Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473037	09/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Broken Arrow Family Clinic	705 West Oakland Street, Broken Arrow, 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 recertification survey was performed 09/17/19. The findings were reviewed with the laboratory director and testing person #1 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) During the survey, the surveyor observed the laboratory and identified the following waived testing kits and materials with the manufacturers' storage requirement: (a) Influenza A & B testing using the BD Veritor reader and test kit - The manufacturer required a storage temperature between 59 and 86 F (Fahrenheit); (b) Strep A screen testing using the OSOM Strep kit - The manufacturer required a storage temperature between 59 and 86 F; (c) Urine pregnancy testing using the Consult Diagnostics HCG test kit - The manufacturer required a storage temperature between 59 and 86 F; (d) Macroscopic urinalysis testing using the Clinitek Status+ dipstick reader - The manufacturer required a storage temperature between 64 and 86 F; (e) Hemoglobin A1C testing using the Alere Afinion - The manufacturer required a storage temperature between 59 and 89 F. (2) The surveyor then reviewed laboratory temperature records from 2018 and 2019. The laboratory's acceptable temperature range was 39.2-71.0 degrees F which allowed the laboratory temperature to be colder than the manufacturers' required storage and testing temperature; (3) The surveyor reviewed the manufacturers' temperature requirements with testing person #1 and explained the only requirement for performing waived

	testing is to follow the manufacturer's instructions, including those for temperature; (4) Testing person #1 stated to the surveyor the laboratory failed to ensure the manufacturers' temperature requirements for the testing listed above had been met.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records, and interview with testing person #1, the laboratory failed to retain records of test requisitions and test authorizations for at least 2 years. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed patient CBC (Complete Blood Count) testing (e.g., WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, automated WBC differential in numbers and percentages (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils), Platelet Count, etc.) using the Beckman Coulter AcT diff 2 hematology analyzer; (2) During the survey, the surveyor identified 2 patient CBC reports which had not been submitted to a reference laboratory as instructed by the laboratory's policy and procedure for flagged CBC results. The surveyor reviewed the findings with testing person #1 who stated to the surveyor the 2 CBC's might have been fingerstick samples and the sample quantity was not enough to be retested. Testing person #1 also stated to the surveyor the test requisitions would indicate if the CBC's were performed on fingerstick samples; (3) Testing person #1 could not locate the test requisitions for the two patients and stated to the surveyor an office employee destroyed the test requisitions. The surveyor explained to testing person #1 all patient test requisitions and authorizations must be retained for at least 2 years after the date of service.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records, and interview with testing person #1, the laboratory failed to retain proficiency testing records for at least 2 years. Findings include: (1) At the beginning of the survey, the surveyor reviewed Hematology proficiency testing records from 2018 and 2019. For 5 of the 5 events reviewed, there were no instrument printouts from the proficiency sample testing for the First, Second, and Third events of 2018; and the First and Second events of 2019; (2) The surveyor asked testing person #1 for the analyzer printouts from the proficiency testing performed for the events listed above. Testing person #1 stated to the surveyor the analyzer printouts from proficiency testing were not retained; (3) The surveyor explained to testing person #1 that all proficiency testing records were to be retained for at least 2 years.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, policy and procedure, and interview with testing person #1, the laboratory failed to follow its policy and procedure for patient testing. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed patient CBC (Complete Blood Count) testing (e.g., WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, automated WBC differential in number and percentages (Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils), Platelet Count, etc.) using the Beckman Coulter AcT diff 2 hematology analyzer; (2) The surveyor reviewed the laboratory's policy and procedure for flagged CBC testing results. The policy stated "patient specimens requiring further testing will be sent to the reference laboratory. Refer to page 167 of the Operator's Manual section 6.10 What Flags and Codes Mean which describes the flags and suggests actions you should perform when they appear. When indicated by instrument flag send all manual differentials to CLIA certified reference laboratory;" (3) The surveyor then reviewed 17 CBC results that obtained flags from June 2018, May 2019, and August 2019. For 2 of the 17 flagged CBC's, there was no documentation the samples had been submitted to a reference laboratory for further testing as instructed in the policy and procedure: (a) Patient #1-Testing performed 06/05/18: Obtained * flags on differential results; (b) Patient #2-Testing performed 06/11/18: Obtained * flags on Platelet count and M flags on Monocytes, number and percentages and Granulocytes, number and percentages. (4) The surveyor asked testing person #1 if the patient CBC's listed above had been submitted to a reference laboratory for further testing. Testing person #1 stated to the surveyor the laboratory failed to follow the policy and procedure and the samples had not been submitted to a reference laboratory for further testing.
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 a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to ensure the manufacturer's environmental specifications had been met. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor the laboratory performed patient CBC (Complete Blood Count) testing (e.g., WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Beckman Coulter AcT diff 2 hematology analyzer; (2) The surveyor reviewed the manufacturer's temperature requirement for the analyzer. The manufacturer required the analyzer be stored and

	operated at a temperature between 61.0 and 95.0 degrees F (Fahrenheit); (3) The surveyor then reviewed laboratory temperature records from January 2018 through the survey. The laboratory's acceptable temperature range was 39.2 to 77.0 degrees F which allowed the laboratory temperature to be colder than the manufacturer's required storage and testing temperature; (4) The surveyor reviewed the findings with testing person #1. Testing person #1 stated to the surveyor the laboratory failed to ensure the manufacturer's temperature requirement for the Beckman Coulter AcT diff 2 hematology analyzer had been met.
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 a review of records and interview with testing person #1, the technical consultant failed to ensure a person was evaluated at least semiannually during the first year of performing moderate complexity testing. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records and identified the following for testing person #2: (a) This person was rehired on 04/12/18; (b) There was no evidence that a semiannual evaluation had been performed. (2) The surveyor reviewed the findings with testing person #1 who stated to the surveyor a semiannual evaluation had not been performed after testing person #2 had been rehired.