Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473593	03/26/2024
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 03/26/2024. The laboratory was found in compliance with a standard-level deficiency cited. The finding was reviewed with the technical consultant at the conclusion of the survey.
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 records, policies and procedures, and interview with the technical consultant and testing person #1, the laboratory failed to follow their written policy for establishing the targets for new lot numbers of control materials prior to implementation for three of 12 lot numbers reviewed during the period of 04/03/2023 through 01/30/2024. Findings include: (1) On 03/26/2024 at 9:11 am, testing person #1 stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN-330 analyzer; (b) Three levels of XN-LCHECK QC (Quality Control) materials were tested each day of patient testing; (c) Beyondcare Quality Monitor (BCQM) was used to set the target values and acceptability of quality control results. (2) A review of the procedure manual titled, "Complete Blood Count of Whole Blood on the Sysmex XN-330 Automated Hematology" under section VI. "Beyondcare Quality Monitor (BCQM), Part - C. "Registering and Modifying QC file lot input" stated the following: (a) "8. Parallel studies must be performed between production lot and new lot prior to production lot expiration. 9. Run NEW QC lots once registered 2 times daily for 5 days to get a total of 10 data points, once in the morning and once before shutdown. 10. Once all 10 data points have been run, auto set the targets." (3) A review of records for three of 12 control lot numbers used from

	04/03/2023 through 01/30/2024 identified the laboratory did not follow their policy as follows: (a) Lot #32941401 used from 11/02/2023 through 12/14/2023 - The controls had been tested eight times over four days as follows: (i) Once on 11/02/2023 (ii) Once on 11/03/2023 (iii) Once on 11/06/2023 (iv) Five times on 11/07/2023 (b) Lot #32941402 used from 11/01/2023 through 11/30/2023 - The controls had been tested ten times over five days as follows: (i) Once on 11/01/2023 (ii) Three times on 11/02 /2023 (iii) Once on 11/03/2023 (iv) Once on 11/06/2023 (v) Four times on 11/07/2023 (c) Lot #32941403 used from 11/02/2023 through 11/29/2023 - The controls had been tested nine times over four days as follows: (i) Once on 11/02/2023 (ii) Once on 11/03 /2023 (iii) Once on 11/06/2023 (iv) Six times on 11/07/2023 (4) The findings were reviewed with the technical consultant who stated on 03/26/2024 at 12:06 pm, the laboratory did not follow their written policy.