

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 53D2058075	(X3) Date Survey Completed 07/20/2021
Name of Provider or Supplier Gastroenterology Associates Pc	Street Address, City, State 1441 Wilkins Circle, Casper, WY	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director and testing personnel failed to attest to the routine integration of proficiency tests into the patient workload for 4 of 4 College of Pathologists (CAP) proficiency testing events reviewed from August 2019 to July 2021. The findings were: 1. Review of the proficiency testing records failed to include the attestation statements signed by the laboratory director and testing personnel for the CAP 2019 microbiology event 2; the 1st and 2nd CAP 2020 microbiology events, and the 1st CAP microbiology event of 2021. 2. Interview with the laboratory director on 7/20/21 at 10:55 AM confirmed the attestation statements had not been signed.</p>
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to ensure proficiency test results were evaluated as indicated by the CLIA surveys conducted on 7/30/19 and 7/20/21 (D5211).

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory failed to ensure bacteriology, parasitology, and virology proficiency test results were reviewed to identify problems in the Biofire test system for 2 of 3 proficiency testing events reviewed (2019, 2020). The findings were: 1. Review of the 2020 College of American Pathologists proficiency module GIP (gastrointestinal panel)- Event A and GIP-Event B showed the laboratory failed to evaluate the proficiency test results. 2. Interview with the laboratory director on 7/20/21 at 10:40 AM confirmed the proficiency testing evaluation forms had not been documented as reviewed. THIS IS A REPEAT DEFICIENCY, previously cited on 7/30/19.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of competency records, lack of documentation, and staff interview, the laboratory failed to ensure an annual competency assessment had been completed for 1 of 3 testing personnel (#1) performing high complexity testing for 1 of 2 years reviewed (2020). The findings were: 1. Review of the laboratory's competency records showed no documentation a competency assessment had been completed for testing personnel #1 in 2020. 2. Interview with the laboratory director on 7/20/21 at 10:40 AM confirmed the annual competency assessment had not been completed.