Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2100790	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Upper Valley Community Health Services	72 S 1st E, Rexburg, 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
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 on proficiency testing (PT) record review and an interview with the laboratory supervisor, the laboratory director and the testing personnel failed to sign the attestation statements from the American Academy of Family Physicians (AAFP) for the specialties of hematology and chemistry for the 2018 event 3 and 2019 event 1. Findings: 1. An AAFP PT document review revealed the laboratory director and the testing personnel failed to sign the attestation statements for complete blood counts (CBCs), human chorionic gonadotropin (hCG), thyroid stimulating hormone (TSH), and free thyroxine (FT4) for the 2018 event 3 and 2019 event 1. 2. An interview with the laboratory supervisor on June 4, 2019 at 3:30 PM, confirmed the laboratory director and testing personnel performing the tests failed to sign the PT attestation statements.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a records review and an interview with the laboratory supervisor, the laboratory failed to retain quality control data from the Medonic complete blood counts (CBCs) and the Qualigen immunoassay manufacturer quality control reference range cards since the last survey. Findings: 1. A review of the Medonic complete blood count (CBCs) analyzer revealed the laboratory failed to retain instrument quality control records, as well as the Medonic manufacturer's assay information sheets for external quality controls prior to February 1, 2019. 2. A review of the Qualigen immunoassay quality control performance records revealed the laboratory failed to retain the manufacturer's quality control reference range cards for human chorionic gonadotropin (hCG), thyroid stimulating hormone (TSH), and free thyroxine (FT4) to ensure the quality control performance met the manufacturer's acceptability requirements since the last survey on July 18, 2017. 3. The laboratory performed approximately 1000 CBCs and 300 endocrinology tests in 2018. 4. An interview with the laboratory supervisor on June 4, 2019 at 4:30 PM, confirmed the laboratory failed to retain CBC quality control data and Qualigen reference range cards since the last survey.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of patient test reports and a review of the Qualigen assay sheets, the laboratory failed to follow the Qualigen manufacturer's instructions to include the test methodology for thyroid stimulating hormone (TSH) and free thyroxine (FT4) on the patient's test reports since the last survey on July 18, 2017. Findings: 1. A review of the patient reports and the Qualigen assay instruction sheets for TSH and FT4 revealed the laboratory failed to include the identity of the assay's method on patient test reports to providers. 2. The laboratory performed approximately 300 endocrinology tests in 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test

	system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review laboratory document, manufacturer manual, and an interview with the laboratory supervisor, the laboratory failed to perform and document calibration verification procedures at least once every 6 months for the Qualigen FastPack immunoassay analyzer since the last survey on July 18, 2017. Findings: 1. A record review of calibration verification reports for human chorionic gonadotropin (hCG), thyroid stimulating hormone (TSH), and free thyroxine (FT4) revealed the laboratory failed to perform calibration verification at least once every 6 months since the last survey. 2. A review of the Qualigen operating manual revealed the requirement to perform calibration verification activities at least once every 6 months. 3. An interview with the laboratory supervisor on June 4, 2018, at 4:00 PM, confirmed the laboratory failed to perform calibration verification activities on TSH, hCG, and FT4.
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 record review and an interview with the laboratory supervisor, the laboratory failed to establish and monitor the accuracy and precision of the Medonic complete blood count (CBC) controls over time to detect changes or problems in the test performance since the last survey on July 18, 2017. Findings: 1. A review of quality control records and laboratory procedure manual revealed the laboratory failed to establish and monitor or record the quality control procedures over time to detect errors and problems with the test system. 2. The laboratory performed approximately 1000 complete blood counts in 2018. 3. An interview with the laboratory manager on June 4, 2019 at 3:55 PM, confirmed the laboratory did not monitor or record control procedures over time to detect errors with the test system.

D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control documents and an interview with the laboratory supervisor, the laboratory failed to verify the acceptability of the Qualigen quality controls for human chorionic gonadotropin (hCG), thyroid stimulating hormone (TSH), and free thyroxine (FT4) before reporting patient results from the dates quality control records reviewed between November 2018 to June 2019. Findings: 1. A review of the quality control records revealed the quality control results failed to be verified by the manufacturer's reference range card before reporting patient test results. 2. The laboratory performed approximately 300 endocrinology tests in 2018. 3. An interview with the laboratory testing person on June 4, 2018, at 4:05 PM, confirmed the testing personnel did not review the quality control results with the reference range card.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory supervisor, the laboratory director failed to ensure all verification procedures for the Qualigen immunoassay analyzer met the performance specifications for the laboratory since the last survey on July 18, 2017. Refer to D5439. Findings: 1. A review of calibration verification reports for the Qualigen immunoassay test performance for human chorionic gonadotropin (hCG), thyroid stimulating hormone (TSH), and free thyroxine (FT4) revealed the laboratory director failed to ensure the performance specifications were met according to the manufacturer's and CLIA requirements. 2. An interview with the laboratory supervisor on June 4, 2019 at 3:55 PM, confirmed the laboratory director failed to ensure that calibration verification procedures were performed.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a records review and an interview with the laboratory supervisor, the laboratory director failed to ensure the quality control program for the Medonic complete blood count (CBC) and the Qualigen immunoassay test system meets the CLIA requirements since the last survey on July 18, 2017. Refer to D3031, D5441, and D5481. Findings: 1. A review of the quality control records for the Medonic CBC and Qualigen immunoassay analyzers revealed the laboratory director failed to ensure all quality control records were retained for at least 2 years. Refer to D3031. 2. A review of the quality control program revealed the laboratory director failed to establish and monitor the controls over time in order to detect errors in the test performance. Refer to D5441. 3. A review of quality control records for the Qualigen revealed the laboratory director failed to ensure that the performance of external quality controls for human chorionic gonadotropin (hCG), thyroid stimulating hormone (TSH), and free thyroxine (FT4) met the manufacturer's acceptability before reporting patient results. Refer to D5481. 4. An interview with the laboratory supervisor on June 4, 2019 at 4:45 PM, confirmed the laboratory director failed to ensure the quality control procedures and activities for the test systems were established.
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 a record review and an interview with the laboratory supervisor, the laboratory director failed to ensure a quality assessment program for the Medonic complete blood count (CBC) and the Qualigen immunoassay test system was maintained to ensure the quality of laboratory testing since the last survey on July 18, 2017. Findings: 1. A record review revealed the laboratory director failed to establish and maintain a system to monitor, identify, and correct problems in the test systems. 2. An interview with the laboratory supervisor on June 4, 2019 at 4:05 PM, confirmed that laboratory director failed to establish and maintain for a system to monitor all quality assessments activities for the laboratory's test performance in CBC and immunoassay tests.