

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0097481	<b>(X3) Date Survey Completed</b>  05/23/2018
<b>Name of Provider or Supplier</b>  Steven A Gaudio Md	<b>Street Address, City, State</b>  929 Boston Post Rd, Old Saybrook, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 surveyor observation and staff interview, the laboratory failed to document maintenance activities as required. Findings include: 1. Surveyor observation on 5/23/18 at 09:00 AM of the microscope used to read pathology slides revealed, a tag indicating the date of the last preventative maintenance and function check was not present. 2. Record review of the laboratory's Quality Control Manual, 'Equipment Quality Control - Microscope' procedure #4 on 5/23/18 revealed, "Every action is documented on the maintenance record form." 3. Record review of the laboratory's Quality Control Manual, 'Maintenance Record-Microscope' sheet on 5/23/18 revealed: a) "Date of maintenance activity must be recorded and initialed." b) "Weekly since Aug 1988," is the only entry written in both the stage and oculars cleaned and grounding/cleaning column. 4. Staff interview with the laboratory director on 5/23/18 at 9:05 AM confirmed the above findings. 5. The laboratory performs 1,150 microscopic tissue evaluations annually.</p>