Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0716134	06/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Utica Park Clinic Elliott	562 S Elliott, Pryor, 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 06/06/2023. 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.
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 the laboratory director, the laboratory failed to follow the manufacturer's storage instructions for one of one case of Sophia 2 SARS Antigen test kits. Findings include: (1) On 06/06/2023 at 10:53 am, the laboratory director stated SARS Antigen testing was performed using the Sophia 2 SARS Antigen test kits; (2) On 06/06/2023 at 12: 56 pm, observation of the storage closet located outside of the laboratory identified one case containing 12 Sophia 2 SARS Antigen test kits, lot #707122. The manufacturer's storage requirement, as stated on the box was 15-35 degrees C (Centigrade); (3) Interview with the laboratory director on 06/06/2023 at 01:05 pm confirmed the temperature of the storage room was not being monitored.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency

	testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) 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 the laboratory director, the laboratory failed to ensure a proficiency testing attestation statement had been signed by the laboratory director for one of five events reviewed during 2021, 2022, and to date in 2023. Findings include: (1) A review of the third 2021; first, second, and third 2022; and first 2023 Hematology proficiency testing records identified the following for one of five events: (a) Third 2021 Event - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the laboratory director who stated on 06/06/2023 at 02:00 pm, the attestation statement had not been signed by the laboratory director.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to take corrective actions for unacceptable proficiency testing scores for two of five Hematology proficiency testing events reviewed. Findings include: (1) On 06/06 /2023 at 11:00 am, the laboratory director stated CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) A review of five Hematology proficiency testing events (Third 2021, First 2022, Second 2022, Third 2022, and First 2023) identified the following failures: (a) First 2022 Event - The laboratory attained a score of 60% for % Monocytes/Mixed. There was no evidence that corrective action had been documented as performed; (b) Third 2022 Event - The laboratory attained a score of 60% for % Monocytes/Mixed. There was no evidence that corrective action had been documented as performed. (3) The records were reviewed with the laboratory director who stated on 06/06/2023 at 02:00 pm, corrective actions had not been taken and documented for the failures.
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 for two of five Hematology Proficiency testing events reviewed. Findings include: FAILURES (1) A review of Hematology Proficiency testing records for five events (Third 2021, First 2022, Second 2022, Third 2022, and First 2023) identified the following failures with no evidence that corrective action had been documented as performed: (a) Second 2022 Event (i) Hemoglobin - The laboratory attained a score of 80% (ii) Hematocrit - The laboratory attained a score of 80% (iii) RBC (Red Blood Cell) count - The laboratory attained a score of 80% (2) The records were reviewed with the laboratory director who stated on 06/06/2023 at 02:00 pm, corrective actions had not been taken and documented for the failures. BIASES (2) During the review of Hematology proficiency testing records, the following biases were identified (using the SDI (Standard Deviation Index) values assigned by the proficiency program) for the Third 2022 Event: (a) % Monocytes/Mixed - five of five results exhibited a positive bias: (i) Sample HSY-11 - SDI of 2.8 (ii) Sample HSY-12 - SDI of 2.6 (iii) Sample HSY-13 - SDI of 2.9 (iv) Sample HSY-14 - SDI of 3.7 (this resulted in a failure) (v) Sample HSY-15 - SDI of 4.9 (this resulted in a failure) (2) There was no evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory director who stated on 06/06/2023 at 02:00 pm, the biases had not been addressed.
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, observation, and interview with the laboratory director, the laboratory failed to ensure blood collection tubes were stored as required for three of three Lithium Heparin tubes and four of four K2 EDTA tubes. Findings include: (1) On 06/06/2023 at 11:45 am, observation of the contents of the laboratory freezer identified the following materials: (a) Two BD Vacutainer K2 EDTA 7.2 mg blood collection tubes, lot #2347068; (b) Two BD Vacutainer K2 EDTA 7.2 mg blood collection tubes, lot 2259065; (c) Two Vacuette LH Lithium Heparin blood collection tubes, lot #B221134G; (d) One BD Vacutainer PST Gel and Lithium Heparin blood collection tube, lot #2166084. (2) Interview with the laboratory director confirmed the tubes were stored in the freezer when collecting blood samples that required the collection tube to be chilled; (3) A review of the manufacturer's storage requirement, which was located on the packaging of unopened containers of blood collection tubes, identified the storage temperature was 4-25 degrees C (Centigrade); (4) The findings were reviewed with the laboratory director who stated on 06/06/2023 at 01:20 pm, the blood collection tubes were not being stored as required by the manufacturer.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly during the review period of July 2021 through the current date. Finding include: (1) On 06/06/2023 at 11:15 am, the laboratory director stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in the Power Spin LX centrifuge at a speed of 2000 rpm (revolutions per minute) for 5 minutes. (2) A review of the following policies identified: (a) The policy titled, "Laboratory Centrifuge Maintenance" stated "Centrifuge RPM verification shall be performed and recorded at least once per year"; (b) The policy titled, "Laboratory Timer Maintenance" stated "Timer verification will be performed and recorded at least once per year". (3) A review of centrifuge records from July 2021 through the current date identified the centrifuge speed and timer checks had not been documented as performed prior to 12/01/2022; (4) The records were reviewed with the laboratory director who stated on 06/06/2023 at 12:55 pm the laboratory had not followed their policy.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to ensure patient test reports included the name of the laboratory location for 1 of 1 patient report reviewed with testing performed on 06/05/2023. Findings include: (1) On 06/06/2023 at 11:00 am, the laboratory director stated the laboratory performed the following: (a) CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (b) Urine Microscopic testing (2) Review of a patient CBC report with the results reported on 06/05/2023 identified the name of the laboratory on the report did not match the name on the Clia certificate. The name on the patient report was "Elliott Medical Plaza" and the name on the Clia certificate was "Utica Park

	Clinic Elliott"; (3) The findings were reviewed with the laboratory director who stated on 06/06/2023 at 02:30 pm, the laboratory name on the patient report did not match the name on the Clia certificate.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for three of three persons during the review period of August 2021 through the current date. Findings include: (1) A review of personnel records for three persons performing moderate complexity testing during the review period of August 2021 through the current date identified no evidence an annual competency evaluation had been performed for three of three testing persons as follows: (a) Testing Person #1 - Not performed prior to 12/01/2022; (b) Testing Person #2 - Not performed prior to 12/01/2022; (c) Testing Person #3 - Not performed prior to 12/01/2022. (2) The records were reviewed with the laboratory director who stated on 06/06/2023 at pm, the annual evaluations had not been performed.