

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2037437	<b>(X3) Date Survey Completed</b>  04/24/2024
<b>Name of Provider or Supplier</b>  Partners In Specialty Pathology	<b>Street Address, City, State</b>  1045 Steeplechase Dr, Lancaster, 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>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 observation of the laboratory, 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 in the tissue pathology laboratory from 07/20/2022 to the day of survey. Findings Include: 1. On the day of survey, 04/24/2024 at 10:58 am, during the observation of the laboratory the surveyor discovered room temperature and humidity was not monitored in the laboratory where 1 of 1 microscope (Nikon eclipse 55i) was located from 07/20/2022 to the day of survey. 2. According to the Nikon Eclipse 55i manufacturer's instructions, the operating conditions for the microscope are below- Temperature: 0 to 40C Humidity: 85% RH max. (no condensation) 3. According to CMS 116 the laboratory performed 3150 tissue pathology microscopic examinations in 2023. 4. The LD confirmed the findings above on 04/24/2024 at 12:30 pm.</p>