

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0862471	(X3) Date Survey Completed 05/04/2018
Name of Provider or Supplier Utica Park Clinic - Jenks	Street Address, City, State 701 E Main, Jenks, 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 findings were reviewed with the technical consultant at the conclusion of the survey.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2016 and 2017 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) Third 2017 Hematology Event (i) RDW (Red Cell Distribution Width) - 5 of 5 results exhibited a negative bias (aa) HSY-11 - SDI -2.3 (bb) HSY-12 - SDI -2.0 (cc) HSY-13 - SDI -2.3 (dd) HSY-14 - SDI -2.0 (ee) HSY-15 - SDI -2.1 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The surveyor reviewed the above findings with the technical consultant who stated the biases had not been addressed.</p>
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>

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 ensure equipment maintenance was performed as required by the manufacturer. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic M Series analyzer; (2) The surveyor reviewed 2017 through the day of the survey (16 months) manufacturer's maintenance logs for the analyzer with the following identified: (a) Monthly Cleaning (i) The monthly cleaning procedure had not been documented as performed during: (aa) February 2018 (bb) April 2018 (3) The surveyor reviewed the records with the technical consultant who stated there was no evidence the above maintenance had been performed as required.