Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0090671	10/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mountain Valley Health Center	38 Vt Route 11, Londonderry, 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
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 record review and staff interview, the laboratory failed to maintain all records for mycology, parasitology, hematology, routine chemistry, urinalysis, and endocrinology proficiency testing in 2017. Findings include: 1) Review on 10/9/2018 of PT records from 2017 and 2018 revealed no records (evaluation, attestation, instrument printouts, and results submission forms) for the following PT events: first "Chemistry Miscellaneous" event in 2017 (prostate specific antigen), the second "Hematology/Coagulation" event in 2017 (complete blood count and cell differential, urine sediment microscopic examination, potassium hydroxide preparation, and direct wet mount preparation), and the second "Chemistry Core" event in 2017 (albumin, alkaline phosphatase, alanine transaminase, amylase, aspartate aminotransferase, direct bilirubin, total bilirubin, calcium, chloride, cholesterol-high density lipoproteins, total cholesterol, carbon dioxide, creatine kinase, creatinine, glucose, potassium, sodium, total protein, triglycerides, urea nitrogen, free thyroxine, thyroid stimulating hormone, and human chorionic gonadotropin). Further review revealed the laboratory obtained a 60% score for human chorionic gonadotropin (hCG) in the

	second event in 2017. The laboratory could not provide documentation that the unsatisfactory results had been reviewed and evaluated. 2) Interview on 10/9/2018 at 10:30 a.m. confirmed the records for the PT events listed above were missing from the laboratory's PT records and could not be provided at the time of the survey.
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 record review and staff interview, the laboratory failed to perform calibration verification every six months and calibration verification procedures performed failed to verify the reportable ranges for routine chemistry and endocrinology tests in 2017 and 2018. Findings include: 1) Review on 10/9/2018 of calibration verification records from 2016, 2017 and 2018 for total bilirubin (tbili) and prostate specific antigen (PSA), revealed calibration verification procedures were performed in October 2016, July 2017, March 2018, and October 2018. Review of the calibration verification summaries for tbili and PSA revealed no peer data was provided in 2017 and 2018 and the materials used were not assayed by the manufacturer. Further review of calibration verification records revealed the laboratory verified calibration of chloride, potassium and sodium in October 2016, July 2017, January 2018 and October 2018. 2) Interview on 10/9/2018 at 11:30 a.m. with the technical consultant confirmed the above finding. 3) The laboratory performs approximately 43,000 chemistry tests annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the manufacturers' assayed ranges for hematology and routine chemistry control materials prior to use in 2017 and 2018. Findings include: 1) Review on 10/9/2018 of package inserts for control materials used for complete blood count (CBC) and routine chemistry analytes albumin, alkaline phosphatase, alanine transaminase, amylase, aspartate aminotransferase, direct bilirubin, total bilirubin, calcium, chloride, cholesterol-high density lipoproteins, total cholesterol, carbon dioxide, creatine kinase, creatinine, glucose, potassium, sodium, total protein, triglycerides, urea nitrogen, and lipase revealed the control materials were assayed by the manufacturer and included the acceptable ranges for results. 2) Review on 10/9/2018 of the laboratory's "Quality Control Policy" effective April 2018 revealed instruction to test new lots of control materials to verify the manufacturers' acceptable ranges. 3) Review on 10/9/2018 of control records from 2017 and 2018 revealed the laboratory failed to verify each lot numbers for two of two control materials used for routine chemistry analytes listed above in 2017 and 2018 and failed to verify the current lot of three CBC control materials prior to putting them into use on 8/29/2018. 4) Interview on 10/9/2018 at 12:00 p.m. with testing personnel confirmed the above findings. 5) The laboratory performs approximately 43,000 chemistry tests annually and approximately 937 hematology tests monthly.