

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473593	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Utica Pediatrics, Llc	Street Address, City, State 1589 E 19th St, 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 findings were reviewed with technical supervisor #1 at the conclusion of the survey.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to maintain copies of proficiency testing records. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified for 1 of 6 testing events: (a) Third 2016 Hematology Event (i) The attestation could not be located. (2) The findings were reviewed with the technical consultant #1 who stated the attestation could not be located.</p>
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</p>

performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #1, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, surveyor #2 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 2016 Hematology Event (i) MCV (Mean Corpuscular Volume) - 5 of 5 results exhibited a positive bias (aa) HSY-11- SDI 2.1 (bb) HSY-12- SDI 2.5 (cc) HSY-13- SDI 2.4 (dd) HSY-14- SDI 2.3 (ee) HSY-15 - SDI 2.6 (2) Surveyor #2 could not locate evidence in the records proving the biases had been identified and addressed; (3) Surveyor #2 reviewed the above findings with the technical consultant #1 who stated the biases had not been addressed.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to ensure equipment maintenance was performed as required by the manufacturer. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyors CBC (Complete Blood Count) testing was performed on the Sysmex KX-21 N analyzer; (2) Surveyor #2 reviewed 2016 and 2017 (24 months) manufacturer's maintenance logs for the analyzer with the following identified: (a) Daily - Execute Shutdown (i) The daily maintenance procedures had not been documented as performed: (aa) March 2016 - Day 4 (bb) April 2016 - Day 1 (cc) July 2017 - Days 5,6,7 (dd) August 2017 - Days 1,2,3,4 (ee) November 2017 - Day 2 (b) Quarterly - Clean SRV (Sample Rotator Value). The quarterly maintenance had not been documented as performed between: (i) 07/24/17 and 01/23/18 (3) Surveyor #2 reviewed the records with technical consultant #1 who stated there was no evidence the above maintenance had been performed as required.