Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473884	05/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Utica Park Clinic-Family Medical	3316 E 21st, Suite A, Tulsa, 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 05/22/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director at the conclusion of the survey.
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 written policies and procedures and interview with the laboratory director, the written policy did not define the frequency of the assessments for the clinical consultant based on the position responsibilities for one of one clinical consultant. Findings include: (1) A review of the competency assessment policy titled, "Competency Assessment for Clinical Consultant" identified it did not define the frequency of the assessments; (2) Interview with the laboratory director on 05/22 /2025 at 11:05 am confirmed that although the competencies based on the position responsibilities of the clincal consultant had been performed annually, the policy did not define the frequency of assessments.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by:

	Based on a review of records and interview with the laboratory director, the laboratory failed to review and evaluate proficiency testing results to identify biases for one of four Hematology proficiency testing events reviewed in 2024 and 2025. Findings include: (1) A review of Hematology proficiency testing records for 2024 (first, second, and third events), and 2025 (first event) identified the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) for one of four events: (a) Third 2024 Event: (i) RDW-CV (Hem-3S)(x10E9E/L)**- five of five results exhibited positive biases: (aa) Sample HSY-11 - SDI of 2.0 (bb) Sample HSY-12 - SDI of 2.3 (cc) Sample HSY-13 - SDI of 2.3 (dd) Sample HSY-14 - SDI of 2.4 (ee) Sample HSY-15 - SDI of 2.4 (2) There was no evidence in the records to prove the biases had been identified and addressed; (3) The records were reviewed with the technical consultant who stated on 05/22/2025 at 10:30 am, the biases had not been addressed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 the laboratory director, the laboratory failed to ensure the room temperature, relative humidity, and refrigerator temperatures had been documented as observed during the review period of June 2024 through May 2025. Findings include: I. RT (ROOM TEMPERATURE) AND RH (RELATIVE HUMIDITY): (1) On 05/22/2025 at 08:55 am the laboratory director stated the laboratory performed CBC (Complete Blood Count) using the Medonic M-Series analyzer; (2) A review of the operator's manual titled, "Medonic M-series User's Manual" under Section 2: "Installation/Operating Environment" required an operating temperature range of 18 to 32 degrees C (Centigrade) and a maximum of 80% RH; (3) A review of the daily logs from June 2024 through May 2025 identified RT and RH readings had not been recorded as follows: (a) Room Temperatures (three of 12 months): (i) January 2025 - 31 of 31 days (ii) February 2025 - 28 of 28 days (iii) March 2025 - 31 of 31 days (b) Relative Humidity (one of 12 months): (i) March 2025 - 31 of 31 days (4) The records were reviewed with the laboratory director who stated on 05/22/2025 at 11:20 am, the RT and RH readings had not been documented as stated above. II. REFRIGERATOR TEMPERATURE: (1) Observation of the laboratory on 05/22/2025 at 10:45 am, identified three bottles of Boule Con-Diff quality control materials (lot #22503-01, lot #22503-02, and lot #22503-01) stored in the refrigerator with a manufacturer's storage requirement of 2-8 degrees Centigrade (C); (2) A review of temperature logs from June 2024 through May 2025 identified the refrigerator temperature had not been recorded for two of 12 months as follows: (a) February 2025 - 28 of 28 days (days1 through day 28) (b) March 2025 - 31 of 31 days (days 1 through day 31) (3) Interview with the laboratory director on 05/22/2025 at 11:20 am confirmed the refrigerator temperatures had not been documented as performed as stated above.