

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2285488	(X3) Date Survey Completed 05/20/2024
Name of Provider or Supplier Kurt Vernon Md Pa (Pathology Lab)	Street Address, City, State 1004 Procure St, Fuquay Varina, 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
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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of laboratory maintenance records and interview with testing personnel (TP #1) 05/22/24, the laboratory failed to document maintenance as defined in the laboratory policy for the Milestone KOS Processor. Findings: Review of laboratory policy "Tissue Processing Using the Milestone KOS Processor" revealed the following maintenance and/or function protocols: 1. Under "SAFETY/PPE"...."The filters will be replaced every six months." 2. Under "PROCEDURE" ..."Prowave should be changed every other week or sooner if the color of the solution turns pink." 3. Under "QUALITY CONTROL"..."A Dailly QC log of all reagents and paraffin changes will be kept. The checklists will be marked with a check mark with those reagents or paraffin stations that have been changed and the technician initials....The paraffin wax and the processing solutions will be changed on a bi-weekly basis or more depending on case load." Interview with TP #1 at approximately 11:00 a.m. confirmed the laboratory was not documenting the maintenance protocols defined in the laboratory policy for the Milestone KOS Processor. She stated they do not keep that log.</p>