

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0723803	(X3) Date Survey Completed 04/29/2026
Name of Provider or Supplier Nc State University Student Health Services	Street Address, City, State 2815 Cates Avenue Campus Box 7304, Raleigh, NC	
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	A validation survey was conducted April 29, 2026 with the following standard level deficiency cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: I. Based on observation, review of manufacturers' instructions, laboratory environmental records, and confirmed in interview with the Technical Consultant, the laboratory failed to ensure manufacturer's specified storage room temperature for 30 of 30 boxes of Cepheid test cartridges. Findings: 1. During a tour of the laboratory area on 04/29/2026 at 3:05 pm, the following Cepheid GeneXpert test cartridges were observed in the storage room: a. 12 boxes Cepheid GeneXpert CoV-2/Flu/RSV test cartridges; Lot number 1001515614; Expiration date 05/30/2027 b. 18 boxes Cepheid GeneXpert TV (Trichomonas vaginalis) test cartridges; Lot number 100518384; Expiration date 07/25/2024 2. The manufacturer's storage specifications, indicated on the label of each box of cartridges, stated a storage temperature of 2C-28C. 3. Review of the laboratory's environmental records for the storage room revealed an acceptable room temperature range of 64-86 F (17.78 - 30 C). This acceptable range exceeded the manufacturer's specified upper limit of 28C. 4. In an interview on 04/29/2026 at 3:18 pm, Technical Consultant #2 (as listed on the submitted CMS-209 form), confirmed</p>

the finding. II. Based on observation, review of manufacturers' instructions, laboratory environmental records, and confirmed in interview with the Technical Consultant, the laboratory failed to ensure manufacturer's specified relative humidity temperature for one of three instruments: Findings: 1. During a tour of the laboratory area on April 29, 2026 at 3:05pm, a Sysmex XN-430 hematology instrument and two Cepheid GeneXpert polymerase chain reaction instruments were observed to be in use by the laboratory. 2. The manufacturer's instructions for the Sysmex XN-430 stated "Chapter 5 Instrument Specifications ...Operating Environment ...Relative Humidity: 20 to 85%..." 3. Review of the laboratory's environmental records for the laboratory testing area revealed an acceptable relative humidity range of 10 - 80%. This acceptable range exceeded the manufacturer's specified lower limit of 20%. 4. In an interview on 04/29/2026 at 3:18 pm, Technical Consultant #2 confirmed the finding.