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and a procedure manual review, the laboratory failed to include corrective actions to take when control or calibration material fails to meet the lab's specified requirement and steps to take when the Medonic complete blood count (CBC) analyzer becomes inoperable since the last survey on July 17, 2016. Findings: 1. A procedure manual review revealed the laboratory's procedure failed to include corrective actions to take when the quality controls or calibration fail or instructions to take when the Medonic analyzer becomes inoperable. 2. An interview on March 14, 2018 at 10:00 AM, with the laboratory manager, confirmed the laboratory's procedure manual failed to include these requirements
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and a record review, the laboratory failed to identify the temperature ranges for the refrigerator where quality controls for complete blood counts are stored, and the room temperature where patient specimens are tested since the last survey on July 17, 2016. Findings: 1. A record review revealed the laboratory failed to write the temperature ranges on the document to monitor the temperatures for the refrigerator and room temperature. 2. An interview on March 14, 2018, at 9:45 AM, with the laboratory manager, confirmed the laboratory failed to write the temperature ranges on the document used to monitor the temperatures.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) 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-- Over time, rotate control material testing among all operators who perform the test. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and quality control records review, the laboratory failed to rotate the Boule Con-Diff Tri-level liquid quality controls used for the Medonic complete blood count (CBC) analyzer among all testing personnel since the last survey on July 17, 2016. Findings: 1. A review of the quality control records from October 17, 2017 through October 20, 2017 for the Medonic CBC analyzer revealed one testing personnel performed the quality control. 2. An interview on March 14, 2018, at 10:15 AM, with the laboratory manager, confirmed the laboratory failed to rotate the testing personnel who perform CBC testing on patient specimens.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on an interview with the laboratory manager and personnel records review, the laboratory failed to have a qualified individual perform competency assessments on the 10 testing personnel performing complete blood counts since the last survey on July 17, 2016. Findings: 1. A review of personnel records revealed the laboratory failed to have a qualified individual perform competency assessments on the 10 personnel listed on the CMS-209 Personnel Report form. 2. An interview on March 14, 2018 at 9:15 AM, with the laboratory manager, confirmed the laboratory failed to have a qualified individual perform competency assessments on the testing personnel.