

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2145680	(X3) Date Survey Completed 08/11/2020
Name of Provider or Supplier Gastroenterology Institute Of Orlando Llc	Street Address, City, State 812 W Oak Street, Kissimmee, 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	An initial certification survey was conducted on August 11, 2020. Gastroenterology Institute of Orlando clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to have negative control slides for recording the negative reactivity for 3 (#1, 2, 4) out of 4 (#1, 2, 3, 4) patients with Immunohistochemical (IHC) stained slides. Findings: The laboratory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), and H. pylori (Helicobacter pylori, bacteria IHC stain). Review of the "Technical Quality Assurance Form and Slide Delivery Log" indicated that a CD3 IHC slide was performed on patient #1. Observation of the slides for patient #1 showed that the patient had a CD3 IHC stain slide and no negative control slide was available for review. Review of the "Technical Quality Assurance Form and Slide Delivery Log" indicated that a CD3 and H. pylori IHC slide was performed on patient #2 and #4. Observation of the slides for patient #2 and 4 showed that the patients had a CD3 and H. pylori IHC stain slides and no negative control slides were available for review. During an interview on 8/11/20 at 1:45 PM, the Laboratory Consultant stated she was unable to locate the negative control slides for IHC stained slides.</p>

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, observation, and interview, the laboratory's pathology reports failed to provide the test results of the special stains in 2 (#3, 4) out of 4 (#1, 2, 3, 4) patient pathology reports examined. Findings: Review of the "Technical Quality Assurance Form and Slide Delivery Log" indicated that an Alcain Blue stained slide was performed on patient #3. Observation of the slides for patient #3 showed an Alcain Blue slide for biopsy "A: Stomach, Body, Biopsy" was included with the other slides for the patients. Review of the "GI Pathology Report" for patient #3 showed that the test results of the Alcain Blue slide were not included in the "GI Pathology Report." report. Review of the "Technical Quality Assurance Form and Slide Delivery Log" indicated that a Periodic Acid - Schiff (PAS) - Hematoxylin stained slide was performed on patient #4. Observation of the slides for patient #4 showed a PAS - Hematoxylin slide for biopsy "D: Duodenum, Bulb, Distal, Biopsy" was included with the other slides for the patients. Review of the "GI Pathology Report" for patient #4 showed that the test results of the PAS - Hematoxylin slide were not included in the "GI Pathology Report." During an interview on 8/11/20 at 2:05 PM, the Laboratory Director stated the test result for the Alcain Blue and PAS stains were not mentioned on the pathology reports.