Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0664964	12/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Elmwood Pediatric Group Llp	919 Westfall Road - Bldg A, Ste 105, Rochester, NY	

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
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 direct observation, review of Standard Operating Procedures (SOPs), as well as interview with the Testing Person (TP), the laboratory failed to follow manufacturers' instructions for performing the waived test. FINDINGS: 1. The surveyor's observations on December 16, 2025, at approximately 3:00 P.M., confirmed the following Quality Control (QC) materials utilized for monitoring the accuracy of the Quintet AC blood glucose monitor were not removed from inventory when they exceeded their expiration date: a. Quintet AC Blood Glucose Control Solution Level 2, lot: 2WE29A, expiration: April 30, 2025. b. Quintet AC Blood Glucose Control Solution Level 4, lot: 2WE29A, expiration: May 1, 2025. 2. The current, approved SOPs did not include instructions for removal of expired testing and QC materials from inventory. 3. The TP informed the surveyor that the expired QC blood glucose monitoring materials were utilized prior to patient specimen processing. The number of patient specimens processed utilizing the respective expired QC materials could not be determined. 4. The Quintet AC Blood Glucose manufacturer's package insert specified operating ambient temperature range of 10C to 40C (50F to 104F) and humidity range of 10% to 90%. 5. There was no documentation of temperature and humidity for the area where test kits were stored, patient specimens processed, and testing was performed. 6. No thermometer or humidistat were present to monitor ambient room temperature or humidity. 7. The TP confirmed the findings on December 16, 2025, at approximately 4:00 P.M.
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 review of Proficiency Testing (PT) records, as well as interview with the TP, the laboratory failed to complete the attestation statement provided by the PT program, signed by the analyst and Laboratory Director (LD), documenting that PT samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the PT event. FINDINGS: 1. There was no documentation of LD signature and date of signature on the College of American Pathologists attestation statements for events NB-C 2024, NB-A 2025, NB-B 2025, and NB-C 2025. 2. It was noted the analyst signatures were documented on the attestation forms. 3. The TP confirmed the findings on December 16, 2025, at approximately 4:00 P.M.