Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0902455	08/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Milford Pediatric Group	One Golden Hill St, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure that the Laboratory Director (or Designee) and testing personnel performing the Proficiency Testing (PT) sign the attestation statement certifying that PT samples were tested in the same manner as patient specimens in the specialty of Hematology. Findings include: 1. Record review on 08/05/2025 of the laboratory's PT binder revealed the laboratory performed the PT offered by the "American Proficiency Institute" (API) for the years 2023, 2024 and currently 2025. 2. Record review on 08/05/2025 of the laboratory's "Attestation Statement" provided by the API revealed lack of signatures of the Testing Personnel (TP) and the Laboratory Director (or designee) to certify that the PT samples were tested in the same manner as patient samples for all 8 of 8 events from 2023 until to-date. 3. Staff interview on 08/05/2025 at 10:27 AM with the testing personnel #1 confirmed the findings listed in 2 above. 4. The laboratory performs 902 complete blood count tests annually in the specialty of Hematology.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)

	(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when the humidity was outside of the acceptable range in the specialty of Hematology. Findings include: 1. Record review on 08/05/2025 of the laboratory's 'Temperature/Humidity Log' revealed the following: a. The acceptable humidity range: 30 to 85 percent. b. Lack of documentation of corrective action for 120 out of 579 working days from January 2024 to July 2025 when the humidity was outside of the acceptable range listed in 1(a) above. 2. Record review on 08/05/2025 of the laboratory's established policies and procedure revealed lack of documentation of a standard operating procedure highlighting the steps to take when the humidity was out of the acceptable range. 3. Staff interview on 08/05/2025 at 11:30 AM with testing personnel #1 confirmed the above findings. 4. The laboratory performs 902 complete blood count tests annually in the specialty of Hematology.