Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2132371	09/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urgent Care	5907 W 63rd Street, Chicago, IL	

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
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review, proficiency testing (PT) reports, and an interview with the laboratory director (LD), the laboratory failed to take remedial action when it received an unsatisfactory performance score for Hematocrit testing in the year of 2019. Findings: 1. The laboratory's manuals and the College of American Pathologists (CAP) -PT documents for 2018 and 2019 were reviewed. 2. The CAP-PT reports revealed the following: *The laboratory scored 60% for Hematocrit testing during event #1 of 2019. *The PT failure was noted but no documented evidence was provided to show the failure was investigated by the LD or technical consultant (TC). 3. The laboratory's PT policies and procedures failed to include a step-by-step method to investigate PT failures. 4. On a Recertification survey conducted on 09/05/2019 at 2: 35 PM, the LD confirmed the above findings.
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 records review, manual, and an interview with the laboratory director (LD), the laboratory failed to verify the accuracy of its D-Dimer and Troponin tests it performs, for the years of 2018 and 2019. Findings include: 1. Patients' test records, the College of American Pathologists (CAP) PT reports for 2018 and 2019, and manual were reviewed. 2. The patients' test reports revealed that the laboratory had been performing Troponin and D-Dimer testing. 3. The CAP-PT documents showed the analytes Troponin and D-Dimer were not included in the Routine Chemistry panel for PT sample testing during the years 2018 and 2019. 4. The laboratory's manual failed to include an establish method to verify the accuracy it's Troponin and D-Dimer testing. 5. On a Recertification survey conducted on 09/05/2019 at 2:35 PM, the LD confirmed the above findings and stated they thought the test for Troponin and D-Dimer were waived.
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 direct observation, manual review, and an interview with the laboratory director (LD), the laboratory failed to ensure supplies are not to be used when they have exceeded their expiration date. Findings: 1. On 09/05/2019 at 11:45 AM during a tour of the laboratory, the surveyor observed the following expired supplies in the laboratory: *3 Green Top Heparin tubes with expiration date 08/09/2019; and *2 Blue Top tubes with the expiration date 07/31/2019. 2. The laboratory's manual failed to include a written method that would ensure supplies are not used pass their expiration dates. 3. On a Recertification survey conducted on 09/05/2019 at 2:35 PM, the LD confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, manual review, lack of documentation, and an interview with the laboratory director (LD), the laboratory failed to perform, and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for the years of 2018 through 2019. Findings Include: 1. On 09/05 /2019 at 12:00 PM, during a tour of the laboratory, the surveyor observed the following equipment, instruments, and test systems in the laboratory: *An Alere Triage analyzer; *A Cell Blood Count (CBC) analyzer; and *A Piccolo Chemistry analyzer 2. The laboratory's procedures manuals and operator's manuals for the Triage, CBC, and Chemistry analyzers were reviewed. 3. The procedures and operator's manuals revealed the following: *Each manufacturer has maintenance

	requirements for their analyzers. *The laboratory's procedures manual failed to include the manufacturer's maintenance requirements for 3 out of 3 analyzers. *No documentation was provided as evidence the laboratory performed any maintenance on the 3 analyzers. 4. On a Recertification survey conducted on 09/05/2019 at 2:35 PM, the LD confirmed the above findings and stated that maintenance was not performed on all the analyzers and if maintenance had been performed, it was not documented.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review, manufacturer's instructions, and an interview with the laboratory director (LD), the laboratory failed to follow the manufacturer's instructions to perform calibration every 6 months on the analyzer used for Cell Blood Count (CBC) testing, during the years 2018 and 2019. Findings Include: 1. The CBC analyzer's manual and quality control (QC) test records were reviewed. 2. The CBC analyzer's manual states calibrations are to be performed "every 6 months" to verify the manufacturer's reportable ranges. 3. The QC records revealed the following: *Calibrations were performed on 05/23/2018 and 01/12/2019. *In 2018, after the 05 /23/2018 calibration, the next calibration was due in the November 2018; *In 2019, after the 01/12/2019 calibration, the next calibration was due in July of 2019. The laboratory repeatedly failed to verify the CBC analyzer's reportable ranges in the time frame required by the manufacturer. 4. On a Recertification survey conducted on 09/05 /2019 at 2:35 PM, the LD confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, patients test records, and an interview with the laboratory director (LD), the laboratory failed to include two control materials of different concentrations at least once a day patient specimens are assayed, affecting 2 out of 2 patients. Findings Include: 1. The laboratory was using the Alere Triage MeterPro Troponin and D-Dimer cassette kits. 2. The quality control (QC) records for the month of March of 2019 for D-Dimer and Troponin and patients' test results were reviewed. 3. QC was not performed on 03/12/2019 and 03/21/2019. 4. Review of patient test records revealed 2 patients' test results were reported on the above dates. 5. On a Recertification survey conducted on 09/05/2019 at 2:35 PM, the LD confirmed the above findings and stated they thought the tests were waived and did not require QC each day of patient testing.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and an interview with the laboratory director (LD); the LD failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. Findings: The laboratory's procedures manual and proficiency testing (PT) policy and procedures were reviewed. 1. The LD failed to establish written procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the following systems: *PT failure investigation. *General Laboratory systems - Verifying the accuracy of Troponin and D-Dimer testing. *Pre-analytic & Analytic - monitoring expired supplies, performing maintenance, timely calibrations, control procedures, etc. and *Post-analytic systems 2. On a Recertification survey conducted on 09/05 /2019 at 2:35 PM, the LD confirmed the above findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on review of personnel files, review of the Laboratory Personnel Report (CMS-209), and an interview with the laboratory director (LD), the LD failed to ensure all personnel have the appropriate education prior to testing patients' specimens, affecting 1 out of 7 testing personnel (TP). Findings: 1. The employee files and CMS-209 were reviewed. 2. The CMS 209 lists 7 TP (TP1, TP2, TP3, TP4, TP5, TP6, and TP7) performing Hematology and Routine Chemistry testing in the laboratory. 3. The personnel file revealed that TP6 diploma was from Canada. The LD failed to ensure TP6 education credentials had been evaluated and proven to have met the requirements to perform moderately complex testing, prior to testing patients. 4. On a Recertification survey conducted on 09/05/2019 at 2:35 PM, the LD confirmed the above findings.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review, manuals, and an interview with the laboratory director (LD), the technical consultant (TC) failed to establish a quality control program appropriate for the testing performed, affecting 2 out 2 patients. Findings: 1. The laboratory was using the Alere Triage MeterPro Troponin and D-Dimer cassette kits. 2. The quality control (QC) records, patients' reports, and procedures manual were reviewed. 3. QC records and patient test records revealed the following: *Liquid controls were ran when a new lot of cassette kits were received. *QCs were not perform on the dates when patient testing was performed and results reported. 4. The TC failed to establish quality control procedures for Troponin and D-Dimer testing, prior to testing patients. 5. On a Recertification survey conducted on 09/05/2019 at 2:35 PM, the LD confirmed the above findings. 6. Refer to 5447.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS-209) and an interview with the laboatory director (LD); the laboratory failed to employ individuals who meet the qualification requirements of 493.1423 for testing personnel (TP) for 1 out of 7 TP. Finding: 1. The laboratory failed to ensure laboratory personnel meet the qualification requirements for performing moderately complex testing in the specialties of Hematology and Chemistry. See D6065

D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review, lack of documentation, the Laboratory Personnel Report (CMS-209) and an interview with the laboratory director (LD); the laboratory failed to ensure laboratory employees meet the education qualification requirements for performing moderately complex testing prior to testing patients, affecting 1 out of 7 testing personnel (TP). Findings: 1. The employee files and CMS-209 were reviewed. 2. The CMS 209 lists 7 TP (TP1, TP2, TP3, TP4, TP5, TP6, and TP7) performing Hematology and Routine Chemistry testing in the laboratory. 3. The employee files of TP6 revealed the following: *TP6 was authorized to perform patient testing; *TP6 failed to have their foreign education credentials evaluated for United States equivalency. *The laboratory failed to ensure TP2 met the education requirement for performing moderately complex testing, prior to testing patients. 4. On a Recertification survey conducted on 09/05/2019 at 2:35 PM, the LD confirmed the above findings.