Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236881	(X3) Date Survey Completed 08/30/2019
Name of Provider or Supplier Fairview Health Associates	**Street Address, City, State** 350 Fairview Heights Road, Summersville, 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
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 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 8/30/19 at approximately 11:00 AM, confirmed the findings
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon a review of the laboratory Quality Control (QC) records, patient testing logs, and an interview with Testing Personnel 1 (TP1), the laboratory failed to perform and document a daily external negative and positive control for serum HCG testing. Findings: 1. A review of QC records and patient testing logs for 2018 and 2019 of serum HCG testing, identified that a negative and positive control were being ran only with the introduction of new lots. 2. No IQCP could be located. 3. An interview with TP1, on 8/30/19 at approximately 10:30 AM, confirmed that a negative and positive control were only be ran on new lots of serum HCG testing kits and there was not an IQCP for serum HCG testing.