Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D1028524	06/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Upper Valley Family Medicine	711 Rigby Lake Dr #1500, Rigby, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) desk review, the laboratory failed to successfully participate in proficiency testing for the overall testing events in hematology. Refer to D2131.
D2131	HEMATOLOGY CFR(s): 493.851(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is

	unsuccessful performance. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) desk review and the laboratory's graded PT results from American Association of Bioanalysts (AAB), the laboratory failed to achieve an overall testing event score of satisfactory performance for two out of three consecutive testing events for hematology with differential. Findings: Analyte Year Event Score Hematology with differential 2017 3 0 Hematology with differential 2018 1 0
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 a procedure review and an interview with the laboratory lead, the laboratory procedure manual failed to include corrective actions when control or calibration material failed to meet the laboratory's specified criteria, panic values, and actions to take when the Horiba Micros 60 complete blood count (CBC) analyzer becomes inoperable since the last survey on September 27, 2016. Findings: 1. A procedure review revealed the laboratory's testing personnel were using the operating manual for the Horiba Micros 60 analyzer and failed to include panic values for patient CBC results, corrective actions to take when controls or calibrations fail, or instructions for when the Medonic analyzer becomes inoperable. 2. An interview on June 27, 2018 at 3:00 PM, with the laboratory lead, confirmed the laboratory's procedure manual failed to include all requirements for the procedure manual.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system

	performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory lead, the laboratory failed to establish a maintenance protocol for the Horiba Micros 60 ABX hematology analyzer used to test patient complete blood counts (CBCs) since the last survey on September 27, 2016. Findings: 1. A record review of the laboratory procedures and observation of lack of documentation for maintenance activities revealed the laboratory failed to establish a maintenance protocol and document unscheduled repairs and maintenance activities performed on the ABX since the last survey. 2. An interview on June 27, 2018 at 4:00 PM, with the laboratory lead, confirmed the laboratory failed to establish and document maintenance activities for the CBC analyzer.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the laboratory lead, the laboratory failed to follow the manufacturer's instructions for testing quality control materials after the calibration of the Horiba Micros 60 complete blood count analyzer for the dates reviewed on October 11, 2017 and April 20, 2018. Findings: 1. A review of the quality control records for the Horiba revealed the laboratory failed to follow the manufacturer's instructions for performing quality control after the calibration of the analyzer. 2. An interview on June 27, 2018 at 3:20 PM, with the laboratory lead, confirmed the laboratory failed to ensure quality control materials for the Horiba were performed after calibration was performed on the analyzer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with the laboratory lead, the laboratory failed to test at least two quality control materials of different concentrations for the Horiba Micros 60 ABX complete blood count (CBC) analyzer prior to reporting 107 patient CBC results from September 28, 2017 to October 11, 2017. Findings: 1. A review of CBC quality control records from September 28, 2017 to October 11, 2017 revealed 107 patient CBC results were reported without two levels of quality control materials performed on the days of testing. 2. An interview on June 27, 2018, at 4:30 PM, with the laboratory lead, confirmed two levels of quality control materials were not tested before patient CBC results were reported.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on an observation of the laboratory refrigerator and freezer and an interview with the laboratory lead, the laboratory director failed to ensure employees are protected from chemical and biological hazards as found on-site during the survey. Findings: 1. An observation of the laboratory refrigerator and freezer on June 27, 2018 at 4:10 PM revealed 4 ice cream sundaes, 1 plastic container with food, and 2 containers of dip were stored with chemical reagents. 2. An interview on June 27, 2018, at 4:10 PM, with the laboratory lead, confirmed the medical staff stored their food in the laboratory refrigerator instead of the office fridge on occasion.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on records review and an interview with the laboratory lead, the laboratory director failed to ensure the quality assessment program for the Horiba Micros 60 ABX complete blood count test system meets the CLIA requirements since the last survey on September 27, 2016. Refer to D5403, D5433, D5437, and D5447. Findings: 1. A record review revealed the laboratory director failed to identify and correct problems in the analytic system. 2. An interview on June 27, 2018, at 4:50 PM, with the laboratory lead, confirmed the laboratory failed to identify, document, and correct problems in analytic system for the CBC testing on the Horiba analyzer.

D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel training records and an interview with the laboratory lead, the laboratory director failed to ensure that new testing personnel demonstrate they are trained to perform complete blood counts (CBCs) testing since the last survey on September 27, 2016. Findings: 1. A review of the CMS-209 Personnel Report and lack of training documents revealed the laboratory failed to document 7 out of 9 testing personnel are trained in performing CBCs. 2. An interview on June 27, 2018 at 3:00 PM with the laboratory lead, confirmed testing personnel trained on the Horiba Micros 60 CBC analyzer was not documented.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the procedure manual and an interview with the laboratory lead, the laboratory director failed to ensure that policies and procedures were established for monitoring the competency of 9 out of 9 testing personnel performing complete blood counts (CBCs) since the last survey on September 27, 2016. Findings: 1. A review of the laboratory's quality assurance plan revealed the laboratory failed to establish a procedure for monitoring the competency of 9 out of 9 testing personnel listed on the CMS-209 Personnel Report form performing CBCs. 2. A review of personnel competency documents revealed assessments for the 9 testing personnel was not documented for 2017. 3. A review of personnel competency documents revealed assessments for the 8 out of 9 testing personnel was not performed by a qualified consultant for 2018. 4. An interview on June 27, 2018 at 2:15 PM, with the laboratory lead, confirmed the laboratory director failed to establish procedures and document competencies for 9 out of 9 testing personnel.

D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory director failed to delegate in writing the responsibilities and duties for the technical consultant's oversight of the laboratory test performance in complete blood counts since the last survey on September 27, 2016. Findings: 1. A record review of personnel documents revealed the laboratory director failed to provide in writing a delegation of responsibilities and duties to the technical consultant who has oversight of the proficiency testing program and quality control program for the laboratory since the last survey. 2. An interview on June 27, 2018 at 3:15 PM with the technical consultant, confirmed the laboratory director failed to provide in writing a delegation of duties and responsibilities for the laboratory's technical oversight.