

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0953704	(X3) Date Survey Completed 08/24/2023
Name of Provider or Supplier New England Cancer Specialists	Street Address, City, State 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 Technical Consultant (TC), the laboratory failed to follow the written procedure to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's 2022 employee competency records on 8/24/2023 revealed the Laboratory Director (LD) did not document a competency for the Technical Consultant (TC) for his/her CLIA federal regulatory responsibilities. 2. Review on 8/24/2023 of the laboratory's 'Competency Assessment' Policy revealed: "..competency assessments required of the Technical Supervisor (TS) and Technical Consultant (TC) roles that are done by the Lab Director (LD). If the TS or TC also perform testing in the lab, the technical competency assessment must also be done." 3. Staff interview with the TC on 8/24/2023 at 12:00pm confirmed the above findings. 4. The laboratory performs 115,469 tests annually in the specialty of Chemistry and 73,310 tests annually in the specialty of Hematology.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on documentation and interview with the Technical Consultant (TC), the laboratory failed to document routine maintenance and function checks on the Vitros 350 Chemistry analyzer. Findings include: 1. Record review of the Vitros 350 weekly maintenance log on 8/24/2023 revealed 8 of 52 weeks undocumented weekly maintenance. 2. Interview with the TC on 8/24/2023 at 12:00pm confirmed the above findings. 3. The laboratory performs 115'469 test annually in the specialty of Chemistry.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the Technical Consultant (TC) failed to evaluate the competency of all testing personnel (TP) to perform moderate complexity testing in the specialties of Hematology and Chemistry. Findings include: 1. Record review on 8/24/2023 of the laboratory's 2022 competency documentation for 2 or 2 TP, revealed the TC had not completed the competencies and peer review to be documented. 2. Record review on 8/24/2023 of the laboratory's competency assessment policy revealed: "The assessments are the responsibility of the technical personnel to complete." 3. Staff interview with the TC on 8/24/2023 at 12:00pm confirmed the above findings. 4. The laboratory performs 73'310 tests annually in the specialty of Hematology and and 115'469 tests annually in the specialty of Chemistry.