

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0231462	(X3) Date Survey Completed 10/03/2019
Name of Provider or Supplier Gastroenterology Consultants Of Southwest Virginia	Street Address, City, State 202 Duke Of Gloucester Street, Roanoke, VA	
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
D0000	An announced CLIA Recertification survey was conducted at the Gastroenterology Consultants of Southwest Virginia on October 3, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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> <p>This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report form (CMS 209), testing personnel (TP) files, policy and procedures (P&P) and an interview with the laboratory director (LD), the LD failed to ensure the established policy of performing annual competency was followed for three (3) of 3 TP in the calendar year 2018. Findings include: 1. Review of the CMS Form 209: Laboratory Personnel Report revealed that there are 3 testing personnel performing histological slide examination. 2. Review of TP files revealed no competency assessments in 2018 for: TP A, TP B, and TP C. (See Personnel Code Sheet.) 3. Review of the P&P "Pathology Laboratory Gastroenterology Consultants of SWVA- Policies to Ensure Pathologist Competency" (signed by the lab director 6/1/16) revealed the following statement: "2. Yearly evaluation by another pathologist who has reviewed the pathologist's work product as part of the retrospective QA program." The inspector reviewed the "Pathologist Competency Evaluation Forms" for all 3 TP signed on October 1, 2019. The inspector requested to review the documentation of the competency evaluations for all 3 TP for</p>

2018, as describe within the established policy. The documentation was not available for review. 4. An interview with the laboratory director at approximately 1:00 PM confirmed the findings.