Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2162355	01/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Chapmanville Primary Care Clinic	462 Main Street, Chapmanville, 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
D0000	An announced, on site, initial certification survey was conducted at Chapmanville Primary Care Clinic on January 20, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
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 laboratory written policies and procedures (P&P) and an interview with laboratory manager, the laboratory failed to establish written P&P to assess employee competency and initial training of testing personnel (TP). Findings: 1. A review of written P&P could not locate a written policy or procedure for assessing employee competency or initial training of testing personnel. 2. A review of written P&P identified an initial training and competency performed for the 2 testing personnel of the laboratory. 3. During an interview with the laboratory manager, on 1 /20/2021 at approximately 8:30 AM, the laboratory manager stated that there was no written policy or procedure for employee competency or initial training of testing personnel.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory test menu, written policies and procedures (P&P), and an interview with the laboratory manager, the laboratory failed to enroll in a commercial proficiency testing program or establish a policy or procedure to verify accuracy at least twice per year of the analytes, not included in Subpart I, Amphetamine, Methamphetamine, Barbiturate, Benzodiazapine, Cocaine, EDDP, Opiate, THC, and TCA. Findings: 1. A review of the laboratory test menu and testing records identified no enrollment in a commercial proficiency testing program for the analytes Amphetamine, Methamphetamine, Barbiturate, Benzodiazapine, Cocaine, EDDP, Opiate, THC, and TCA tested on the Quidel Triage Meter Pro and not included in Subpart I. 2. A review of the written P&P identified no written policy or procedure to verify accuracy at least twice a year for the analytes Amphetamine, Methamphetamine, Barbiturate, Benzodiazapine, Cocaine, EDDP, Opiate, THC, and TCA tested on the Quidel Triage Meter Pro and not included in Subpart I. 3. During an interview with the laboratory manager, on 1/20/2021 at approximately 8:30 AM, the laboratory manager stated there were no analytes from the test menu enrolled in a commercial proficiency testing program and no written policy or procedure to verify the accuracy of them.
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 on a review of laboratory written policies and procedures (P&P) and an interview with the laboratory manager, the laboratory failed to establish a written P&P for (3) Specimen labeling, including patient name or unique patient identifier (7) Specimen acceptability and rejection and (8) Specimen referral. Findings: 1. A review of the laboratory written P&P identified the manufacturer instructions being utilized as the P&P for the testing of Amphetamine, Methamphetamine, Barbiturate, Benzodiazapine, Cocaine, EDDP, Opiate, THC, and TCA on the Quidel Triage Meter Pro. 2. A review of the Quidel Triage Meter Pro manufacturer instructions revealed no P&P for (3) Specimen labeling, including patient name or unique patient identifier (7) Specimen acceptability and rejection and (9) specimen referral to LabCorp for confirmation testing. 3. During an interview with the laboratory manager, on 1/20 /2021 at approximately 8:45 AM, the laboratory manager stated that the manufacturer instructions were being used as the laboratory P&P for the Quidel Triage Meter Pro testing. The laboratory manager also stated there was not a written P&P for specimen labeling, specimen acceptability and rejection, and specimen referral to LabCorp for confirmation testing when ordered by the physician.
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 (P&P) and an interview with the laboratory manager, the laboratory failed to establish a written policy or procedure for (13) entering results in the patient record. Findings: 1. A review of the laboratory written policies and procedures identified no written P&P for entering the test results of the Quidel Triage Meter Pro into the electronic patient record. 2. During an interview with the laboratory manager, on 1/20/2021 at approximately 9:00 AM, the laboratory manager explained the lab process for entering patient test results into the patient record and stated there was no written policy or procedure.
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 on a review of the laboratory written policies and procedures (P&P), the FDA database on test complexity, quality control (QC) records, and an interview with the laboratory manager, the laboratory failed to perform and document an external negative and positive control for the Quidel Triage Tox Drug Screen test kit each day of patient testing. Findings: 1. Review of the manufacturer instructions, used as the laboratory P&P, identified this statement "Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures." 2. Review of the FDA database for test complexity identified the Quidel Triage Meter Pro testing of Amphetamine, Methamphetamine, Barbiturate, Benzodiazapine, Cocaine, EDDP, Opiate, THC, and TCA analytes as Moderate Complexity. 3. A review of QC records for the Quidel Triage Meter Pro identified

	external positive and negative QC documented as performed 11/30/2020 and 12/9 /2020. 4. No Individualized Quality Control Plan (IQCP) could be located for the Quidel Triage Tox Drug Screen testing for the laboratory. 5. During an interview with the laboratory manager, on 1/20/2021 at approximately 9:00 AM, stated that external negative and positive controls were only being ran every 30 days or with a new lot for the Quidel Triage Tox Drug Screen test kit.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory written policies and procedures (P&P), the laboratory director (LD) failed to ensure the laboratory had established all the required structures and processes necessary to provide accurate and reliable test results. Findings: 1. A review of written P&P identified that no written policy or procedure for the assessment of testing personnel competency and initial training could be located. Refer to D5209. 2. A review of written P&P identified no written policy or procedure for the twice annual verification of the analytes on the test menu not included in Subpart I could be located. Refer to D5217. 3. A review of written P&P identified no written policy or procedure for specimen labeling, specimen acceptability and rejection, and specimen referral to LabCorp for confirmation testing could be located. Refer to D5311. 4. A review of written P&P identified no written policy or procedure for the entering of patient results into the patient electronic record could be located. Refer to D5403. 5. A review of quality control records and written P&P identified no documentation of external negative and positive quality control being performed each day of patient testing and no Individualized Quality Control Plan for the Quidel Triage Tox Drug Screen test kit. Refer to D5449. 6. A review of the laboratory testing personnel records identified that the 2 testing personnel in the laboratory did not have West Virginia laboratory licenses. Refer to D6064.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on review of laboratory personnel files, the West Virginia licensure verification source, and interviews with the testing personnel (TP), the laboratory failed to ensure the testing personnel performing moderate complexity testing possess a current West Virginia laboratory license, as required by the state rule WV 64 CSR 57 Clinical

	Laboratory Technician and Scientist Licensure and Certification Rule. Findings: 1. Based on a review of the West Virginia licensure verification source the 2 testing personnel of the laboratory had no documentation of a West Virginia laboratory license. 2. Interviews with the 2 TP, 1/20/2021 at approximately 9:45 AM, confirmed they had no current West Virginia laboratory license or knowledge they were required to have one. 3. The laboratory immediately began the process of acquiring West Virginia laboratory licenses for testing personnel while surveyor was on site.