

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2090019	(X3) Date Survey Completed 04/19/2021
Name of Provider or Supplier Gastrointestinal & Liver Specialists Of Tidewater	Street Address, City, State 400 Sentara Circle - Suite 103, Williamsburg, 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 virtual CLIA recertification survey was conducted for Gastrointestinal and Liver Specialists of Tidewater on April 19, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), Quality Assurance (QA) policies, available QA and proficiency testing records, and interviews, the laboratory failed to perform twice annual Histopathology peer review in calendar year 2020. Findings include: 1. Review of the laboratory's CMS 116 form revealed one testing personnel (TP A) was identified as performing high complexity Histopathology during the twenty-six months reviewed (January 2019 to March 2021). *See Personnel Code Sheet 2. Review of the laboratory's QA policies revealed a written policy, Title: Pathology Laboratory Quality Assurance Plan, that stated: "Twice per year, 1% of cases will be reviewed by a second board certified pathologist who will be blinded as to the original diagnosis. The second opinion will be compared to the original diagnosis. Discrepancies that are potentially clinically significant will be adjudicated by a third pathologist and the report will be amended as necessary." 3. Review of the laboratory's proficiency documentation for calendar year 2020 to the date of survey revealed no record of Histopathology peer review for TP A. The inspector requested documentation of twice annual peer review for 2020. No documentation was available for review. The lab director (LD) stated on 4/19/21 at approximately 2:30 PM: "We did get behind during 2020 for the QA peer review. I</p>

plan to get the QA completed in the next month". 4. In an exit interview with the LD on 04/19/21 at approximately 3:30 PM, the above findings were confirmed.