

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2168676	(X3) Date Survey Completed 04/16/2021
Name of Provider or Supplier Utica Park Clinic - Owasso North	Street Address, City, State 11402 N 135th East Ave, Owasso, 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 04/16/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written procedure, and interview with the technical consultant, the laboratory failed to ensure the verified reportable ranges were used by the laboratory. Findings include: (1) On 04/16/2021 at 10:00 am, the technical consultant stated to the surveyor the laboratory began using the Medonic M-Series analyzer to perform CBC (Complete Blood Count) testing in August 2019; (2) The surveyor reviewed performance specification records for the analyzer and identified the laboratory had demonstrated the following reportable range for the analyte platelet: (a) 14-894 (3) The surveyor then reviewed the laboratory procedure manual and identified that the procedure defined the reportable range for platelet as follows: (a) 12-900 (4) The surveyor reviewed the findings with the technical consultant who stated on 04/16/2021 at 1:00 pm, the laboratory was not using the reportable range that had been demonstrated by the laboratory for Platelet.</p>
D5437	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to perform calibration procedures as required by the manufacturer. Findings include: (1) On 04/16/2021 at 10:00 am, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) The surveyor reviewed the manufacturer's instructions, contained in the "Medonic M-Series Users Manual" for performing calibration procedures. The section on page 59 titled, "Section 7: Calibration" stated, "This section describes the step-by-step procedure for calibration of the Medonic M-Series. The instrument has been calibrated by Boule prior to shipment. Good laboratory practice, however, requires regular checks and calibration of the measured parameters. It is recommended to calibrate the instrument every 6 months"; (3) The surveyor reviewed records from 01/01/2020 through 03/31/2021. There was no evidence the calibration procedure had been performed between 03/23 /2020 and 01/25/2021; (4) The surveyor reviewed the findings with the technical consultant who stated on 04/16/2021 at 1:30 pm, the calibration procedure had not been performed as indicated above.

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 technical consultant, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 2 of 2 persons. Findings include: (1) On 04/16/2021 at 10:00 am, the technical consultant stated to the surveyor the laboratory performed wet prep analysis; (2) The surveyor reviewed annual evaluations for two persons (testing person #1 and testing person #2) performing testing in the laboratory. (3) The records showed that annual evaluations had been performed for testing person #1 and testing person #2 on 08/18/2020. There was no evidence the evaluations included an assessment of wet prep analysis; (3) The surveyor reviewed the findings with the technical consultant, who stated on 04/16/2021 at 10:40 am, the evaluations did not include wet prep analysis.