Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0953704	03/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
New England Cancer Specialists	105 Topsham Fair Mall Rd, Topsham, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager (LM), the laboratory failed to follow a written procedure to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's 2020 and 2021 employee competency records on 3/8/2022 revealed that the laboratory did not have competency documentation for the Technical Supervisor (TS) for his/her CLIA federal regulatory responsibilities. 2. Staff interview with the LM on 3/8/2022 at 1:00 PM confirmed the laboratory had not assessed the competency of the TS for the specialties of Chemistry and Hematology. 4. The laboratory performs 159,387 tests annually in the specialties of Chemistry and Hematology.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 for the specialty of Chemistry on the laboratory's final patient test report did not correlate with the procedural reference range. Findings include: 1. Comparison on 3/8/2022 of final patient test report's Chemistry reference ranges with the laboratory's "Chemistry reference range studies" documentation revealed the following did not match: a. Creatinine Final report: 0.52-1.25 mg/dL Reference sheet: 0.5-1.3 mg/dL b. Calcium Final report: 8.4-10.2 mg/dL Reference sheet: 8.6-10.4 mg/dL c. Total Protein Final report: 6.3-8.2 g/dL Reference sheet: 5.9-8.4 g/dL d. Alanine Aminotransferase Final report: 10-50U/L Reference sheet: 10-4 7U/L 2. Staff interview with the laboratory manager (LM) at 1:30 PM confirmed the reference ranges for the above analytes on the final patient test report did not correlate with the reference ranges on the Chemistry reference range studies documentation. 3. The laboratory performs 96,024 tests annually in the specialty of Chemistry.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(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 lack of documentation and interview with laboratory manager (LM), the laboratory director (LD) failed to ensure that a signed and dated procedure manual was available before use. Findings include: 1. Record review on 3/8/2022 of the laboratory's quality assurance, Vitros 350, and, Sysmex XN procedure manuals revealed, that the manuals were not signed and dated by the LD. 2. During interview on 3/8/2022 at 1:00 PM the LM confirmed that the lab manuals had not been signed and dated by the LD. 3. The laboratory performs 159,387 tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with laboratory manager (LM), the laboratory failed to document routine maintenance for the Accu-Scope microscope. Findings include: 1. Direct observation on 3/8/2022 revealed the Accu-Scope

	maintenance sticker to note: "Date Due: 31 Aug 2021". 2. Interview with the LD on 3 /8/2022 at 2:00 PM confirmed that annual maintenance of scopes is policy but had not been performed since the expiration noted above. 3. The laboratory performs 159,387 tests in the specialties of Chemistry and Hematology per year.