

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2266132	<b>(X3) Date Survey Completed</b>  02/16/2023
<b>Name of Provider or Supplier</b>  Ruffolo Hooper & Associates Md Pa	<b>Street Address, City, State</b>  30945 Bay Shore Dr, Big Pine Key, 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>	An initial survey conducted on 02/16/2023 found the RUFFOLO HOOPER AND ASSOCIATES PA MD clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<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 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 have and record the negative control reactivity verification for the immunohistochemical (IHC) stain interpretation that the laboratory performed for 163 out of 163 cases since 08/05/2022. The findings include: -The laboratory performs only the microscopic examination of the slides. The laboratory performed interpretation for the following IHC stains since 08/02/2022: Cluster of Differentiation (CD) 20 (CD20): one case; Paired Box Gene 5: one case; CyclinD1: one case; Epithelial Membrane Antigen: one case; Melanoma Antigen Recognized by T Cells one: one case; Human Melanoma Black 45: one case; Estrogen Receptor: one case; Pancytokeratin cocktail (AE1/AE3): eight cases; Calcium Binding Protein (S100): two cases; CD34: one case; Cytomegalovirus: one case; Herpes Simplex Virus I/II: one case; Synaptophysin: two cases; Chromogranin A: two cases; CD117: one case; Desmin: four cases; Ki67: six cases; Helicobacter pylori: 118 cases; P504 &amp; Cytokeratin (beta34E12) +p63 (Pin4): two cases; CD3: one case; CD5: one case; CD10: two cases; Smooth Muscle Actin (SMA): two cases. - Review of patient report 1 and 2, revealed that 2 out of 2 had immunohistochemical</p>

stain for *Helicobacter pylori*, no documentation of the evaluation of the reactivity of the negative control founded in laboratory logs or patient report. During an interview on 02/16/2023 at 03:00 PM, the laboratory director confirmed that the laboratory failed to have and record negative control reactivity for the immunohistochemistry stains for the cases of reference.