

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2091924	(X3) Date Survey Completed 09/17/2019
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 09/17/19. The findings were reviewed with the laboratory director/technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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/technical consultant, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing using the CDS Medonic M-Series hematology analyzer; (2) The surveyor reviewed the manufacturer's 6 month maintenance requirements in the operator manual. It stated, "To increase the life of internal tubing in the instrument, the following cleaning procedure is strongly recommended."; (3) The surveyor then reviewed maintenance records for 24 months (September 2017 through August 2019) and identified the laboratory had not performed the required procedure between 09/16/17 and 07/09/18; (4) The records were reviewed with the laboratory director/technical consultant who stated the 6 month maintenance had not been performed as required by the manufacturer as listed above.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p>

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 laboratory director/technical consultant, the laboratory failed to perform calibration procedures as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the CDS Medonic M-Series hematology analyzer; (2) The surveyor reviewed the manufacturer's instructions (contained in the Operation 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 09/16/17 through 09/17/19. There was no evidence the calibration procedure had been performed between 09/16/17 through 07/09/18; (4) The surveyor asked the technical consultant if the calibration procedure had been performed. The technical consultant stated the calibration procedure had not been performed as indicated above.