

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2139758	(X3) Date Survey Completed 02/26/2019
Name of Provider or Supplier Bay Area Gastrointestinal Endoscopy And Liver Spec	Street Address, City, State 1305 S Ft Harrison Ave Ste E, Clearwater, FL	
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
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 review of policy and procedures, lack of documentation, and interview with the Laboratory Director, the laboratory failed to ensure the accuracy and precision of reading Hematoxylin and Eosin Stain, Alcian Blue/Periodic Acid Schiff (PAS) stain, Trichome Stain, CD3 (a marker for T- Lymphocyte cells) Stain, Helicobacter pyloric (H.pyloric), CDX-2 (marker for colorectal adenocarcinoma) Stain, p53 (tumor suppressor gene) Stain, MutLhomolog 1 (colorectal cancer marker) Stain, MSH-2 (colorectal cancer marker) Stain, MSH-6 (colorectal cancer marker) Stain, and PMS-2 (stain for colorectal cancer purposes) twice a year for for one out of one year (2018) reviewed in the specialty of Histopathology. Findings Included: Review of the policy titled "Bay Area Gastrointestinal and Liver Specialists Surgical Pathology Laboratory Quality Assurance Program" states that " Each month the lab director shall choose a number of cases based on overall volume which will be subjected to peer review." The policy does not state what slide stains would be sent out to the quality control pathologists. Review of the" QA Slide Review for Bay Area Gastro" documentation for 2018 was requested and provided. The forms lacked documentation of what type of slide stains were present. Interview on 02/26/2019 at 2:00 PM, Laboratory Director confirmed that the laboratory had not pulled twice annually slides for all stain for the 2018 "QA Slide Review for Bay Area Gastro."</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p>

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director the laboratory failed to document results of quality control for stains (hematoxylin and eosin stain, Alcian Blue/Periodic Acid Schiff (PAS) stain, Trichome Stain, CD3 (a marker for T-Lymphocyte cells) Stain, Helicobacter pyloric (H.pyloric), CDX-2 (marker for colorectal adenocarcinoma) Stain, p53 (tumor suppressor gene) Stain, MutLhomolog 1 (colorectal cancer marker) Stain, MSH-2 (colorectal cancer marker) Stain, MSH-6 (colorectal cancer marker) Stain, and PMS-2 (stain for colorectal cancer purposes) for 2018. Findings included: Record review of the "Send Out Log Quality Assurance" forms revealed the Laboratory Director was not documenting the results of stain quality controls for 2018. Interview on 02/26/2018 at 2:20 p.m., Laboratory Director confirmed the results of stain quality controls were not documented for 2018.