Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	14D2049789	10/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urgent Care	10 Orland Square Dr, Orland Park, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory records and interview with the laboratory director (LD); the laboratory failed to meet chemistry testing requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. Findings Include: 1. The laboratory failed to perform control procedures as specified by the laboratory's individual quality control plan (IQCP) for chemistry testing on Alere Triage meters for 4 of 6 patient test dates reviewed. See D5445. 2. The laboratory failed to have a system in place that twice yearly evaluates the relationship between the analytes creatinine kinase MB (CK-MB) and troponin I (TNI) tested on two Alere Triage Meters. See D5775. 3. The laboratory failed to immediately alert an individual or entity requesting a test result when panic values were identified for troponin I (TNI) testing. See D5813.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director

	(LD); the laboratory failed to meet the requirements for hematology testing specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. Findings Include: 1. The laboratory failed to include two control materials of different concentrations for complete blood count (CBC) testing on the Beckman Coulter Act diff 2 analyzer each day of patient testing. See D5447. 2. The laboratory failed to have a system in place that twice yearly evaluates the relationship between d-dimer testing on two Alere Triage Meters. See D5775.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform control procedures as specified by the laboratory's individual quality control plan (IQCP) for chemistry testing on Alere Triage meters for 4 of 6 patient test dates reviewed. Findings include: 1. Direct observation of the laboratory equipment on 10-08-2019 at 12:05pm identified two Alere Triage meters used for troponin I (TNI) and creatinine kinase MB (CK-MB) testing, serial numbers 0068964WW and 00079814WW. 2. Review of the IQCP for troponin I (TNI)/Creatinine kinase MB (CK-MB)) testing on Alere Triage meters revealed that external controls will be tested with each new lot or shipment of test material or every 30 days. 3. Review of patient tests results troponin I and CK-MB for 4 of 6 patient testing dates reviewed revealed external quality controls (QC) were not performed each month on the analyzer used for testing as described in the IQCP. Patient Identification Test Date Analyte Analyzer ID External QC Date T1 02-14-2019 Troponin I, CK-MB 8964 11-16-2018 T2 09-13-2019 Troponin I, CK-MB 9814 08-12-2019 T5 04-10-2019 Troponin I, CK-MB 8964 11-16-2018 T6 06-17-2019 Troponin I, CK-MB 9814 02-21-2019 4. Review of external quality control testing for TNI/CK-MB revealed that external quality control testing was not performed on analyzer 9814 for 10 of 19 months reviewed in 2018 through 2019. 5. Review of external quality control testing for TNI/CK-MB revealed that external quality control testing was not performed on analyzer 8964 for 11 of 19 months reviewed in 2018 through 2019. 6. No external quality control were performed every 30 for TNI/CK-MB testing for the following months on either analyzer: September 2019, May 2019, April 2019, March 2019, January 2019, September 2018, August 2018, and June 2018. 7. Review of test volume records from September of 2018 through September of 2019 revealed 316 combined tests were performed for TNI and CM-MB. 8. On survey date 10-08-2019, at 7:15 pm, the LD confirmed that external quality controls were not performed as described for both Alere Triage meters for TNI/CK-MB testing.
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 direct observation, review of laboratory records, and interview with the lab director (LD); the laboratory failed to ensure two levels of quality control (QC) materials were ran each day of testing before reporting complete blood count (CBC) patient test results for 1 of 5 patient testing dates reviewed. Findings include: 1. Direct observation of laboratory equipment on 10-08-2019 at 12:05pm identified a Beckman Coulter AcT diff 2 hematology analyzer used for CBC testing, serial number 44554083. 2. Review of patient test reports for CBC testing found no documented quality control records for 1 of 5 patient testing dates reviewed. Patient Identification Test Date C4 09-13-2019 3. Review of patient testing records revealed 3 patients in total had CBC testing performed on 9-13-2019. 4. On survey date 10-08-2019, at 7:15 pm, the LD confirmed that two levels of quality control material were not performed 9-13-2019.
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 direct observation, review of the laboratory records, and interview with the laboratory director (LD); the laboratory failed to have a system in place that twice yearly evaluates the relationship between the analytes d-dimer, creatinine kinase MB (CK-MB), and troponin I (TNI) tested on two Alere Triage Meters. Findings Include: 1. Direct observation on 10-08-2019, at 12:06 pm, identified two Alere Triage Meters (Serial Numbers: 0068964WW and 00079814WW). 2. Review of laboratory records revealed the laboratory failed to evaluate the relationship between the two Alere Triage meters used for D-Dimer, CK-MB, and TNI testing in 2018 and 2019. 3. On survey date 10-08-2019, at 7:15 PM, the LD confirmed the laboratory failed to evaluate the relationship between the two Triage Meter twice yearly for D-Dimer, CK-MB, and TNI.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to immediately alert an individual or entity requesting a test result when panic values were identified for troponin I (TNI) testing. Findings Include: 1. Review of the laboratory's policy and procedure manual identified panic value documentation for TNI as greater or equal to 01.ng/dL. Additionally the laboratory had a log used to document panic values identified by the laboratory and the notification to the individual or entity requesting the test result. 2. Review of patient testing for TNI identified a patient (Identifier - T7) who had a panic value TNI of 10.3 ng/dL on 02-07-2019. 3. Review of the panic value log revealed the laboratory failed to document the panic value for TNI on 2-07-2019 for patient T7 and document the panic value was reported to the individual or entity that requested the test. 4. Further review of TNI patient testing in 2018 through 2019 identified two additional patients with panic value results for TNI testing. Patient Identification Date TNI Value T8 12-05-2018 5.63 ng/dL T9 07-19-2019 0.16 ng/dL 5. Review of the panic value log revealed the laboratory failed to document the two additional panic values identified for patient's T8 and T9. 6. The last documented panic value in the log was recorded on 09-08-2018. 7. On survey date 10-08-2019, at 7:15 PM, the LD confirmed the laboratory failed to document 3 of 3 TNI panic values and ensure they were immediately alerted to the individual or entity that requested the test.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the facility failed to have a laboratory director (LD) who meets the qualifications requirements of 493.1405 and provide overall management and direction in accordance with 493.1407 of this subpart. Findings Include: 1. The laboratory failed to have a qualified laboratory director who meets the experience requirements to direct a laboratory. See D6003. 2. The LD failed to ensure an approved corrective action plan was followed for unacceptable troponin I proficiency testing (PT) samples for event 2 in 2019. See D6019. 3. The LD failed to ensure the quality control plan was maintained in 2018 through 2019. See D6022. 4. The LD failed to specify in writing the responsibilities and duties for 6 of 6 testing personnel listed on the CMS-209 (Laboratory Personnel Report). See D6032.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or

both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of

	the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have a qualified laboratory director who met the experience requirements to direct a laboratory. Findings include: 1. Review of both the CMS-209 (Laboratory Personnel Report) and the CMS-116 (Application for Certification) identified a new LD. 2. Review of the laboratory personnel records for the new LD found the LD had a bachelor's degree in medical technology but failed to meet the experience requirements for a moderate complexity laboratory director. The laboratory failed to have proof of supervising or directing a non-waived laboratory for at least 2 years. 3. The LD on 10-08-2018, at 7:15 pm, confirmed the laboratory failed to have 2 years of documented evidence of supervising/directing experience for a non-waived laboratory.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory director failed to ensure an approved corrective action plan was followed for unacceptable troponin I proficiency testing (PT) failures for event 2 in

	2019. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Proficiency Testing Exception Investigation Checklist", which outlined all PT testing misses should be investigated and documented on the PT exception investigation checklist. 2. Review of American Association of Bioanalysts (AAB) PT documentation revealed for Chemistry event 2 of 2019 the laboratory received a score of 80% for troponin I (TNI). 3. Review of American Association of Bioanalysts PT documentation found no investigation was documented as outlined in the laboratory policy and procedure for the missed TNI PT sample. 4. On survey date 10-08-2019, at 7:15 pm the LD confirmed the unacceptable PT results for TNI was not reviewed and no corrective actions taken for the failure as outlined in the laboratory policy.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the LD failed to ensure the quality control plan was maintained in 2018 through 2019. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Quality Control Plan" which provided parameters to be monitored by the laboratory to ensure the quality of patient testing. 2. The policy indicated each month 5 patient records are to be reviewed to ensure the quality of patient testing. 3. Review of laboratory records revealed the laboratory failed to review 5 patient records each month to ensure the quality of patient testing for 19 of 19 months reviewed. 4. Additionally, the quality control policy indicated training and competency assessment guidelines for testing personnel. 5. Review of laboratory training and competency assessment records revealed the laboratory failed to follow the quality control plan. See DXXX. 6. On survey date 10-08-2019, at 7:15 pm, the findings were confirmed by the LD.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review laboratory records and interview with the laboratory director (LD); the LD failed to specify in writing the responsibilities and duties for 6 of 6 testing personnel listed on the CMS-209 (Laboratory Personnel Report). Findings Include: 1. Review of laboratory records revealed the laboratory director failed specify in writing, the duties and responsibilities which identifies the procedures each individual is authorized to perform and whether supervision is required for 6 of 6 testing personnel (TP) listed on the CMS-209. 2. On survey date 10-08-2019, at 7:15 pm, the LD confirmed no duties and responsibilities including the procedures each individual is authorized to perform and whether supervision is required was documented for 6 of 6 TP.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the technical consultant (TC) failed to have a TC who meets the qualification requirements of 493.1411and provides the technical oversight in accordance with 493. 1413. Findings Include: 1. The laboratory's TC failed to have the documented experience to qualify as a TC for chemistry and hematology testing performed. See D6035. 2. The TC failed to ensure semi-annual competency assessments were completed for 2 of 4 new testing personnel. See D6053. 3. The TC failed to ensure annual competency assessments were completed for 2 of 2 established testing personnel in 2018 and 2019. See D6054.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is

	responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to have a qualified technical consultant (TC). Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified a new TC. 2. Review of the laboratory personnel records for the new TC found the TC had a bachelor's degree in medical technology but failed to meet the experience requirements for a TC. The laboratory failed to have proof of 2 years of experience in the specialties of chemistry and hematology for the TC. 3. The LD on 10-08-2018, at 7:15 pm, confirmed the laboratory failed to have 2 years of documented evidence of experience in chemistry and hematology testing for the TC.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the technical consultant (TC) failed to ensure semi-annual competency assessments were completed for 2 of 4 new testing personnel. Findings Include: 1. Review of the laboratory policy, "Quality Control Plan", indicated that new testing personnel will have competency assessments at 6 months and 1 year. 2. Review of the CMS-209 (Laboratory Personnel Report) identified 4 new testing personnel (TP). 3. Review of personnel records revealed TP#2's start date was unknown but no competency assessments had been completed for TP#2. 4. Review of personnel records for TP#6 revealed they started testing in March of 2019 but no 6 month competency had been completed in September of 2019. 5. On survey date 10-08-2019, at 7:15 pm, the LD confirmed no competency assessments had been completed for 2 of 4 new TP identified on the CMS-209 as outlined in the laboratory's quality control plan.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least

	annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the technical consultant (TC) failed to ensure annual competency assessments were completed for 2 of 2 established testing personnel in 2018 and 2019. Findings Include: 1. Review of the laboratory policy, "Quality Control Plan", indicated that established testing personnel will have competency assessments annually. 2. Review of the CMS-209 (Laboratory Personnel Report) identified 2 established testing personnel (TP), TP#1 and TP#3. 3. Review of personnel records revealed TP#1 and TP#3 failed to have documented competency assessments in 2018 and 2019. 4. On survey date 10-08-2019, at 7:15 pm, the LD confirmed no competency assessments had been completed for 2 of 2 established TP identified on the CMS-209, as outlined in the laboratory's quality control plan.
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 review of laboratory records and interview with the laboratory director (LD) the laboratory failed to employ testing personnel (TP) who met the qualification requirements of 493.1423. Findings Include: 1. The laboratory failed to ensure 3 of 3 testing personnel (TP) had the required training for chemistry and hematology testing performed prior to patient testing. See D6066.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to ensure 3 of 3 testing personnel (TP) had the required training for chemistry and hematology testing performed. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified 4 new TP. 2. Review of education records revealed 3 of 4 new testing personnel had a high school diploma or equivalent education documentation for moderate complexity testing, TP#2, TP#5, and TP#6. 3. Review of training documentation revealed the laboratory failed to have the required documentation of training for complete blood count testing for 3 of 3 TP with an education equivalent to a high school diploma. 4. Further review of training documentation revealed TP#2 additionally failed to have the required training for d-dimer, creatinine kinase MB, and troponin I testing on the Alere Triage meters. 5. The LD on 10-08-2018, at 7:15 pm, confirmed the laboratory failed to document the training for 3 of 3 new moderate complexity of TP with high school diploma or equivalent education documentation.