

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2122981	<b>(X3) Date Survey Completed</b>  06/18/2020
<b>Name of Provider or Supplier</b>  James Highsmith Md Llc	<b>Street Address, City, State</b>  1809 Collier Parkway, Lutz, FL	
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>D0000</b>	AMENDED An announced CLIA recertification survey was conducted at James Highsmith MD on 06/18/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Lab Assistant the laboratory failed to have the manufacturer's instructions for the microscope to define the maintenance requirements during the time of the survey. Findings Included: Review of instrument manufacturer's instructions (MI) revealed that there was no MI available for review for the microscope. Interview on 06/18/20 at 11:30 AM the Lab Assistant confirmed that the microscope did not come with MI.</p>