Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1075780	08/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mountaineer Family Medicine Lab	4114 1st Avenue, Nitro, WV	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based upon a review of the written policies and procedures of the laboratory and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish written policies and procedures for (7) specimen acceptability and rejection. Findings: 1. A review of written policies and procedures could not locate a written policy for specimen acceptability and rejection criteria. 2. An interview with TP1, on 8/28/19 at approximately 11:30 AM, confirmed there is no written policy/procedure for acceptability and rejection criteria of laboratory 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 a review of the laboratory written policies and procedures and an interview with Testing Personnel 1 (TP1), the laboratory failed to ensure written policies and procedures were available for (13) entering results into the patient record and reporting patient results when a corrected report is issued and to (14) establish a course of action to take if the test system becomes inoperable Findings: 1. A review of laboratory written policies and procedures identified no established course of action to take when the test system becomes inoperable. 2. A review of laboratory written policies and procedures identified no written policy or procedure for entering results in the patient record and reporting patient results when a corrected report is issued. 3. An interview with TP1, on 8/28/19 at approximately 11:30 AM, confirmed the findings.
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 upon a review of laboratory written policies and procedures, Quality Control (QC) records, calibration records, and an interview with Testing Personnel 1 (TP1), the laboratory failed to establish a written control material procedure that identified the number, type, and frequency of testing control materials. Findings: 1. A review of QC and calibration records identified the number, type, and frequency of QC materials testing used by the laboratory. 2. A review of written policies and procedures could not locate a policy or procedure that specifies the number, type, and frequency of testing control materials. 3. An interview with TP1, on 8/28/19 at approximately 11:30 AM, confirmed the findings.