

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 20D0087694	<b>(X3) Date Survey Completed</b> 03/08/2022
<b>Name of Provider or Supplier</b> New England Cancer Specialists	<b>Street Address, City, State</b> 2 Independence Drive, Kennebunk, ME	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and staff interview, the laboratory failed to test PT samples in the same manner as routine patient samples by testing personnel (TP) who routinely perform the testing in the specialty of Hematology. Findings include: 1. Record review on 3/8/2022 of the laboratory's 2021 American Proficiency Institute (API) Hematology/Coagulation PT attestation sheets revealed: a. 2021 API Hematology/Coagulation Event 1 - All samples were tested by TP1 b. 2021 API Hematology/Coagulation Event 2 - All samples were tested by TP1 c. 2021 API Hematology/Coagulation Event 3 - All samples were tested by TP1 d. No PT event samples were tested by TP2, TP3, and TP4 2. Staff interview with the laboratory manager on 3/8/2022 at 10:00 AM confirmed PT was not rotated amongst all TP. 3. The laboratory performs 59,734 tests per year in the specialty of Hematology.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager (LM), the</p>

	<p>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 the laboratory did not have competency documentation for the Technical Consultant (TC) for their CLIA federal regulatory responsibilities and 1 of 4 testing personnel (TP1). 2. Staff interview with the LM on 3/8/2022 at 9:30 AM confirmed the laboratory did not assess the competency of the TC and TP1. 3. The laboratory performs 59,734 tests annually in the specialties of Chemistry and Hematology.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>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 for quality assurance was available before use. Findings include: 1. Record review on 3/8/2022 of the laboratory's quality assurance procedure manuals revealed, that the manual was not signed and dated by the current LD. 2. During interview on 3/8/2022 at 10:00 AM the LM confirmed that the manual had not been signed and dated by the LD. 3. The laboratory performs 159,387 tests annually.</p>
<p><b>D5415</b></p>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the contents of the laboratory refrigerator and interview with the laboratory manager (LM) the laboratory failed to label controls with the preparation/opening date after opening in the specialty of Chemistry. Findings include: 1. Surveyor observation on 3/8/2022 at 11:30 AM of the contents of the laboratory refrigerator revealed: a. XN check level 1, 2, and 3 controls lot#20041101. d. The above controls did not have an open date written on the label. 2. Record review on 3/8/2022 of the XN Check Control package insert revealed, a. "Open vials and vials which have been sampled by cap piercing will retain stability for 7 days if stored at 2-8 (degrees) C after being recapped." 3. Staff interview with the LM on 3/8/2022 at 11:30 AM confirmed the open date was not recorded on the label when controls. 4. The laboratory performs 49,345 tests annually in the specialty of Hematology.</p>