Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2151883	(X3) Date Survey Completed 12/04/2019
Name of Provider or Supplier Chesapeake Healthcare Center, Llc	**Street Address, City, State** 11950 Maccorkle Avenue, Charleston, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures, a tour of the laboratory, and an interview with testing personnel 1 (TP1), the laboratory failed to monitor and document the (2) temperature and (3) humidity for reliable test system operation with an NIST certified calibrated thermometer. Findings: 1. The written policy/procedure of the laboratory states "Temperature and humidity will be documented daily...NIST traceable or certified thermometers will be used and replaced if damaged or faulty." 2. A review of the "Laboratory Temperature/Humidity Log" identifies acceptable temperature and humidity ranges for the laboratory and provides a form for the documentation of the daily temperatures and humidity. a. Room Temperature 20 to 24 degrees Celsius b. Refrigerator Temperature 2 to 8 degrees Celsius c. Humidity 20 to 80 percent d. Freezer Temperature -20 degrees Celsius or colder 3. A review of the laboratory temperature and humidity logs showed the daily documentation of temperature and humidity conditions. 4. No documentation of the thermometers and hydrometers NIST certified calibration or traceability could be located. 5. An interview with TP1, on 12/4/19 at approximately 11:00 AM, confirmed that no NIST certified documentation could be located on site at the time of survey.
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, quality control (QC) records, patient testing logs, and an interview with testing personnel 1 (TP1), the laboratory failed to perform and document an external negative and positive control for the Quidel Triage Tox Drug Screen test kit daily. Findings: 1. Review of the laboratory written policies and procedures established that external negative and positive controls were ran with "each new lot and every 30 days." 2. Review of the laboratory QC records identified external negative and positive controls were ran on the Quidel Triage Tox Drug Screen test kit 10/31/19, 11/15/19, 11/18/19. 3. A review of patient testing logs revealed that patient testing on the Quidel Triage Tox Drug Screen test kit occurred 10/17/19, 10/18/19, 10/23/19,10/24/19, 10/25/19, 10/26/19, 10 /30/19, 10/31/19, 11/1/19, 11/2/19, 11/3/19, 11/15/19, 11/18/19, 11/19/19, 11/21/19, 11/22/19, 11/25/19, 11/26/19, 11/27/19, 12/2/19, and 12/3/19. 4. No Individual Quality Control Plan (IQCP) could be located for the Quidel Triage Tox Drug Screen testing for the laboratory. 5. An interview with TP1, on 12/4/19 at approximately 10: 00 AM, confirmed that external negative and positive controls were only ran every 30 days or with a new lot for the Quidel Triage Tox Drug Screen test kit.
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 upon review of laboratory personnel files, West Virginia licensure verification source, and interviews with testing personnel, there were no individuals performing laboratory testing that possess a current West Virginia laboratory license as required by the West Virginia state rule WV 64 CFR 57 Clinical Laboratory Technician and Scientist Licensure and Certification Rule. Findings: 1. The 2 testing personnel of the laboratory had no knowledge or documentation of a West Virginia Laboratory license. 2. Interviews with the 2 testing personnel, 12/4/19 at approximately 9:00 AM, confirmed they had no current West Virginia laboratory license or knowledge that 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.