Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0102621	02/24/2026
Name of Provider or Supplier	**Street Address, City, State**	
Stamford Health Medical Group, Inc	126 Morgan Street, Stamford, 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
D2128	HEMATOLOGY CFR(s): 493.851(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document remedial action when unacceptable Proficiency Testing (PT) scores were received in the specialty of hematology. Findings include: 1. Record review on 02/24/2026 of the 'Wisconsin State Laboratory of Hygiene (WSLH) PT Evaluation' form for 3 of 3 events in 2025 revealed the following unacceptable PT results: a. 'WSLH PT 2025-HemeReg1' i. 'Analyte: Erythrocyte (RBC) 10^12/L' ii. 'Analyte Score: 80%' iii. 'Sample: AT-3' iv. 'Results: 2.49' v. 'Range: 2.26 - 2.44' vi. 'Status: Fail' b. 'WSLH PT 2025-HemeReg2' i. 'Analyte: Lymphocytes %' ii. 'Analyte Score: 80%' iii. 'Sample: AT-7' iv. 'Results: 14.8' v. 'Range: 11.3 - 14.3' vi. 'Status: Fail' c. 'WSLH PT 2025-HemeReg3' i. 'Analyte: Platelets 10^9/L' ii. 'Analyte Score: 80%' iii. 'Sample: AT-15' iv. 'Results: 91' v. 'Range: 209 - 348' vi. 'Status: Fail' d. Lack of documentation of an investigation and remedial action for the above unacceptable PT results in 1(a) through (c) listed above. 2. Record review on 02/24/2026 of the laboratory's policies and procedures revealed 'Unacceptable proficiency result documentation form must be completed for any scores lower than 100%'. 3. Staff interview on 02/24/2026 at 12:15 PM with the laboratory's technical consultant confirmed the above findings. 4. The laboratory performs 7,728 tests annually in the specialty of hematology.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and document reference ranges for the following hematology parameters: - Platelet count - Mean Corpuscular Hemoglobin (MCH) - Red Cell Distribution Width (RDW) - Mean Platelet Volume (MPV) - Granulocyte relative count - Granulocyte absolute count - Monocyte absolute count The absence of established reference ranges for these analytes in the specialty of hematology may result in inaccurate interpretation of patient test results and may compromise the laboratory's ability to ensure accurate, reliable, and clinically meaningful results are being reported. Findings include: 1. Record review on 02/24/2026 of a complete blood count test report for patient#1 revealed the following reported reference ranges: a. 'Platelet count: 150 - 390 10*3 /uL' b.'MCH: 26.5 - 33.5 pg' c.'RDW: 10.0 - 15.0 %' d.'MPV: 6.5 - 11.0 fm*3' e. 'Granulocytes Relative: 43.0 - 76.0 %' f. 'Monocytes Absolute: 0.30 - 0.80 10*3/uL' g. 'Granulocytes Absolute: 1.2 - 6.8 10*3/uL' 2. Record review on 02/24/2026 of the laboratory's established policies and procedure for 'Complete Blood Count Normal Pediatric Values' revealed lack of documentation of reference ranges for the above analytes listed in 1(a) through (g) above. 3. Staff interview on 02/24/2026 at 11:30 AM with the laboratory's technical consultant confirmed the above findings. 4. The laboratory performs 7,728 tests annually in the specialty of hematology.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the laboratory director (LD) failed to review, approve, sign and date the laboratory policies and

	procedure prior to the initiation of patient testing within the specialty of hematology. Findings include: 1. Record review on 02/24/2026 of the laboratory's policies and procedures revealed lack of documentation of the LD's approval of the current policies and procedures in use. 2. Staff interview on 02/24/2026 at 11:15 AM with the laboratory's technical consultant (TC) confirmed the above findings. The TC further commented that he/she was unaware that the LD was required to review and approve the laboratory policies and procedures upon onboarding. 3. The laboratory performs 7,728 tests annually in the specialty of hematology.
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 surveyor observation, record review and staff interview, the laboratory failed to define, monitor, and document humidity requirements in the specialty of hematology. Findings include: 1. Surveyor observation on 02/24/2026 at 12:30 PM of the laboratory working area revealed a 'Horiba Medical ABX Micros 60 Hematology Analyzer' in use. 2. Record review on 02/24/2026 of the laboratory's equipment maintenance records revealed lack of documentation of humidity levels. 3. Record review on 02/24/2026 of the 'Horiba Medical ABX Micros 60 Hematology Analyzer User Manual' revealed operating humidity conditions requirements of 80% maximum. 4. Staff interview on 02/24/2026 at 12:45 PM with the laboratory's technical consultant confirmed the above findings. 5. The laboratory performs 7,728 tests annually in the specialty of hematology.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that the normal reference ranges listed on the patient's final test report matched with the laboratory's established normal reference ranges within the specialty of hematology. Findings include: 1. Record review on 02/24/2026 of the laboratory's policies and procedures revealed the following established complete blood count normal reference ranges for patients 6 months to 1 year of age: a. White blood cells (WBC): 6.0 - 17.5 (10^3/uL) b. Red blood cells (RBC): 3.80 - 5.20 (10^6/uL) c. Hemoglobin: 10.0 - 13.2 (g/dL) d. Hematocrit: 30 -39 (%) e. Mean corpuscular volume (MCV): 70 - 90 (fL) f. Mean corpuscular hemoglobin concentration (MCHC): 32 - 36 (%) g. Lymphocytes

	relatives: 1.4 - 22 (%) h. Monocytes relatives: 0 - 2.4 (%) i. Lymphocytes absolute: 1.4 - 22 (10^3/uL) 2. Record review on 02/24/2026 of patient #1 (10 month of age) test report revealed the following discrepancies in the normal reference ranges and units of measurements: a. White blood cells (WBC): 3.5 - 10.0 (10^3/uL) b. Red blood cells (RBC): 3.80 - 5.80 (10^6/uL) c. Hemoglobin: 11.0 - 16.5 (g/dL) d. Hematocrit: 35 -50 (%) e. Mean corpuscular volume (MCV): 80 - 97 (fm*3) f. Mean corpuscular hemoglobin concentration (MCHC): 31.5 - 35 (g/dL) g. Lymphocytes relatives: 17 - 48 (%) h. Monocytes relatives: 4.0 - 10.0 (%) i. Lymphocytes absolute: 1.20 - 3.20 (10^3/uL) 3. Staff interview on 02/24/2026 at 11:00 AM with the laboratory's technical consultant (TC) confirmed the above findings. 4. The laboratory performs 7,728 tests annually in the specialty of hematology.