Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	47D0091966	05/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Ne Vt Regional Hospital Laboratory	1315 Hospital Drive, Saint Johnsbury, VT	

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
D0000	An on-site validation survey was conducted on May 05, 2026 with the following standard level deficiencies cited.
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 review of the laboratory's submitted Form Centers for Medicare and Medicaid Services (CMS) 209, written policies and procedures, lack of competency assessment documentation and interview with the Laboratory Director (LD), the laboratory failed to establish and follow written policies and procedures for assessing competency assessments for 3 of 3 General Supervisors (GS). Findings Included: 1) Review of the Form CMS 209 revealed 3 laboratory personnel were listed as GS consultant roles. 2) Review of the laboratory's policy titled, 'Northern Vermont Regional Hospital Competency Testing of Personnel' stated the following: "Purpose - This procedure describes the requirements for assessing competency for waived and non-waived testing of laboratory staff ... Policies - All laboratory personnel on all work shifts are evaluated to test their competency at performing work activities ... Definitions - Competency: The ability of an individual to perform a specific task according to established policies, procedures and processes ..." The established written policy contained procedures for testing personnel (TP), but not for consultants (e.g. GS, TS, CC). 3) The laboratory could not provide competency assessment documentation for the 3 GSs. 4) In an interview on 5/05/2026 at 10:22 AM, the LD confirmed GS competencies were not assessed or documented.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's written policies and procedures, proficiency testing (PT) records, laboratory test records, and interview with the Laboratory Director, the laboratory failed to verify the accuracy of Fine Needle Aspiration (FNA) Biopsies twice a year for 1 of 2 years. Findings Included: 1. Review of the laboratory's policy titled 'Northeastern Vermont Regional Hospital 89645.273 Proficiency Testing Policies and Responsibilities' stated the following: "Alternative Assessment - Determination of laboratory testing performance by means other than PT - for example split sample testing, testing by different method, etc. This system must: Be used when accrediting agency approved PT is not available. Mimic proficiency testing program to the degree possible. Be performed at least twice annually. Contain at least 2 challenges (2 levels, positive and negative, etc.) Be evaluated against established (documented) grading expectations. Be reviewed by the same individuals who review PT performance. Have documented corrective action when grading expectations are not met." 2. Review of the laboratory's proficiency testing records for 2024 and 2025 revealed no alternative assessments performed twice a year for FNA in 2024. 3. Review of the laboratory's test volumes revealed the following annual FNA testing volumes: a. 2024 - 54 FNAs b. 2025 - 61 FNAs 4. In an interview on 5/5/2026 at 2:00 PM, the Laboratory Director confirmed alternative assessments for FNAs were not performed and documented twice a year in 2024.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, direct observation, laboratory test records, and interview with General Supervisor (GS) #2 according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to establish and follow conditions for specimen transportation (temperature) for 671 of 671 stool specimens for Clostridium Difficile (C. diff) testing on the Cepheid Innovation GeneXpert analyzer in 2024 and 2025. Findings Included: 1) Review of the laboratory's policies 89645.225 'Stool Specimen collections container and transport' and 89645.29 'Packaging and Transport specimens for couriers' did not reveal requirements for specimen transportation/storage temperatures. 2) Review of the Cepheid Innovation GeneXpert manufacturer's instructions in which stool samples were tested for C. diff, the following requirements were stated: "12. Specimen Collection and Transport ... 3. Store specimens at 2 to 8 degrees Celsius. The specimen is stable for up to 5 days when stored at 2 to 8 degrees Celsius. Alternatively, specimens can be kept at room temperature (20 to 30 degrees

	Celsius) for up to 24 hours ..." 4) Upon direct observation of the courier drop-off of specimens at 1:30 PM in the laboratory, no temperatures were measured and recorded by specimen processors upon transit or receipt. 5) In an interview on 5/05/2026 at 1: 35 PM, GS #3 confirmed the laboratory did not define specimen transport temperatures to clients and couriers, and did not measure temperatures to verify specimen suitability upon receipt.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on direct observation, manufacturer's instructions, review of the laboratory's defined Stanley Temperature acceptable humidity ranges, and interview with the Laboratory Services Director, the laboratory failed to define humidity ranges in accordance with manufacturer instructions for 2 of 2 Siemens Atellica CI 1900 analyzers. Findings Included: 1) During a tour of the laboratory at 12:56 PM, two Siemens Atellica CI 1900 analyzers (Serial Numbers IRC013032449, IRC01302249) were observed in use. 2) Review of the Siemens Atellica manufacturer's instructions (Atellica CI Analyzer 11597559 02 2023-06) stated the following on page 587: "Atellica CI Analyzer Environmental Specifications: Laboratory ambient relative humidity 20-80%, noncodensing ..." 3) Review of the laboratory's defined Stanley Temperature continuous monitoring acceptable room humidity ranges revealed a setpoint of 5 to 95%. 4) In an interview on 5/5/2026 at 1:39 PM, the Laboratory Services Director confirmed the defined room humidity setpoints were not in accordance with manufacturer requirements. II. Based on direct observation, manufacturer's instructions, lack of room temperature records of the storage room, and interview with the Laboratory Services Director, the laboratory failed to define, monitor and document the room temperature of the storage room area for 2 of 2 years (2024 and 2025). Findings Included: 1) During a tour of the laboratory at 1:54 PM, the following reagents/supplies were observed in the laboratory's storage room with no room temperatures defined, monitored and documented: a. Six Siemens Healthineers A-LYTE IMT Standard, Lot Number 0000204436, Manufacturer storage temperature requirements 2 to 30 degrees Celsius. b. Two Siemens Healthineers IM Cleaner, Lot Number 0000201311, Manufacturer storage temperature requirements 2 to 30 degrees Celsius. c. Seven Siemens Healthineers IM Acid, Lot Number 0000201326, Manufacturer storage temperature requirements 2 to 30 degees Celsius. d. Three Siemens Healthineers CH Wash, Lot Number 0000201296, Manufacturer storage temperature requirements 2 to 30 degrees Celsius. e. Three Siemens Healthineers CH Conditioner, Lot Number 0000201303, Manufacturer storage temperature requirements 2 to 30 degrees Celsius. 2) Review of the laboratory's temperature record monitoring via Stanley Temperature continuous monitoring revealed no temperatures defined, monitored and documented for the laboratory's storage room, and no records could be provided for 2024 and 2025. 3) In an interview

	on 5/5/2026 at 1:54 PM, the Laboratory Services Director confirmed the storage room did not have established temperature setpoints defined, monitored and documented.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on direct observation, review of quality control (QC) records, laboratory test records, and confirmed in interview with the General Supervisor #1 according to the Form Centers for Medicare and Medicaid Services (CMS) 209, the laboratory failed to take corrective action since the last acceptable test run after QC failures required recalibration on the Siemens Atellica CI 1900 analyzer for 3 of 31 days in January 2026 (random review). Findings Included: 1) During a tour of the laboratory at 12:56 PM, two Siemens Atellica CI 1900 analyzers (Serial Numbers IRC013032449, IRC01302249) were observed in use. 2) Review of the laboratory's QC records between January 1, 2026 and January 31, 2026 (random review) revealed the following QC failures with subsequent recalibrations where evaluation of patient test results since the last acceptable test run was not performed: a) Calcium (Ca): QC Failures/Recalibration Date(s) - 1/16/2026, 1/23/2026 Patients tested in last acceptable test runs - 1/15/2026, 156 Ca tests run (Sample IDs: V035659606, V035654185, V035662774, V035667898 ...) 1/22/2026, 151 Ca tests run (Sample IDs: V035633031, V035637271, V035633072, V035630078 ...) b) Triglycerides (Trig): QC Failures/Recalibration Date(s) - 1/19/2026 Patients tested in last acceptable test runs - 1/17/2026, 2 Trig tests run (Sample IDs: V035652015, V035642362) 3) Review of the laboratory's chemistry test volumes revealed 524,559 tests run annually. 4) In an interview on 5/5/2026 at 1:00 PM, the GS confirmed the QC failures with subsequent recalibrations performed and lack of patient evaluations to the last acceptable test run.