

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2280131	(X3) Date Survey Completed 07/12/2024
Name of Provider or Supplier Utica Park Clinic Muskogee	Street Address, City, State 615 S 32nd Street, Muskogee, 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 initial survey was performed on 07/12/2024. 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.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES 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 or designee for one of three Hematology events reviewed in 2023 and 2024. Findings include: (1) A review of the second and third 2023, and first 2024 Hematology proficiency testing records identified the following for one of three events: (a) First 2024 Event - The attestation statement had not been signed by the laboratory director or designee. (2) The records were reviewed with the laboratory director who stated on 07/12/2024 at 11:48 am, the attestation statement had not been signed.</p>
D5401	PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of records, policies and procedures, and interview with the laboratory director, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for six of 30 lot numbers used during the review period of 05/01/2023 through 05/29/2024. Findings include: (1) On 07/12/2024 at 09:30 am, the laboratory director stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (b) Three levels of Boule Con-Diff Tri-Level (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. (2) A review of the "Laboratory Procedure Manual" identified a policy titled "CBC new Lot Verification" which stated "Before New lot of CBC control can be used, they must be verified, and the new lot will be run alongside of current lot until (3) runs of each Low, Normal and High control has been ran. The new lot must be in range with new lot reportable ranges in order to use them as verification of this lot." (3) A review of records for 30 control lot numbers used from 05/01/2023 through 05/29/2024 identified no documentation to prove six of the 30 lot numbers had been implemented per policy: (a) Low-level lot #22306-01, normal-level lot #22306-02, and high-level lot #22306-03 used from 09/27/2023 through 10/26/2023 - The controls had been tested as follows: (i) The new lots were tested three times on 09/27/2023, after the current lot expired. (b) Low-level lot #22307-31, normal-level lot #22307-32, and high-level lot #22307-33 used from 11/14/2023 through 12/07/2023 - The controls had been tested as follows: (i) The new lots were tested three times on 11/14/2023, after the current lot expired. (4) The findings were reviewed with the laboratory director who stated on 07/12/2024 at 3:25 pm, the laboratory did not follow their written policy.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

protocol for reporting imminently life threatening results, or panic, or alert values.
(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the hematology policy and procedure manual, and interview with the laboratory director, the laboratory failed to have a complete written procedure for one of one procedure reviewed. Findings include: (1) On 07/12/2024 at 09:30 am, the laboratory director stated the laboratory performed CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (2) A review of the "Laboratory Procedure Manual" identified the procedure did not include the following: (a) Reportable ranges for test results that had been demonstrated during the verification of performance specification; (b) Normal patient reference ranges. (3) The findings were reviewed with the laboratory director who stated on 07/12/2024 at 03:25 pm, the CBC policy and procedure had not included all the required information.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 and interview with the laboratory director, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Medonic M-Series analyzer during the review period of June 2023 through June 2024. Findings include: (1) On 07/12/2024 at 09:30 am, the laboratory director stated the laboratory performed CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (2) A review of the manufacturer's instruction manual titled, "Medonic M-series User's Manual", Section 8, required the following maintenance procedures: (a) Daily: (i) Clean the aspiration and pre-dilute probes using and alcohol wipe; (ii) Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute probes, probe rinse cup, and around top of sampling device probe inlet (if applicable) using a paper tissue with a disinfecting solution. (b) Monthly: (i) Clean using hypochlorite solution and perform clot prevention using enzymatic solution (3) A review of maintenance logs from June 2023 through June 2024 identified maintenance had not been documented as performed for the following: (a) Daily: (i) Between 07/26/2023 and 08/08/2023 (ii) Between 10/25/2023 and 11/16/2023 (b) Monthly: (i) Between 06/08/2023 and 10/24/2023 (ii) Between 10/24/2023 and 12/01/2023 (4) The records were reviewed with the laboratory director who stated on 07/11/2024 at 04:45 pm, maintenance procedures had not been documented as performed as stated above.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are

reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory director failed to ensure proficiency testing reports were reviewed for three of three Hematology events reviewed in 2023 and 2024. Findings include: (1) A review of 2023 and 2024 Hematology proficiency testing events identified the "Performance Evaluations" included a space for the laboratory director or designee signature and date (indicating review of the graded evaluation). The following was identified for three of three events: (a) API Second event of 2023 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (b) API Third event of 2023 - There was no evidence the Performance Evaluation had been signed and dated as reviewed by the laboratory director or designee; (b) API First event of 2024 - 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 the laboratory director on 07/12/2024 at 11:48 am, the graded evaluations, as indicated above, had not been signed and dated as reviewed by the laboratory director or designee.