

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2135585	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier Gastroenterology Consultants Cfl Pa	Street Address, City, State 7364 Stonerock Cir Ste B, Orlando, 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
D0000	A Recertification survey was conducted on April 21, 2022. Gastroenterology Consultants CFL PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 record review and interview, the laboratory failed to verify accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain, Special Stains, and Immunohistochemistry (IHC) stains at least twice annually in 2020 and 2021. Findings: The procedure manual was reviewed by the Laboratory Director on 10/24/2017, 01/07/2019, and 04/20/2022. No revisions were noted between 10/24/2017 and 04/20/2022. Review of Quality Management Plan noted, "At least biannually, the director will communicate and perform a quality assurance review with the technical processing laboratory" No documentation of Proficiency Testing/Peer Review was available for review for 2020 and 2021. The Laboratory Directory evaluated the H&E stains and the following special stains: Alcian Blue (mucopolysaccharides and glycoproteins stain), Alcian Blue/PAS (mucopolysaccharides and glycoproteins stain /Periodic Acid Schiff, polysaccharides stain), PAS Hematoxylin (Periodic Acid Schiff, polysaccharides hematoxylin stain), and Trichrome (connective tissues stain). The Laboratory Directory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD117 (Cluster of Differentiation 117, stem cell IHC stain), and H. pylori (Helicobacter pylori IHC stain). On 04/21/2022 at 12:19 PM, the Laboratory Director stated the peer review was not done in 2020 and 2021.</p>

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview, the laboratory failed to record the reactivity of the quality control slides read out at the laboratory for six of six days (05/29/2019, 01/08/2020, 08/19/2020, 01/20/2021, 08/23/2021, 01/05/2022). Based on observation and interview, the laboratory failed to have a control slide for Hematoxylin and Eosin (H&E) stain for six of six (#1, #2, #3, #4, #5, #6) patient's slides reviewed, and failed to have a negative control slide for CD3 (Cluster of Differentiation 3 T cell Lymphocytic) Immunohistochemical (IHC) for four (#1, #3, #4 & #6) of six (#1, #2, #3, #4, #5 & #6) patient's slides reviewed. Findings: The laboratory performs only the microscopic examination of the slides. The Laboratory Directory evaluated the H&E stains and the following special stains: Alcian Blue (mucopolysaccharides and glycoproteins stain), Alcian Blue/PAS (mucopolysaccharides and glycoproteins stain/Periodic Acid Schiff, polysaccharides stain), PAS Hematoxylin (Periodic Acid Schiff, polysaccharides hematoxylin stain), and Trichrome (connective tissues stain). The Laboratory Directory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD117 (Cluster of Differentiation 117, stem cell IHC stain), and H. pylori (Helicobacter pylori IHC stain). 1. The Laboratory Director records the acceptability of the stain on the "Technical Quality Assurance Form and Slide Delivery Log." Review of the logs showed for the stain quality of acceptable/rejected was not recorded for the patients listed on the log for the following dates: 05/29/2019 - 3 patients - H&E 01/08/2020 - 5 patients - H&E, H. pylori, PAS, CD3, AB/PAS, 08/19/2020 - 2 patients - H&E 01/20/2021 - 2 patients - H&E, PAS 08/23/2021 - 2 patients - H&E, H. pylori, PAS, CD3, AB/PAS 01/05/2022 - 3 patients - H&E On 04/21/2022 at 2:55 PM, the Laboratory Director stated the not all the stain quality was indicated as acceptable/rejected and there was no place to record the quality of the H&E stain. 2. On 04/21/2022 at 2:00 PM, observation of the slides for six patients showed each patient had a H&E stained slide and a H&E control slides were not available for review. Review of the "Technical Quality Assurance Form and Slide Delivery Log." showed the following: Patient #1 - had 4 H&E slides Patient #2 - had 1 H&E slide Patient #3 - had 3 H&E slides Patient #4 - had 3 H&E slides Patient #5 - had 3 H&E slides Patient #6 - had 3 H&E slides On 04/21/2022 at 2:11 PM, the Laboratory Director stated the laboratory performing the technical component (slide staining) did not send a control slide for the H&E. 3. On 04/21/2022 at 2:00 PM, observation of the slides for six patients showed Patients #1, #3, #4, and #6 had a CD3 IHC stained slide and negative control slides were not available for review. Review of the "Technical Quality Assurance Form and Slide Delivery Log." showed Patients #1, #3, #4, and #6 had CD3 IHC stained slides. On 04/21/2022 at 2:51 PM, the Laboratory Director stated she did not receive a negative control slide for CD3.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have the correct address of the laboratory for three (#4, #5 & #6) of six patients' pathology reports. Findings: Review of the patients' laboratory pathology reports showed the address on the reports of patients #4, #5, and #6 was the address of the laboratory's previous location. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification and letter from the laboratory requesting the change of address, stated the effective date of the move to the new locations was 09/30/2020. On 04/21/2022 at 2:57 PM, the Laboratory Director stated the laboratory address was not changed on the pathology reports after the laboratory moved.