Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475217	11/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Okmulgee Pediatrics & Family Care	916 E 8th St, Okmulgee, 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 11/18/2025. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to ensure a proficiency testing attestation statement had been signed and dated by the laboratory director or designee for one of five Hematology events reviewed from 2024 through 2025. Findings include: (1) A review of the first, second, and third 2024; and first and second 2025 Hematology proficiency testing records identified the following for one of five events: (a) Second 2025 Event - The attestation statement had not been signed and dated by the laboratory director or designee. (2) The findings were reviewed with testing person #1 who stated on 11/18/2025 at 12:20 pm, the attestation statement had not been signed and dated by the laboratory director or designee.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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, assay sheet, and interview with testing person #1, the laboratory failed to ensure materials were not used beyond the open vial stability. Findings include: (1) On 11/18/2025 at 10:30 am, testing person #1 stated the following: (a) The laboratory performed Hemogram testing using the ABX Horiba Micros 60 analyzer; (b) Three levels of ABX Minotrol 16 QC (Quality Control) materials were tested each day of patient testing. (2) A review of the manufacturer's storage and stability instructions and assay sheet for the control materials contained in Minotrol 16 package insert required once the controls are opened, the controls are stable for 30 days when stored at 2 - 8 degrees C (Centigrade); (3) On 11/18/2025 at 10:40 am, observation of the refrigerator contents identified the following: (a) ABX Minotrol 16 QC material level 1, lot #52651601 - open date was not posted on the bottle, and modified expiration date could not be determined; (b) ABX Minotrol 16 QC material level 2, lot #52651602 - open date was not posted on the bottle, and modified expiration date could not be determined; (c) ABX Minotrol 16 QC material level 3, lot #52651603 - open date was not posted on the bottle, and modified expiration date could not be determined. (4) The findings were reviewed with testing person #1, who stated on 11/18/2025 at 01:00 pm, the controls had not been dated with the appropriate modified expiration date.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. 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 instructions were followed for performing maintenance procedures for one of one analyzer reviewed from January 2025 through the current date. Findings include: (1) On 11/18/2025 at 10:40 am, testing person #1 stated the laboratory performed hemogram (WBC (White Blood Cell), RBC (Red Blood Cell), Hgb (Hemoglobin), Hct (Hematocrit), MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), and PLT (Platelet Count) testing using the ABX Horiba Micro 60 analyzer; (2) On 11/18/2025, a review of the manufacturer's maintenance log showed the following required daily maintenance procedures: (a) Daily Cleaning (b) Check Reagents (c) Check Waste Level (d) Check Printer Paper (e) Run Start Up (3) A review of maintenance logs from January 2025 through the current date identified daily maintenance had not been documented as performed as follows: (a) January 21, 22, 23 (b) February 18, 19, 20 (c) March 28, 31 (d) April 01, 02, 03, 04, 07 (e) May 22, 23, 26, 27, 28, 29, 30 (f) June 02, 03, 04, 05, 06, 09, 10, 11, 12, 13 (g) July 24, 25, 28, 29, 30, 31 (h) September 30 (i) October 30,31 (4) The records were reviewed with testing person #1 who stated on 11/18/2025 at 01:20 pm, the daily maintenance procedures had not been documented as performed as stated above.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number

	of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory failed to verify the stated value of control materials before they were put into use for nine of 12 lot numbers. Findings include: (1) On 11/18/2025 at 10:30 am, testing person #1 stated the following: (a) The laboratory performed Hemogram testing using the ABX Horiba Micros 60 analyzer; (b) Three levels of ABX Minotrol 16 QC (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results; (d) Laboratory ran the new lot of QC materials in parallel with the old lots for 10 to 20 times before putting it into use. (2) A review of records for 12 control lot numbers identified no evidence the provided ranges were verified before the lot numbers were put into use for nine of 12 lot numbers as follows: (a) Low-level lot #51531601, normal-level lot #51531602, and high-level lot #51531603 - No evidence the QC materials had been parallel tested prior to implementation on 06/17/2025; (b) Low-level lot #52091601, normal-level lot #52091602, and high-level lot #52091603 - No evidence the QC materials had been parallel tested prior to implementation on 09 /02/2025; (c) Low-level lot #52651601, normal-level lot #52651602, and high-level lot #52651603 - No evidence the QC materials had been parallel tested prior to implementation on 10/27/2025; (3) The findings were reviewed with the testing person who stated on 05/15/2025 at 12:15 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory director failed to ensure proficiency testing reports were reviewed for one of five Hematology events reviewed in 2024 and 2025. Findings include: (1) A review of 2024 and 2025 Hematology proficiency testing events identified the "Performance Evaluations" included a space for the laboratory director or designee's signature and date (indicating review of the graded evaluation). The following was identified for one of five events: (a) API First event of 2025 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (2) The records were reviewed with testing person #1 on 11/18 /2025 at 12:22 pm, the graded evaluations, as indicated above, had not been signed and dated as reviewed by the laboratory director or designee.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	(b)(9) Thereafter, evaluations must be performed at least annually 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 personnel performing moderate complexity testing had been evaluated at least annually for two of two testing persons during the review period of January 2024 through the current date. Findings include: (1) On 11/18/2025, a review of personnel records for two persons performing moderate complexity testing from January 2024 through the current date identified no evidence an annual competency evaluation had been performed for two of two testing persons as follows: (a) Testing Person #1 - not performed between January 2024 through the current date; (b) Testing Person #2 - not performed between January 2024 through the current date. (2) The records were reviewed with testing person #1 who stated on 11/18/2025 at 11: 45 am, the annual evaluations had not been documented as performed as stated above.