Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473593	02/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
Utica Pediatrics, Llc	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 recertification survey was performed on 02/22/2022. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the technical consultant, the laboratory failed to follow written procedures for verifying quality control materials for three of 12 lot numbers. Findings include: (1) On 02/22 /2022 at 10:15 am, the technical consultant stated to the surveyor routine CBC (Complete Blood Count) testing was performed on the Sysmex KX-21N analyzer; (2) On 02/22/2022, the surveyor reviewed the written laboratory procedure titled, "LABORATORY POLICY AND PROCEDURE MANUAL" under the procedure titled, "COMPLETE BLOOD COUNT OF WHOLE BLOOD ON THE SYSMEX KX-21N AUTOMATED HEMATOLOGY ANALYZER" it stated, (a) "E. Starting a New Lot of Controls" (i) "Parallel test new controls by analyzing the three levels of control a minimum of 5 times prior to expiration of the previous lot.". (3) The surveyor reviewed 12 QC (quality control) lot numbers. For three of 12 lot numbers there was no indication the laboratory staff followed their written procedure as follows: (a) Eightcheck-3WP Lot# 00850710 low control ran one time before put into use; (b) Eightcheck-3WP Lot# 00850711 normal control ran one time before put into use; (c) Eightcheck-3WP Lot# 00850712 high control ran one time before put into use. (4) The surveyor reviewed the findings with the technical consultant. The

	technical consultant stated on 02/22/22 at 11:45 am that the procedure had not been followed as indicated above.
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 the technical consultant and testing person #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for five of eight quarterly maintenance procedures. Findings include: (1) On 02/222022 at 10:15 am, the technical consultant stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex KX-21N analyzer; (2) On 02/22/2022, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. (a) Quarterly maintenance (i) Clean SRV (3) The surveyor reviewed maintenance records for 24 months (January 2020 through December 2021) and identified the following: (a) There was no evidence the quarterly maintenance had been performed (i) Until 08/06/2020 (missing 2020 first quarter and second quarter); (ii) Between 09/02/2020 and 02/03/2021 (missing 2020 fourth quarter); (iii) After 05/05/2021 (missing 2021 third quarter and fourth quarter). (4) The surveyor reviewed the records with the technical consultant and testing person #1. Testing person #1 stated on 02/22/2022 at 11:05 am, the quarterly maintenance had been performed but not documented as performed as required.