

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0870415	(X3) Date Survey Completed 01/24/2019
Name of Provider or Supplier Endoscopy Center Of Ocala	Street Address, City, State 1160 Se 18th Pl, Ocala, 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	Endoscopy Center of Ocala dba Gastroenterology Associates of Ocala clinical laboratory was found to be in non-compliance with the 42 CFR Part 493, Requirements for Laboratories. Biennial certification survey was conducted January 24, 2019.
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 record review and staff interview, the laboratory failed to check immunohistochemical (IHC) tissue stains for negative reactivity each time of use for 4 of 4 different IHC stains for two out of two years reviewed. The findings include: Review of the logbook on immunohistochemical (IHC) stain test results showed there was a positive control run with the stain and no negative control was run for four IHC stains performed. The following IHC stains did not show a negative control run with the stain on the day that the patient slides were stained from January 2017 through January 2019: S100, HP (H. Pylori), KER (Cytokeratin) and CHROM (Chromogranin A). During an interview on 1/24/19 at 10:00 AM, testing person # 2 confirmed that the laboratory did not run a negative control with the IHC stains and the laboratory was not aware that quality control for negative reactivity was required for the IHC stains along with the check for positive reactivity.</p>