

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0981311	(X3) Date Survey Completed 10/27/2022
Name of Provider or Supplier Wilmington Gastroenterology Associates, Pa	Street Address, City, State 5115 Oleander Drive, Wilmington, NC	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory quality assurance (QA) checklist, review of 2020, 2021 and 2022 proficiency testing (PT) records and interview with testing personnel (TP #3) 10/27/22, the laboratory failed to ensure all TP who performed Complete Blood Cell Count (CBC) testing participated in PT. Findings: Review of laboratory QA checklist revealed "Our proficiency testing policies were followed:...PT samples were tested exactly like patient specimens, i.e., the same number of times and using the same personnel and methods as patient testing.". Review of 2020, 2021 and 2022 PT records revealed TP #3 and TP #4 had not participated in the last 8 PT events performed. Interview with TP #3 at approximately 11:00 a.m. confirmed TP #3 and TP #4 performed CBC testing and also did not participate in PT for approximately 30 months.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p>

This STANDARD is not met as evidenced by:
Based on review of 2020, 2021 and 2022 testing personnel (TP) and technical supervisor (TS) competency records, review of personnel records, review of laboratory director (LD) delegations and interview with TP #3 10/27/22, the LD failed to ensure TP competency assessments for moderate complexity testing were performed by personnel who qualified as a technical consultant (TC) and failed to perform yearly competency evaluations for the duties delegated to the technical supervisors (TS). The laboratory performs high and moderate complexity testing. The moderate complexity testing performed is the Complete Blood Cell Count (CBC). 1. The LD failed to ensure TP competency assessments for moderate complexity testing were performed by personnel who qualified as a TC. Findings: Review of 2020, 2021 and 2022 TP competency records for CBC testing revealed TP #2 reviewed competency of TP #3 and TP #3 reviewed the competencies of TP #2, TP #4, TP #5, TP #6, TP #7, TP #8, TP #9 and TP #10. Review of personnel records revealed TP #2 has an associates degree in nursing and does not qualify as a TC. TP #3 has a high school diploma and does not qualify as a TC. Review of LD delegations revealed competency assessments were delegated in May of 2019 to technical supervisor (TS) #2. Interview with TP #3 at approximately 11:00 a.m. confirmed she performed the competencies of all TP whom performed CBC testing. She also confirmed her competency was performed by TP #2. 2. The LD failed to perform yearly competency evaluations for the duties delegated to TS #1 and TS #2. Findings: Review of LD delegation documentation for TS #1 signed April 30, 2021 revealed "...and the designee for signing all quality control documents for the hematology analyzer and in the histology department beginning May 1st 2021.". Review of LD delegation documentation for TS #2 dated May 1, 2019 revealed "...will be responsible for the day to day activities to include quality control, quality assurance, employee competency and proficiency.". Review of laboratory records revealed no documentation of competency assessments for TS #1 in 2020, 2021 or 2022. Review of laboratory records revealed no documentation of competency assessments for TS #2 in 2022.