

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1048038	(X3) Date Survey Completed 10/16/2024
Name of Provider or Supplier Surgery Center Of Pinehurst	Street Address, City, State 10 First Village Dr, Pinehurst, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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: Based on review of the Microtome Cryostat Microm HM 524 Instruction Manual, the absence of 2022, 2023, and 2024 laboratory records, and interview with Director of Nursing and Admin RN, CEO 10/16/2024, the laboratory failed to define and monitor the conditions required for accurate and reliable test performance. Findings: Review of instruction manual, "Thermo Scientific Microtome Cryostat Microm HM 525, page 12, section 1-2 Technical Data HM 525 page 2...+5C up to + 35C (at a max. rel. humidity of 60%)..." Review of laboratory records revealed no documentation of temperature or humidity readings for 2022, 2023, and 2024. During interview at approximately 2:38 p.m. the Director of Nursing and Admin RN, CEO stated the following: 1. The Director of Nursing confirmed that room temperature and humidity are not monitored or recorded in the laboratory, but will be corrected. 2. The Admin RN, CEO stated the laboratory wasn't aware of these two requirements.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check</p>

protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on laboratory policy review for cryostat maintenance, and review of 2022, 2023, and 2024 cryostat maintenance records on 10.16.2024, the laboratory failed to perform cryostat bi-monthly maintenance as required 21 out of 32 months from February 2022 to September 2024. Findings: Review of laboratory policy, "10.7013. HIS.7 Maintenance, Cleaning and Inventory for Frozen Section Rooms," cryostat maintenance page 2, revealed "Bimonthly: see schedule below...For cryostats that are used less than daily...This should be done where there are no scheduled frozen sections." The policy then states what is performed for the bi-monthly maintenance. Review of 2022, 2023, and 2024 maintenance records, "Off-Site Frozen Section Area Maintenance Log/Pathology Area Maintenance Log," revealed bi-monthly maintenance was not performed as required for 21 out of 32 months from February 2022 to September 2024. Bi-monthly maintenance was not performed for the following months per year: 1. 8 months in 2022 (February, March, April, May, June, July, September, November) 2. 8 months in 2023 (January, February, May, July, August, September, November, December) 3. 5 months in 2024 (February, June, July, August, September) Interview with Director of Nursing and Admin RN, CEO, at approximately 1:54 p.m., confirmed the laboratory failed to meet the bi-monthly maintenance requirements. This deficiency was cited on the previous survey 02/02/2022.