

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2148247	(X3) Date Survey Completed 11/14/2024
Name of Provider or Supplier Premier Gastroenterology Associates, PLLC	Street Address, City, State 10915 Rodney Parham, Suite B, Little Rock, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<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: Through a review of 2023 and 2024 temperature and humidity records for the laboratory, and interview with laboratory staff, it was determined the laboratory failed to document daily humidity. Survey findings include: A. A review of laboratory instrumentation manuals revealed performance specifications of 20 to 80% relative humidity for the Biofire Film Array Torch System (FilmArray Torch Operator's Manual, Biofire, bioMerieux, CE IVD) and 30 to 85% relative humidity for the Tissue-Tek DRS 2000 Automatic Slide Stainer (Tissue Tek DRS 2000 Automatic Slide Stainer Operating Manual, Sakura, Revised 05/07/03) B. Through a review of temperature records for 2023 and 2024 it was revealed the laboratory failed to document humidity on 23 of 23 months for 2023 and 2024. C. Upon request, humidity recordings were not available for 2023 and 2024. D. In an interview, at 10:34 a.m. on 11/15/24, Testing Personnel #6 (as listed on form CMS-209) confirmed the laboratory humidities were not documented on days the laboratory was in operation.</p>