Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2079383	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Firmus Labs	9001 Woodyard Road #A-2, Clinton, MD	

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 review of the proficiency testing (PT) records and interview with the laboratory manager, the laboratory did not ensure that all the PT records were saved for the last two years. Findings: 1. The PT records from 2017 and 2018 (5 events) were reviewed. The attestation sheets and PT worksheets for recording the test results prior to submitting to the PT agency were not available for the forensic urine drug-conformation (UDC), events UDC-B and UDC-C for 2017. 2. During the survey on 07/25/2018 at 1:30 PM the laboratory manager confirmed that the PT attestation sheets and PT worksheets for UDC-B and UDC-C of 2017 were not available at the time of the survey.
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 observation and interview with the general supervisor, the Director acting as technical supervisor did not perform competency assessments for the general supervisor. Findings: 1. It was observed that the lab did not have documentation showing competency assessments are made for the general supervisor to assess his supervisory duties assigned to him; and 2. This was confirmed with the general supervisor during interview at 1:00 pm on the day of survey.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with testing staff, the lab did not ensure reagents were not used past expiration. Findings: 1. It was observed that a bottle of acetic acid stored near the toxicology analyzers (LCMS analyzers) was labeled with an expiration date of January 31, 2018; 2. It was confirmed during interview with the testing person at 1:30 pm on the day of survey, that the acetic acid was expired and was not labeled as do not use for patient testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the "Proficiency Testing between LC-1/LC-2" procedure and interview with the manager, the laboratory's written procedure did not define the frequency of comparisons to be performed between the two Liquid Chromatography-Mass spectrometry (LC-MS) analyzers used at the laboratory. Findings: 1. The laboratory has two LC-MS analyzers that report patient results on any given day. The "Proficiency Testing between LC-1/LC-2" procedure does not define the frequency that the comparisons are to be performed and evaluated. 2. During the exit interview on 07/25/18 at 1:30 PM the manager confirmed that the "Proficiency Testing between LC-1/LC-2" procedure did not define the frequency that the comparisons were to be performed.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the laboratory manager, the laboratory director did not ensure that the PT final summary reports were reviewed and all corrective actions were documented. Findings: 1. The PT records for forensic urine drug-conformation, UDC, from the first event of 2017 through the second event of 2018 were reviewed. The PT final summary reports showed that two of five summaries did not included a documented review (signature and date) by the laboratory director and the PT worksheets for submitting the final results. 2. The PT records did not include worksheets, instrument printouts, attestation records and the review of the summary of results for the first event of 2018 (UDC-A). 3. During the exit interview on 07/25/18 at 1:30 PM the manager confirmed that two of five summaries did not included a documented review by the laboratory director and the first event of 2018 was not available.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A. Based on review of the quality assessment (QA) records and interview with the laboratory manager, the laboratory director did not ensure that the QA documentation included problems with proficiency testing events and documentation of annual and semi-annual evaluations. Findings: 1. During the survey the monthly laboratory director QA worksheets for 2017 and 2018 were reviewed. The section labeled "PT problems" indicated that no problems were found each month during that time period. 2. The PT records showed that for the first event in 2017, UDC-A, there were no records. When interviewed the laboratory manager stated that the laboratory had not contacted the PT agency to renew their subscription to receive Forensic urine drug specimens for 2017. The laboratory enrolled late and only received 3 of the 4 events for 2017. 3. The PT records showed that for the second event in 2017, UDC-B and the second event of 2018 UDC-B the investigation worksheet did not include documentation of "Corrective action documentation " and "Review of patient results in response to PT failure" on the worksheet. 4. During the survey the monthly laboratory director QA worksheets for 2017 and 2018 were reviewed. The section labeled "Annual or semi-annual evaluations due? Y or N" showed that the "Y or N" was not circled or the "N" was circled indicating that no annual or semi-annual evaluations due were due. 5. The laboratory has three employees listed on the "Laboratory Personnel Report (CLIA)." The manager stated that one of the three had been hired in January 2018 and the other two had been at the lab for over two years. The QA reviews should have included at least one semi-annual review and two annual reviews from 2017 and 2018. 6. The monthly "Laboratory Director Review" QA worksheets did not indicate the failure to enroll in PT in a timely manner; that the PT summary reports were not being reviewed (signed and dated) for two of five events (cross refer to D6091 for details); and that annual and semi-annual reviews were not being documented. 7. During the survey on 07/25/18 at 1:30 PM the laboratory

	manager confirmed that the monthly QA worksheets did not include documentation of the failure to enroll in PT; that the PT summaries were not being documented as having been reviewed as required and annual and semi-annual evaluations were not being documented. B. Based on review of the policies and procedure manuals and interview with the laboratory manager, the laboratory director did not ensure that the humidity was documented per the procedure manual and that the temperature worksheet had the correct reference range listed. Findings: 1. The procedure labeled "Test Systems, Reagents, Supplies" states: "The laboratory has defined criteria for conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria are consistent with the manufacturer's instructions. These conditions are monitored and documented and include the following: ... Humidity (20-80%, non-condensing)." 2. The laboratory's maintenance records for 2017 and 2018 were reviewed and there were no records showing that the humidity was being documented. 3. The room temperature worksheets for 2017 and 2018 were reviewed. The reference range listed on the room temperature worksheets were 15-30 degrees Celsius. The temperatures recorded for the last 19 months were 69, 71, 72 and 73. None of those values were within the defined reference range of 15-30. 4. During the survey on 07/25/18 at 1:30 PM the laboratory manager confirmed that the humidity was not being documented per the procedure manual and the recorded room temperature was not within the defined limits.