Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1071480	12/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Legacy Pediatrics Pllc	1815 South Clinton Ave Ste 360, 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 11, 2025, at approximately 1:30 P.M., confirmed the following Quality Control (QC) material utilized for monitoring the accuracy of the Ascensia Contour blood glucose monitor were not removed from inventory when they exceeded their expiration date: a. Contour Low QC, lot: 3BW1B42, expiration: August 31, 2025. b. Contour High QC, lot: 3BW3L39, expiration: August 31, 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 TP confirmed the findings on December 11, 2025, at approximately 1:30 P.M.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of SOPs, test kit manufacturer's package inserts, lack of room temperature and humidity records, as well as interview with the TP, the laboratory failed to monitor and document conditions that are essential for proper storage of reagents and specimens in the area where test kits were stored, patient specimens processed, and testing was performed. FINDINGS: 1. Sysmex XP-300 automated hematology analyzer manufacturer instructions specified operating ambient temperature range of 15C to 30C (59F to 86F) and humidity range of 30% to 85%. 2. There was no documentation of ambient room temperature and humidity for the area where test kits were stored, patient specimens processed, and testing was performed. 3. No thermometer or humidistat were present to monitor ambient room temperature or humidity. 4. The current, approved SOPs did not include instructions for performing such activity. 5. The TP confirmed the findings on December 11, 2025, at approximately 1:30 P.M.