Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473037	12/06/2023
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 on 12/06/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant, testing person #1, and testing person #2 at the conclusion of the survey.
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, observation, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for room temperature storage for two of two reagent cartridges for Hemoglobin A1c testing. Findings include: (1) On 12/06/2023 at 10:32 am, the laboratory supervisor stated Hemoglobin A1c testing was performed using the Alere Affinion analyzer; (2) Observation of the laboratory on 12/06/2023 at 10:35 am identified two Affinion Hemoglobin A1c reagent cartridges, lot #10222982 stored at room temperature which had not been dated; (3) Review of the manufacturer's package insert under the heading "Cartridge Storage" stated, "Recommended storage is refrigerated at 2-8 C for maximum reagent life. Alternately, the cartridges can remain at room temperature (15-25 C) provided the expiration date on the carton is changed to 90 days from the date the carton is removed from the refrigerator"; (4) The findings were discussed with testing person #2 who stated on 12/06/2023 at 10:35 am, the cartridges were being stored at room temperature and had not been dated with the 90 day room temperature expiration date.
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 observation and interview with the laboratory manager, the laboratory failed to ensure two of two types of blood collection tubes were stored as required by the manufacturer, in a room denoted as exam room one. Findings include: (1) Observation of the exam room and interview with testing person #1 on 12/06/2023 at 10:05 am, identified the following: (a) 300 BD Vacutainer EDTA tubes, lot # 3257721, storage temperature of 4-25 degrees Celsius; (b) 300 BD Vacutainer SST tubes, lot # 3244717, storage temperature of 4-25 degrees Celsius. (2) Interview with testing person #1 on 10/25/2023 at 10:05 am confirmed the laboratory was not monitoring the temperature of exam room one.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process; and failed to have control procedures that would detect immediate errors that would occur due to test system failure, adverse environmental conditions, and operator performance for eight of eight months reviewed for testing performed using the Sysmex XN 330 Hematology analyzer. Findings include: LEVEY-JENNINGS (1) On 12/06/2023 at 11:05 am, testing person #1 stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN 330 analyzer; (b) Three levels of QC (quality control) materials were tested each day of patient testing. (2) A review of records from January 2023 through August 2023 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (i.e., biases, shifts, and trends); (3) Interview with testing person #1 on 12/06/2023 at 11:15 am confirmed that QC data to include Levey-Jennings graphs and cumulative statistical data had not been printed and reviewed during the review period. QUALITY

	CONTROL RANGES (1) On 12/06/2023 at 11:05 am, testing person #1 stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN 330 analyzer; (b) Three levels of QC (quality control) materials were tested each day of patient testing. (2) A review of records from January 2023 through August 2023 identified no evidence, that lower limits of acceptability for QC had been entered into the analyzer for three of three lot numbers as follows; (a) QC Level I - lot# 32101401 (i) White blood cells (WBC) 0.00 - 4.96 with a mean of 2.48 (ii) Red blood cells (RBC) 0.00 - 4.68, with a mean of 2.34 (iii) Hemoglobin (HGB) 0.0 - 12.4 with a mean of 6.2 (iv) Hematocrit (HCT) 0.0 - 35.4, with a mean of 17.7 (v) Platelets (PLT) 0 - 130, with a mean of 65 (b) QC Level 2 - lot# 32101402 (i) WBC 0.00 - 13.68 with a mean of 6.84 (ii) RBC 0.00 - 8.82, with a mean of 4.41 (iii) HGB 0.0 - 25.8 with a mean of 12.9 (iv) HCT 0.0 - 72.6, with a mean of 36.3 (v) PLT 0 - 498, with a mean of 249 (c) QC Level # 3 - lot# 32101403 (i) WBC 0.00 - 32.80 with a mean of 16.40 (ii) RBC 0.00 - 10.72, with a mean of 5.36 (iii) HGB 0.0 - 33.8 with a mean of 16.9 (iv) HCT 0.0 - 93.8, with a mean of 46.9 (v) PLT 0 - 1190, with a mean of 595 (3) Interview with testing person #1 on 12/06/2023 at 11:15 am confirmed that lower limits of acceptability for quality control had not been entered into the analyzer.