Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	14D2049789	02/06/2018
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
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 review of the laboratory records and interviews with testing personnel (TP) #10 and TP#14; the laboratory failed to establish policies and procedures to assess employee competency. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of personnel listed on the CMS-209. 2. On survey date 02-06-2018 at 04:25 pm, TP#10 and TP#14 confirmed the laboratory failed to establish a competency assessment policy.
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 review of laboratory records and interviews with testing personnel (TP) #10

	and TP#14; the laboratory failed to monitor refrigerator/freezer temperatures to ensure accurate and reliable storage of hematology and chemistry reagents in 2017 through the date of survey (02-06-2018). Findings Include: 1. Review of the laboratory log, "Daily Refrigerator/Freezer Temperature Log", states "1. Temperatures of the fridge and the Freezer should be documented daily". 2. Review of the laboratory's temperature logs from November 20, 2017 through the date of survey, February 6, 2018 identified multiple dates when daily temperatures of the Frigidaire, Serial #BA2022411, refrigerator/freezer were not documented on the "Daily Refrigerator /Freezer Temperature log". Dates when no refrigerator/freezer temperatures were documented December 8, 2017 through January 18, 2018 January 25, 2018 January 28, 2018 3. On survey date 02-06-2018, at 4:24 pm, TP#10 and TP#14 confirmed the laboratory failed to document the temperature of the refrigerator/freezer used to store chemistry and hematology reagents daily for 2 of 4 months reviewed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews with testing personnel (TP) #10 and TP#14; the laboratory failed to perform corrective actions for out of range refrigerator temperatures in which chemistry and hematology reagents are stored for 3 of 11 days in January of 2018 when temperatures were documented. 1. Review of the laboratory "Daily Refrigerator/Freezer Temperature Log" documents found the refrigerator temperature range is 36 to 46 degrees Fahrenheit. 2. Review of the "Daily Refrigerator/Freezer Temperature Log" for January of 2018 found for 01-21-2018 through 01-23-2018 the refrigerator temperature was 47 degrees Fahrenheit and no corrective actions were documented. 3. On survey date 02-06-2018, at 4:25 pm, TP#10 and TP#14 confirmed no corrective actions were taken for out of range refrigerator temperatures found for 3 of 11 days during the month of January 2018 when temperatures were documented.
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 laboratory testing personnel (TP) #14; the laboratory failed to have a technical consultant (TC) who meets the

	qualification requirements of 493.1411. Findings Include: 1. The laboratory director failed to have documented experience or training in the specialties of hematology and chemistry in order to meet the qualification requirements to be the technical consultant. See D6035.
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 the laboratory records and interview with laboratory testing personnel (TP) #14; the laboratory failed to delegate the responsibilities of the technical consultant to a qualified individual. Findings Include: 1. Review of qualifying documentation for the laboratory director, who is also identified as the technical consultant on the CMS-209, failed to have training or experience documentation for non-waived testing in the specialties of chemistry and hematology. 2. On survey date 02-06-2018, at 12:34 pm TP#14 confirmed the laboratory director failed to have any previous training or experience for the specialties of chemistry and hematology.
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 laboratory testing personnel (TP) #10 and TP#14; the laboratory failed to employ testing personnel (TP) who meet the qualification requirements of 493.1423. Findings Include: 1. The laboratory failed to have qualifying documents for 20 of 23 testing personnel listed on the CMS-209. 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 review of laboratory records and interview with laboratory testing personnel (TP) #10 and TP#14; the laboratory failed to have qualifying documents for 20 of 23 testing personnel listed on the CMS-209. Findings Include: 1. Review of testing personnel qualifying documents found that 20 of 23 TP failed to have foreign equivalency or diplomas required for TP qualification. Testing Personnel Identification Missing Documentation Page 1 of the CMS-209 TP#2 No Degree /Foreign equivalency TP#3 No Degree/Foreign equivalency TP#4 No Degree/Foreign equivalency TP#5 No Degree/Foreign equivalency TP#6 No Degree/Foreign equivalency TP#7 No Degree/Foreign equivalency TP#8 No Degree/Foreign equivalency TP#9 No Degree/Foreign equivalency TP#10 No Degree/Foreign equivalency TP#11 No Degree/Foreign equivalency TP#12 No Degree/Foreign equivalency TP#13 No Degree/Foreign equivalency TP#15 No Degree/Foreign equivalency TP#16 No Degree/Foreign equivalency Page 2 of CMS-209 TP#19 No Degree/Foreign equivalency TP#20 No Degree/Foreign equivalency TP#21 No Degree /Foreign equivalency TP#22 No Degree/Foreign equivalency TP#23 No Degree /Foreign equivalency 2. On survey date 02-06-2018, at 4:25 pm TP#10 and TP#14 confirmed that 20 of 23 above mentioned TP failed to have degrees or United States foreign equivalency documentation required to meet moderate complexity testing requirements.