

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0716134	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Utica Park Clinic Elliott	Street Address, City, State 562 S Elliott, Pryor, 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 05/14/2024. 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.
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</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 follow the manufacturer's instructions for performing calibrations for one of one Medonic analyzer. Findings include: (1) On 05/14/2025 at 10:00 am, the laboratory director stated the laboratory performed CBC (Complete Blood Count) testing on the Medonic M series analyzer; (2) A review of the M series procedure manual, page seven titled, "Calibration" stated calibration should occur at a minimum of every six months; (3) A review of records from October 2023 through the current date identified no documentation to prove the</p>

analyzer had been calibrated between 10/06/2023 and 08/09/2024; (4) Interview with the laboratory director on 05/14/2025 at 10:00 am confirmed there were no records to prove the analyzer had been calibrated as required by the manufacturer.