

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0473884	<b>(X3) Date Survey Completed</b> 09/14/2023
<b>Name of Provider or Supplier</b> Utica Park Clinic-Family Medical	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 09/14/2023. 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.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>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 six 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 and second 2023 Hematology proficiency testing records identified the following for one of six events: (a) Second 2022 Event - The attestation statement had not been signed by the laboratory director. (2) The findings were reviewed with the laboratory director who stated on 09/14/2023 at 10:45 am, the attestation statement had not been signed by the laboratory director.</p>
<b>D5215</b>	<b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b>

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for one of six 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 and second 2023 Hematology proficiency testing records identified the following analytes had not been evaluated by the proficiency testing program for the First 2022 Event for five of five samples (HEM-01, HEM-02, HEM-03, HEM-04, and HEM-05): (a) %Granulocytes (b) Hematocrit (c) Hemoglobin (d) %Lymphocytes (e) MCH (Mean Corpuscular Hemoglobin) (f) MCHC (Mean Corpuscular Hemoglobin Concentration) (g) MCV (Mean Corpuscular Volume) (h) %Monocytes/Mids (i) Platelet Count (j) Red Cell Count (k) White Cell Count (2) A review of the records identified no evidence verifying the laboratory had performed a self-evaluation of the non-graded results utilizing the participant data summary; (3) The records were reviewed with the laboratory director who stated on 09/14/2023 at 10:45 am, the laboratory had not performed a self-evaluation of the non-graded results.

**D5407**

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on a review of policy and procedure manual and interview with the laboratory director, the laboratory failed to ensure the procedure manual had been approved and signed by the laboratory director. Findings include: (1) On 09/14/2023 at 09:15 am, the laboratory director stated CBC (Complete Blood Count) test was performed using the Medonic M Series hematology analyzer; (2) A review of the "Policy & Procedures 21st" manual identified no evidence it had been signed as approved by the laboratory director. Examples of policies and procedures contained in the manuals were listed as follows: (a) "Policy 11.0 - CBC"; (b) "Policy 13.4 - Criteria for Repeating CBC's"; (c) "Policy 40.1 - CBC Reportable Range"; (d) "Policy 40.5 - CBC New Lot Verification: (3) The manual was reviewed with the laboratory director who stated on 09/14/2023 at 09:50 am, the policy and procedure manual had not been approved and signed by the laboratory director.

**D5409**

PROCEDURE MANUAL

CFR(s): 493.1251(e)

The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

This STANDARD is not met as evidenced by:  
Based on a review of the procedure manual and interview with the laboratory director, the laboratory failed to ensure that a procedure no longer in use, had been indicated as discontinued, with the date of discontinuance. Findings include: (1) On 09/14/2023 at 11:05 am, the laboratory director verified CBC testing was performed using the Medonic M analyzer; (2) The surveyor reviewed the procedure manual, and identified a procedure titled "CBC Policy", which was used for the Medonic CA670 analyzer; (3) Interview with the laboratory director on 09/14/2023 at 11:05 am, confirmed the procedure was no longer being used because the Medonic CA 620 was no longer in use.

**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 director, the laboratory failed to ensure collection tubes were stored as required in 16 of 16 patient rooms. Findings include: BLOOD COLLECTION TUBES (1) On 09/14/2023 at 09:58 am, observation of the patient room #9 identified the following examples of blood collection tubes, stored in the room: (a) BD Vacuette K2 EDTA 7.2 mg tubes - 27 tubes of lot #2347070; storage requirement of 4-25 degrees C (Centigrade); (b) BD Vacutainer SST tubes - 8 tubes of lot #2326098; storage requirement of 4-25 degrees C; (c) BD Vacutainer PST Gel Lithium Heparin tubes - 14 tubes of lot #2321412; storage requirement of 4-25 degrees C; (2) On 09/14/2023 at 09:58 am, observation of the patient room #10 identified the following examples of blood collection tubes, stored in the room: (a) BD Vacutainer K2 EDTA 7.2 mg tubes - 9 tubes of lot #2347070; storage requirement of 4-25 degrees C (Centigrade); (b) BD Vacutainer SST tubes - 11 tubes of lot #2326098; storage requirement of 4-25 degrees C; (c) BD Vacutainer PST Gel Lithium Heparin tubes - 10 tubes of lot #2321412; storage requirement of 4-25 degrees C; (3) Interview with the laboratory director 09/14/2023 at 09:58 am confirmed the laboratory was not monitoring the temperature of the patient rooms.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(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 observation and interview with the laboratory director, the laboratory failed

to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory 09/14/2023 at 09:15 am, identified the following expired collection tubes were available for use: (a) 31 BD Vacutainer buffered sodium citrate 0.109M, 3.2% tubes, lot 2321334, expired 08/31/2023. (2) Interview with the laboratory director on 09/14/2023 at 09:17 am confirmed the collection tubes were available for use.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on a review of records and interview with the laboratory director, the laboratory failed to demonstrate the performance specifications for one of one replacement analyzer. Findings include: (1) On 09/14/2023 at 09:15 am, the laboratory director stated the following: (a) The laboratory began using the Medonic M Series hematology analyzer to perform CBC (Complete Blood Count) on 08/24/2021; (b) The laboratory received the Medonic M Series hematology analyzer (serial number 25112) from a sister laboratory as a replacement for the Medonic CA 620 hematology analyzer. (2) A review of records from August 2021 to the current date identified no evidence the performance specifications (i.e., accuracy, precision, reportable range) had been demonstrated on the replacement analyzer; (3) The findings were reviewed with the laboratory director who stated on 09/14/2023 at 10:00 am, the laboratory had not demonstrated the performance specifications for the replacement analyzer.

**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 included the name of the laboratory location and the performing location for three of three patient testing reports reviewed. Findings Include: (1) On 09/14/2023 at 11:45 am, the laboratory director stated CBC testing was performed on the Medonic M analyzer; (2) A review of three patient reports (testing performed on 07/10/2023, 09/05/2023, 09/08/2023) identified

they did not include the name and address of the laboratory location where testing was performed for three of three patient reports: (a) The facility name was not on the reports. (b) The performing location was not on the reports. (3) The findings were reviewed with the laboratory director who stated on 09/14/2023 at 11:45 am; the name and address of the performing location was not on the patient reports.