Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0008253	10/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Medical Station Of North Shore Pc, The	480 Forest Avenue, Suite 403, Locust Valley, 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
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 review of American Proficiency Institute (API) Proficiency Testing (PT) records as well as interview with the Testing Person (TP), the laboratory failed to document attestation to the routine integration of the samples into the patient workload using the laboratory's routine methods. FINDINGS: 1. There was no documentation of API testing personnel attestation for all events in 2024 and 2025. 2. The TP confirmed the findings on October 14, 2025, at approximately 11:30 A.M.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare & Medicaid Services (CMS) PT Certification and Survey Provider Enhanced Reporting system (CASPER 0155D), API PT summary reports, Standard Operating Procedures (SOPs), lack of corrective action records, as well as interview with the TP, the laboratory failed to perform and document plan of correction for all unsatisfactory PT scores. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory score: a. White Blood Cell (WBC) Differential Test Analyte: 2025 First Event = 67% 2. A review of the API reports from 2025 revealed the following unsatisfactory scores: a.

	Granulocytes Test Analyte: 2025 First Event = 60% b. Lymphocytes Test Analyte: 2025 First Event = 60% c. Lymphocytes Test Analyte: 2025 Second Event = 60% 3. There was no documentation of plan of correction performance for the respective unsatisfactory PT scores. 4. This is contrary to instructions included in the current, approved SOPs. 5. The TP confirmed the findings on October 14, 2025, at approximately 11:30 A.M.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of analyzer system operations manuals, lack of analyzer calibration records, as well as interview with the TP, the laboratory failed to follow manufacturer's calibration and verification instructions. FINDINGS: 1. There was no documentation of Medonic M Hematology analyzer calibration verification performance in 2025. 2. This is contrary to instructions indicated in the analyzer system operations manuals. 3. The TP confirmed the findings on October 14, 2025, at approximately 11:00 A.M.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of CMS CASPER 0155D and API PT reports, current, approved SOPs, analyzer system operations manuals, lack of analyzer calibration and corrective actions records, as well as interview with the TP, the Laboratory Director (LD) failed to ensure that the quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as the occur. Refer to D2009, D5221, and D5439.