

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1026446	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Reliance Pathology Partners Llc	Street Address, City, State 2901 Swann Ave, Tampa, 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 announced CLIA recertification survey was conducted at Reliance Pathology Partners LLC on 11/05/2019. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
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 Read - Only laboratory failed to document the negative reactivity for Histopathology for each Immunohistochemical (IHC) stain for 2 out of 2 years (2018-2019). Findings included: Review of patient reports showed that there was no documentation for the reactivity of the negative control. IHC stains at the laboratory include: B-cell lymphoma (BCL) 1, BCL -2, BCL -6, BerEP4 (known as epithelial cell adhesion molecule), Cluster of differentiation (CD) 3, CD5, CD10, CD20, CD34, CD43, CD45, CD68, CDX2, Carcinoembryonic Antigen(CEA), Cytokeratin (CK)5/6, CK7, CK20, D2-40 (new marker for lymphatic endothelium, Desmin, Epithelial Membrane Antigen (EMA), Endoplasmic Reticulum (ER), Human Herpes Virus (HHV8), Helicobacter pylori (h. pylori), Herpes Simplex Virus (HSV I/II), Ki-67 (protein encoded by the MKI67 gene), Melanoma Antigen Recognized by T-cells (MART-1), p16 (marker for human papillomavirus), p53 (marker for ovarian cancer), Pankeratin, Prostate Specific Antigen (PSA), s11 (cancer marker), Synaptophysin, and Thyroid Transcription Factor (TTF-1). The laboratory performed</p>

92 IHC stains from 1/22/2018 to 10/03/2019. On 11/05/19 at 10:45 AM, the Laboratory Manager and Laboratory Director stated they did not know that the laboratory needed to document the reactivity of a negative control.