Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473593	05/11/2026
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 05/11/2026. Standard-level deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records, observation of the laboratory, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for expiration dates of waived testing materials. Findings include: (1) On 05/11/2026 at 12:26 pm, observation of the laboratory identified the following expired materials which appeared to be available for use: (a) One vial of Henry Schein - One step + Ultra Mono Test reagent, lot 062521166, manufacturer's expiration date 04/30/2026; (b) One vial of Henry Schein - One step + Ultra Mono Test Sticks, lot 06251165, manufacturer's expiration date 04/30/2026. (2) The findings were reviewed with the technical consultant, who stated on 05/11/2026 at 12:30 pm the test materials had expired and were available for use.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) 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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure proficiency testing attestation statements had been signed by the testing person for one of four Hematology events reviewed in 2025 and 2026. Findings include: (1) A review of 2025 and 2026 Hematology Proficiency testing records identified the following for one of four events: (a) API Hematology Second Event of 2025 - there was no evidence the attestation statement had been signed by the testing person. (2) The findings were reviewed with the technical consultant who stated on 05/011/2026 at 03:00 pm, the attestation statements had not been signed as stated above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the technical consultant, the laboratory failed to establish a written policy to assess the competency of the clinical consultant, based on the position responsibilities as listed in Subpart M, for one of two persons. Findings include: (1) On 05/11/2026, a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the clinical consultant based on the position responsibilities, including the frequency of the assessment; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of March 2024 through the current date identified competencies, based on the position responsibilities, had not been performed for one of two persons listed as the clinical consultant (clinical consultant #2); (3) The findings were reviewed with the technical consultant who stated on 05/11 /2026 at 12:21 pm, a written policy was not available, and competencies had not been performed for the position as stated above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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, 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 six lot numbers reviewed during the period of November

	2025 through the current date. Findings include: (1) On 05/11/2026 at 12:24 pm, The technical consultant 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) Beyond Care 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 VII. "Quality Control", 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 from November 2025 through the current date identified the laboratory failed to follow their policy for implementing new lot of QC for three of six control lot numbers reviewed: (a) Lot #60381401 used from 02/25/2026 through the current date - The controls had been tested nine times over four days prior to implementation as follows: (i) Twice on 02/18 /2026; (ii) Four times on 02/20/2026; (iii) One time on 02/23/2026; (iv) Twice on 02 /24/2026. (b) Lot #60381402 used from 02/25/2026 through the current date - The controls had been tested nine times over four days prior to implementation as follows: (i) Twice on 02/18/2026; (ii) Four times on 02/20/2026; (iii) One time on 02/23/2026; (iv) Twice on 02/24/2026. (c) Lot #60381403 used from 02/25/2026 through the current date - The controls had been tested nine times over four days prior to implementation as follows: (i) Twice on 02/18/2026; (ii) Four times on 02/20/2026; (iii) One time on 02/23/2026; (iv) Twice on 02/24/2026. (4) The findings were reviewed with the technical consultant who stated on 05/11/2026 at 02:45 pm, the laboratory did not follow their written policy.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions and interview with the technical consultant, the laboratory failed to ensure quality control (QC) materials were not used beyond the open vial stability for three of three lot numbers reviewed. Findings include: (1) On 05/11/2026 at 12:24 pm, the technical consultant stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN-330 analyzer; (b) Three levels of Sysmex XN-L Check QC (Quality Control) materials were tested each day of patient testing. (2) A review of the manufacturer's storage and stability instructions for the control materials contained in Sysmex XN-L Check package insert required once the controls were opened, the controls were stable for 15 days when stored at 2 - 8 degrees C (Centigrade); (3) Observation of the refrigerator contents identified the following: (a) Low control lot #60381401 QC material - open date was not posted on the bottle, and modified expiration date could not be determined; (b) Normal control lot #60381402 QC material - open date was not posted on the bottle, and modified expiration date could not be determined; (c) High control lot #60381403 QC material - open date was not posted on the bottle, and modified expiration date could not be determined. (4) The findings were reviewed

	with the technical consultant, who stated on 05/11/2026 at 12:35 pm, the controls had not been dated with the appropriate modified expiration date.