Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D1028524	04/25/2024
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
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documents from the American Association of Bioanalysts (AAB), the Centers for Medicare and Medicaid Services (CMS) CASPER Report 96D and an interview with the technical consultant (TC) on 4/25/2024, the laboratory failed to participate in one (1) of three (3) testing events in 2023 for the specialty of hematology. The findings include: 1. A review PT documents from AAB and the CMS Report 96D identified that the laboratory failed to participate in testing for event one (1) in 2023 for the specialty of hematology resulting in a score of zero (0). 2. An interview with the TC on 4/25/2024 at 9:52 am confirmed the above finding. 3. The laboratory reports performing 16,110 hematology tests annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory policies, training and competency assessment records and an interview with the technical consultant (TC) on 4/25/2024, the laboratory failed to establish and follow written policies to assess employee competency. The findings include: 1. The CMS 209 identified 12 testing personnel (TP) performing moderate complexity testing. Five (5) of the 12 TP were new since the previous inspection on 6 /24/2022. 2. A review of laboratory policies identified that the laboratory failed to establish in their personnel policy TP assessments semiannually during the first year of employment and competency of the technical consultant (TC). 3. A review of training and competency assessment records identified that the laboratory failed to have an annual competency assessments for one (1) of eight (8) TP in 2023. 4. A review of training and competency assessment records identified that the laboratory failed to have a six month competency assessments for one (1) TP in 2023. 5. A review of training and competency assessment records identified that the laboratory failed to have a competency assessment for the TC. 6. An interview with the TC on 4 /25/2024 at 9:51 am confirmed the above findings. 7. The laboratory reports performing 16,110 moderate tests annually. 8. This is a repeat deficiency from the survey on 2/23/21 for a failure to perform competency assessments of TP in 2019 and 2020.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Association of Bioanalysts (AAB) and an interview with the technical consultant (TC) on 4/25/2024, the laboratory director failed to review and evaluate PT results for the specialty of hematology. The findings include: 1. A review of PT results for the specialty of hematology from AAB for 2022 identified that the laboratory director failed to review and evaluate PT results for event three (3). 2. A review of PT results for the specialty of hematology from AAB for 2023 identified that the laboratory director failed to review and evaluate PT results for events two (2) and three (3). 3. A review of PT results for the specialty of hematology from AAB for 2024 identified that the laboratory director failed to review and evaluate PT results for event one (1). 4. An interview with the TC on 4/25/2024 at 9:52 am confirmed that the laboratory director failed to review and evaluate PT results for hematology. 5. The laboratory reports performing 16,110 hematology tests annually. 6. This is a repeat deficiency from the previous inspection on 6/24/2022.
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 review of laboratory hematology quality control (QC) records, hematology procedures and an interview with the technical consultant (TC) on 4/25/2024, the laboratory failed to establish corrective actions to be taken when QC fails to meet acceptability criteria. The findings include: 1. A review of the laboratory's hematology QC records identified that the laboratory ran three levels of QC 12 times on 8/31 /2023, 16 times on 1/29/2024, nine (9) times on 2/12/2024 and 20 times on 2/21/2024 to get acceptable results. 2. A review of the facilities hematology procedures identified that the laboratory failed to establish and document corrective actions taken when QC failed to meet the laboratories acceptability criteria. 3. An interview with the TC on 4/25/2024 at 11:00 am confirmed the above findings. 4. The laboratory report performing 16,110 hematology tests annually. 5. This is a repeat deficiency from the previous on 6/27/2018 for QC and calibration corrective actions.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of hematology quality control (QC) records, laboratory procedures and an interview with the technical consultant (TC) on 4/25/2024, the laboratory failed to establish the number, frequency and acceptability of control materials performed to ensure accurate and precise test results. The findings include: 1. A review of the laboratory's hematology QC records identified that the laboratory ran three levels of QC 12 times on 8/31/2023, 16 times on 1/29/2024, nine (9) times on 2 /12/2024 and 20 times on 2/21/2024 to get acceptable results. 2. A review of the

	laboratory's hematology procedures identified that the laboratory failed to establish the number of QC, the number of times QC can be repeated and the acceptability criteria for QC. 3. An interview with the TC on 4/25/2024 at 10:56 am confirmed the above findings. 4. The laboratory report performing 16,110 hematology tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) documents from the American Association of Bioanalysts (AAB), the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records, laboratory policies and procedures, hematology quality control records, a lack of documentation and interviews with the technical consultant on 4/25/2024, the laboratory director failed to ensure acceptable analytic performance of hematology , that PT results were returned and reviewed, that testing personnel were competent to perform testing and that the technical consultant was competent. See D6017, D6018, D6033, and D6030.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documents from the American Association of Bioanalysts (AAB), the Centers for Medicare and Medicaid Services (CMS) CASPER Report 96D and an interview with the technical consultant (TC) on 4 /25/2024, the laboratory director failed to ensure participation in PT testing events in 2023 for the specialty of hematology. The findings include: 1. A review PT documents from AAB and the CMS Report 96D identified that the laboratory director failed to ensure participation in testing for event one (1) in 2023. See D2123 2. An interview with the TC on 4/25/2024 at 9:52 am confirmed the above finding. 3. The laboratory reports performing 16,110 hematology tests annually.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Association of Bioanalysts (AAB) and an interview with the technical consultant (TC) on 4/25/2024, the laboratory director failed to review and evaluate PT results for the specialty of hematology. The findings include: 1. A review of PT results for the specialty of hematology 2022 identified that the laboratory director failed to review and evaluate PT for one event in 2022, two events in 2023 and one event in 2024. See D5211 2. An interview with the TC on 4/25/2024 at 9:52 am confirmed that the laboratory director failed to review and evaluate PT results for hematology. 3. The laboratory reports performing 16,110 hematology tests annually.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on a review of laboratory hematology quality control (QC) records, hematology procedures and an interview with the technical consultant (TC) on 4/25/2024, the laboratory director failed to establish an ensure acceptable analytic performance of hematology testing. The findings include: 1. A review of the laboratory's hematology QC records identified that the laboratory ran three levels of QC 12 times on 8/31 /2023, 16 times on 1/29/2024, nine (9) times on 2/12/2024 and 20 times on 2/21/2024 to get acceptable results. See D5441 2. A review of the laboratory's hematology procedures identified that the laboratory failed to establish and document corrective actions taken when QC failed to meet the laboratories acceptability criteria. See D5403 3. An interview with the TC on 4/25/2024 at 11:00 am confirmed the above findings. 4. The laboratory report performing 16,110 hematology tests annually.
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 laboratory procedures, training and competency assessment records and an interview with the technical consultant (TC) on 4/25/2024, the laboratory director failed to establish and follow policies and procedures to assess testing personnel (TP) and TC competency. The findings include: 1. A review of laboratory procedures identified that the laboratory director failed to establish policies and procedures for competency assessments and ensure competency of the TP and TC. See D5209 2. An interview with the TC on 4/25/2024 at 9:51 am confirmed the above findings. 3. The laboratory reports performing 16,110 moderate tests annually.