Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2000206	06/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care Of Ardmore	908 N Rockford Rd, Ardmore, OK	

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
D0000	The findings were reviewed with the technical consultant at the the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to test proficiency testing samples using the laboratory's routine methods. Findings include: (1) During the survey, the surveyor reviewed proficiency testing records for 5 events performed in 2016, 2017, and 2018 for CBC (Complete Blood Count) testing. The following was identified for 2 of the 5 events: (a) Second 2017 Hematology Event. The event had been tested on 07/15/17, with 1 specimen tested in duplicate. It appeared to the surveyor that the results from the first run had been reported to the proficiency testing program for each analyte as follows: (i) Specimen HEM-07 had been tested at 01:34 pm and repeated at 01:36 pm as follows (aa) RBC (Red Blood Cell) - A result of 5.31 was obtained on the first run and 5.24 was obtained on the second run. 5.31 was reported to the proficiency testing program; (bb) Hemoglobin - A result of 14.7 was obtained on the first run and 14.5 was obtained on the second run. 14.7 was reported to the proficiency testing program; (cc) Hematocrit - A result of 45.0 was obtained on the first run and 44.3 was obtained on the second run. 45 was reported to the proficiency testing program; (dd) Platelet Count - A result of 114 was obtained on the first run and 121 was obtained on the second run. 114 was reported to the proficiency testing program; (ee) MCV (Mean Corpuscular Volume) - A result of 84.7 was obtained on the first run and 84.5 was

	obtained on the second run. 84.7 was reported to the proficiency testing program; (ff) Granulocytes % - A result of 68.2 was obtained on the first run and 67.7 was obtained on the second run. 68.2 was reported to the proficiency testing program; (gg) Lymphocytes % - A result of 12.7 was obtained on the first run and 13.5 was obtained on the second run. 12.7 was reported to the proficiency testing program; (hh) Monocytes % - A result of 19.1 was obtained on the first run and 18.8 was obtained on the second run. 19.1 was reported to the proficiency testing program; (ii) WBC (White Blood Cell) - A result of 13.4 was obtained on the first run and 13.1 was obtained on the second run. 13.4 was reported to the proficiency testing program. (b) First 2018 Hematology Event. The event had been tested on 03/21/18, with 1 specimen tested in duplicate. It appeared to the surveyor that the results from the first run had been reported to the proficiency testing program for each analyte as follows: (i) Specimen HEM-05 had been tested at 03:53 pm and repeated at 04:08 pm as follows (aa) RBC (Red Blood Cell) - A result of 6.73 was obtained on the first run and 6.71 was obtained on the second run. 6.73 was reported to the proficiency testing program; (bb) Hemoglobin - A result of 17.3 was obtained on the first run and 17.3 was obtained on the second run. 17.3 was reported to the proficiency testing program; (cc) Hematocrit - A result of 52.9 was obtained on the first run and 53.1 was obtained on the second run. 53 was reported to the proficiency testing program; (dd) Platelet Count - A result of 113 was obtained on the first run and 105 was obtained on the second run. 113 was reported to the proficiency testing program; (ee) MCV (Mean Corpuscular Volume) - A result of 78.6 was obtained on the first run and 79.1 was obtained on the second run. 78.6 was reported to the proficiency testing program; (ff) Granulocytes % - A result of 64.5 was obtained on the first run and 64.8 was obtained on the second run. 64.5 was reported to the proficiency testing program; (gg) Lymphocytes % - A result of 12.0 was obtained on the first run and 12.2 was obtained on the second run. 12.0 was reported to the proficiency testing program; (hh) Monocytes % - A result of 23.5 was obtained on the first run and 23.0 was obtained on the second run. 23.5 was reported to the proficiency testing program; (ii) WBC (White Blood Cell) - A result of 4.1 was obtained on the first run and 4.0 was obtained on the second run. 4.1 was reported to the proficiency testing program. (2) The records were then shown to the technical consultant. After reviewing the records, the technical consultant stated to the surveyor that the proficiency testing samples had been tested in duplicate. The results from the first run were reported to the proficiency testing program as indicated above. In addition, the technical consultant stated that patient specimens were not routinely tested in this manner.
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 a review of manufacturer's instructions, records, and interview with the technical consultant and testing person #1, the laboratory failed to ensure materials were not used beyond the open vial stability. Findings include: (1) At the beginning of the survey, testing person #1 verified to the surveyor CBC (Complete Blood Count) testing was performed on the Beckman Coulter AcT Diff 2 analyzer; (2) Later during the survey, testing person #1 stated three levels of Coulter 4C-ES Cell Control quality control materials (abnormal low, normal, and abnormal high) were analyzed each day

	of patient testing; (3) The surveyor observed the current quality control materials in use: 1 vial of Abnormal Low control (lot #069400), 1 vial of Normal control (lot #079400), and 1 vial of Abnormal High control (lot #089400); (4) The surveyor reviewed the manufacturer's package insert for the control materials. The insert verified the open vial stability was 35 days; "Assumes that the Instruction Section of the package insert is performed a maximum of 20 times within 35 days"; (5) The surveyor then reviewed the quality control records for the current lot numbers of controls materials, which were put into use on 03/13/18. The records verified the controls had been used for 35 days instead of the maximum use of 20 times as follows: (a) A set of controls had been opened on 03/13/18 and used until 04/17/18 (b) A set of controls had been opened on 04/17/18 and used until 05/22/18 (6) Testing person #1 stated to the surveyor the laboratory routinely documented the open vial expiration date as 35 days after opening the control materials and were not aware the manufacturer specified the controls were to be performed a maximum of 20 times within the 35 days; (7) The surveyor explained to testing person #1 and the technical consultant that the vials must be dated to ensure they are not used beyond the maximum of 20 times within 35 days.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Beckman Coulter AcT Diff 2 analyzer; (2) Later during the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 06/04/18 at 08:54 am; the second report was for an adult female patient with the testing performed on 06/06/18 at 09:42 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit, which were: (a) RBC - 4.20 - 5.80 10^6/L (b) Hemoglobin - 13.2 - 17.1 g/dL (c) Hematocrit - 38 - 50% (3) The surveyor reviewed the findings with the technical consultant who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.