

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2074190	<b>(X3) Date Survey Completed</b>  03/10/2026
<b>Name of Provider or Supplier</b>  South Hills Gastroenterology	<b>Street Address, City, State</b>  1200 Brooks Lane, Suite 220, Clairton, PA	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus BX43 microscope used to perform histopathology microscopic slide examinations from 03/07/2024 to 03/10/2026. Findings include: 1. The manufacturers operating environment specifications stated: "Olympus BX43 microscope: 5-40 degrees Celsius (ambient temperature); maximum 80 % relative humidity." 2. On the day of the survey, 03/10/2026 at 01:15 pm, the laboratory failed to provide documentation for the monitoring of room temperature and humidity to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 03/07/24 to 03/10 /2026: - 1 of 1 Olympus BX43 microscope 3. The laboratory performed 1,666 histopathology microscopic slide examinations in 2025 (CMS 116, estimated annual volume, dated 02/22/2026). 4. The LD confirmed the above findings on 03/10/2026 at 01:40 pm.</p>