

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1105837	<b>(X3) Date Survey Completed</b>  01/10/2022
<b>Name of Provider or Supplier</b>  Florida Digestive And Liver Specialist	<b>Street Address, City, State</b>  25 E Silver Palm Ave Ste B, Melbourne, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A recertification survey was conducted on January 10, 2022. Florida Digestive and Liver Specialists clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5400</b>	<p><b>ANALYTIC SYSTEMS</b> CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and identify problems. Findings: Cross Reference D5601. Based on observation, record review and interview, the laboratory failed to have and record the reactivity of a negative control slides for Immunohistochemical (IHC) stains for three (#2, #3, #4) of five (#1 - #5) patients' slides and Pathology Reports reviewed. This is a repeat deficiency from the survey on 12/09/2019.</p>
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> 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</p>

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 have and record the reactivity of negative control slides for Immunohistochemical (IHC) stains for three (#2, #3, #4) of five (#1 - #5) patients' slides and Pathology Reports reviewed. This is a repeat deficiency from the survey on 12/09/2019. Findings: The laboratory performs only the microscopic examination of the slides. Three of five patients' slides and Pathology Reports reviewed had IHC stained slides. The laboratory evaluated the following IHC stains: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), H. pylori (Helicobacter pylori IHC stain) MLH1 (MutL Homolog 1 Colorectal Cancer IHC stain), MSH2 (Melanocyte Stimulation Hormone 2 Tumor Suppressor Gene IHC stain), MSH6 (Melanocyte Stimulation Hormone 6 Colorectal Cancer and Endometrial Cancer IHC stain), PMS2 (Postmeiotic Segregation Increase 2 IHC stain), and S100 (Neural Tissue/Lesion and Melanoma IHC stain). Observation of the patient slides showed there were no negative control slides for the IHC stains. Patient #2 had an IHC stained slide for S100. Review of the Pathology Report for patient #2 noted the "IHC stain for S100 is done with positive control." Patient #3 had an IHC stained slide for H. pylori. Review of the Pathology Report for patient #3 noted the "IHC stain for H pylori is done with positive control." Patient #4 had an IHC stained slides for MLH1, PMS2, MSH6, and MSH2. Review of the Pathology Report for patient #4 noted the "IHC stains for MLH1, PMS2, MSH6, and MSH2 are done with positive controls." On 01/10/2022 at 12:59 PM, the Registered Nurse stated she could not find any negative control slides for IHC stained slides.