

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2091924	(X3) Date Survey Completed 01/12/2022
Name of Provider or Supplier Utica Park Clinic-Midtown	Street Address, City, State 4408 S Harvard Ave, 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 01/11,12/2022. 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.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>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 perform maintenance procedures as required by the manufacturer. Findings include: (1) On 01/12/2022, the laboratory director stated the laboratory performed CBC (Complete Blood Count) testing using the CDS Medonic M-Series analyzer; (2) The surveyor reviewed the manufacturer's 6 month maintenance requirements in the operator's manual. Section 8, titled, "Cleaning, Maintenance, & Transport" required a cleaning procedure be performed every 6 months; (3) The surveyor reviewed maintenance records from November 2019 through December 2021 and identified the cleaning procedure had not been performed between 11/25/2019 and 07/23/2020 (due 05/2020); (4) The surveyor asked the laboratory director if the analyzer had been cleaned during May 2020. The laboratory director reviewed the records and stated on 01/12/2022 at 09:50 am, the analyzer had not been cleaned as stated above.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

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 laboratory director, the laboratory failed to follow the manufacturer's instructions for performing calibrations. Findings include: (1) On 01/12/2022, the laboratory director stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic M Series analyzer; (2) The surveyor reviewed the manufacturer's instructions, contained in the operator's manual. Section 7 titled, "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 then reviewed calibration records from November 2019 through December 2021. There was no documentation to prove the analyzer had been calibrated between 11/25/2019 and 07/23/2020 (due 05/2020); (4) The surveyor asked the laboratory supervisor if the analyzer had been calibrated during May 2020. The laboratory supervisor reviewed the records and stated on 01/12/2022 at 09:50 am, the analyzer had not been calibrated as stated above.