Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0698130	02/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Milford Pediatric Group	50 Commerce Park, Milford, CT	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish policies and procedure to monitor and assess unacceptable proficiency testing results in the specialty of hematology. Findings Include: 1. Record review on 02/13/2025 of the laboratory's 'College of American Pathologists' proficiency testing (PT) evaluation report for 'FH1-C 2024' revealed the following unacceptable results: a. 'Test: White Blood Cell Count, Specimen: FH1-11'. b. 'Test: Red Blood Cell Count, Specimen: FH1-11/FH1-12'. c. 'Test: Hemoglobin, Specimen: FH1-11/FH1-12'. d. 'Test: Hematocrit, Specimen: FH1-11/FH1-12'. e. 'Test: Neut/Gran %, Specimen: FH1-11 /FH1-12'. f. 'Test: Neut/Gran Absolute, Specimen: FH1-12'. g. 'Test: Lymph %, Specimen: FH1-11/FH1-12'. h. 'Test: Mixed/Mono %, Specimen: FH1-12'. i. 'Test: Mixed/Mono Absolute, Specimen: FH1-12'. 2. Record review on 02/13/2025 of the laboratory's standard operating procedures revealed lack of documentation of an established policies and procedures to monitor and assess issues related to proficiency testing performance. 3. Record review on 02/13/2025 of the laboratory's 'Corrective Action Log Sheet' for the above unacceptable PT grades revealed the following: a. 'Staff had reports back with unacceptable results for their CBC proficiency testing. Staff was retrained and tested on CBC machine'. b. Lack of investigation and resolution of the problem and development of new policies and procedures that will prevent recurrence. 4. Staff interview on 02/13/2025 at 11:15 AM with the laboratory supervisor confirmed the above findings. He/she further commented that the laboratory does not have policies and procedures pertaining to evaluation of

	proficiency testing and corrective action. 5. The laboratory performs 8,522 complete blood count tests in the specialty of hematology.
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 record review and staff interview, the laboratory failed to follow their established quality assurance policies and procedures in the specialty of hematology. Findings Include: 1. Record review on 02/13/25 of the laboratory's 'Pre-Analytic, Analytic and Post Systems Assessment' standard operating procedure revealed 'Personnel will be selected at random for no less than one assessment per month'. 2. Record review on 02/13/25 of the laboratory's pre-analytic, analytic and post-analytical systems assessment for 2024 revealed lack of documentation of monthly assessments for 10 of 10 laboratory testing personnel. 3. Staff interview on 02/13 /2025 at 11:45 AM with laboratory supervisor confirmed the above findings. 4. The laboratory performs 8,522 complete blood count tests in the specialty of hematology.