

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2168003	(X3) Date Survey Completed 08/05/2021
Name of Provider or Supplier Pinehurst Surgical Clinic - Pa Ent	Street Address, City, State 5 First Village Drive, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and interview with Quality Manager 8/5/21, the laboratory procedure manual failed to include a procedure for the performance of the polychrome methylene blue stain. Findings: Review of laboratory procedure manual revealed no documentation of a procedure for the performance on the polychrome methylene blue stain. Interview with Quality Manager at approximately 12:20 p.m. confirmed the laboratory procedure manual failed to include a procedure for the performance of the polychrome methylene blue stain.</p>

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check 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 review of laboratory policy for cryostat maintenance, review of cryostat maintenance records and interview with Quality Manager 8/5/21, the laboratory failed to perform and/or document cryostat bi-monthly maintenance as required 3 times in approximately 2 years. Findings: Review of laboratory policy for cryostat maintenance revealed on page 2 "Bimonthly: see schedule below...For cryostats that are used less than daily...This should be done when there are no scheduled frozen sections." The policy then states what is performed for the bi-monthly maintenance. Review of May 2019 through June 2021 cryostat maintenance records, "Off-site Frozen Section Area Maintenance Log", revealed bi-monthly maintenance was not performed as required 3 times in a 2 year period: 1. Bi-monthly maintenance was performed on 7/3/19 and not performed again until 10/31/19. 2. Bi-monthly maintenance was performed on 9/28/20 and not performed again until 1/29/21. 3. Bi-monthly maintenance was performed on 3/29/21 and not performed again until 6/14/21. Interview with Quality Manager at approximately 12:15 p.m. confirmed maintenance was not performed and/or documented. She stated that the maintenance was performed but it must not have been documented.