

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2100043	(X3) Date Survey Completed 04/09/2019
Name of Provider or Supplier Steven D Fayne Md Pa	Street Address, City, State 8890 W Oakland Park Blvd Ste 100, Sunrise, 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
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 interview, the laboratory failed to record the Immunohistochemical (IHC) stains for negative reactivity for each IHC stained slide that were examined from 4/9/17 to 4/9/19. Findings: Review of the log titled, "Daily Quality Control for Special Stains" showed the laboratory failed to document a negative control slide for IHC stains. Review of patient slides showed that for 3 (#1, 3, 5) out of 5 (#1, 2, 3, 4, 5) patient slides reviewed that had a Helicobacter pylori IHC stains and that there was no negative controls slides available for review. IHC stains performed at the laboratory include, AE1/AE3 (Epithelial IHC stain), CD45 (Cluster of Differentiation 45 leukocyte IHC stain), Helicobacter pylori (bacteria), and Pan Keratin (Epithelial IHC stain). During an interview on 4/9/19 at 10:30 AM, the Office Manager confirmed that the negative reactivity for the IHC stains were not recorded and that there were no negative control slides.</p>