

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2148247	<b>(X3) Date Survey Completed</b> 03/13/2023
<b>Name of Provider or Supplier</b> Premier Gastroenterology Associates, PLLC	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Through a review of the Premier Gastroenterology Individualized Quality Control Plan (IQCP) for BioFire FilmArray Gastrointestinal Panel, review of daily run logs, and interviews with laboratory staff, it was determined the laboratory did not perform external Quality Control (QC) controls when they received new lots of Gastrointestinal (GI) panel. Survey findings include: A. A review of the Premier Gastroenterology Individualized Quality Control Plan (IQCP) for the BioFire FilmArray Gastrointestinal Panel states "External Quality Control (QC) will be completed on any new shipment or lot numbers of FilmArray Pouches and reagents." B. Employee #2 (as listed on the form CMS-209) stated, in an interview at 10:52 on 3/13/2023, that no external QC is being performed on new lots FilmArray Pouches. C. Through a review of the daily run log for The BioFire instrument it was determined that 7 out of 7 lots used through January 2022 to December 2022 (lot# 22NC21, lot# 29HK21, lot# 29F921, lot# 2D8422, lot# 2FU022, lot# 2H2X22, and lot# 2H9222) failed to include documentation of external QC performed on lots for the full year 2022.</p>
<b>D6128</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case,</p>

prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Through a review of personnel records for all laboratory personnel, a review of laboratory maintenance and temperature logs, and through interviews with staff, it was determined that the technical supervisor failed to assess competency of two of three testing personnel annually. Survey findings include: A. A review of personnel records for three testing personnel revealed that two of three failed to have annual competency documented. The last documented competency assessment for laboratory employee #3 (as listed on the form CMS-209) was dated 10/21/2020 and the last documented competency assessment for laboratory employee #5 was dated 4/17/2021. B. A review of maintenance and temperature logs revealed laboratory employee #3 had initialed as testing person in June, November, and December of 2022 and employee #5 had initialed as testing person in January 2023. C. In an interview, at 10:29 a.m. on 3/13/2023, the laboratory director confirmed that although employees #3 and #5 had documentation of working in the laboratory, competencies were not documented annually, as required.