Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D1074511	01/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
York Hospital Medical Services	75 Us 1 Bypass, Kittery, ME	

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 with the Clinical Consultant (CC), the laboratory director (LD) failed to sign the attestation sheet for the College of American Pathologists (CAP) proficiency testing (PT) samples in the specialty of Chemistry. Findings include: 1. Record review on 1/7/2025 of the laboratory's PT attestation sheets for CAP Chemistry survey 1 2024 revealed the LD did not sign the attestation sheet. 2. Record review of tha laboratory PT procedure manual on 1/7/2025 revealed: "The Attestation Statement is sicned by the Laboratory Director or Designee." 2. Staff interview on 1/7/2025 at 10:00am with the CC confirmed the above findings. 3. The laboratory performs 1,000 tests annually in the specialty of Chemistry.
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, it was determined that the reference ranges in the specialty of Hematology on the laboratory's final patient test report did not correlate with the reference range in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test report's reference ranges on 1/7/2025 for patient #1 (male) with the laboratory's procedure for Hematology revealed the following: a. Final report Monocytes 0.01-12.00 % b. Procedure: Monocytes 0-12 % c. Final report: Eosinophils 0.01-7.00 % d. Procedure: Eosinophils 0-7 % e. Final report: Basophils 0.01-2.50 % f. Procedure: Basophils 0-2.5 % 2. Staff interview with the Clinical Consultant on 1/7/2025 at 10:00am confirmed the reference range for Hematology did not correlate with the reference range on the final patient test report. 3. The laboratory performs 1,200 tests annually in the specialty of Hematology.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) graded results from the College of American Pathologists (CAP) and staff interview, the laboratory failed to ensure that all PT reports received were reviewed by the appropriate staff. Findings include: 1. Record review on 1/7/2025 of CAP Chemistry events C-B 2024, C-A2024 and Hematology event FH9-A 2024 evaluation documentation revealed no review signature by the Laboratory director or a designee. 2. Record review of the laboratory's PT policy on 1/7/2025 revealed: "When the peer group data report is received, the report is reviewed by the Laboratory Coordinator." 3. Staff interview with the Clinical Consultant on 1/7/2025 at 9:30am confirmed the above findings. 4. The laboratory performs 1,000 tests annually in the specialty of Chemistry and 1,200 tests annually in the specialty of Hematology.