

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D1093630	<b>(X3) Date Survey Completed</b>  03/06/2025
<b>Name of Provider or Supplier</b>  Bryn Mawr Med Spec Asso Dpt Of Gastro	<b>Street Address, City, State</b>  825 Old Lancaster Road, Suite 340, Bryn Mawr, 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 review of laboratory records, 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 BX45 Microscope used to perform histopathology slide examinations from 02/22/2023 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the Olympus BX45 microscope states: "ambient temperature: 5 C to 40C, maximum relative humidity: 80%." 2. On the date of the survey, 03/06/2025 at 9:30 am, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for the 1 of 1 Olympus BX45 microscope (s/n 8K21167) used to perform histopathology slide examinations from 02/22/2023 to 03/06/2025. 3. The laboratory performed 6904 histopathology slide examinations from 02/22/2023 to 03/06/2025. 4. The LD confirmed the findings above on 03/06/2025 at 10:25 am.</p>