

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2048182	<b>(X3) Date Survey Completed</b>  07/30/2018
<b>Name of Provider or Supplier</b>  Alliant Dermatology Pa	<b>Street Address, City, State</b>  8620a E Cr 466, The Villages, 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>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 check and document the immunohistochemical (IHC) stains for negative reactivity for all patients whose IHC stains were performed from 7/30/16 to 7/30/18. Findings: Review of the log titled "Special Stain/Immuno Log" showed that the laboratory failed to record the negative reactive on IHC stains. IHC stains performed at the laboratory include BerEp4 (Epithelial Antigen IHC stain), CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD4 (Cluster of Differentiation 4 T cell Lymphocytic IHC stain), CD8 (Cluster of Differentiation 8 T cell Lymphocytic IHC stain), CD10 (Cluster of Differentiation 10 Cell Surface Enzyme IHC stain), CD34 (Cluster of Differentiation 34 progenitor cells IHC stain), CEA (carcinoembryonic antigen IHC stain), CK 5/6 (Cytokeratin 5/6 IHC stain), CK7 (Cytokeratin 7 glandular and transitional epithelial IHC stain), CK20 (Cytokeratin 20 IHC stain), Desmin (Smooth Muscle Tumor IHC stain), Factor XIIIa (Factor XIIIa protein IHC stain), Ki 67 (cell proliferation IHC stain), MART-1/Melan-A (Melanocytic Marker IHC stain), MITF (Microphthalmia Transcription Factor IHC stain), P63 (P63 gene IHC stain), Pan-Keratin (MCK-muscle creatine kinase antibody IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), Sox-10 (melanoma marker IHC stain), SMA (Smooth Muscle Actin IHC stain), Spirochetes (Treponema Palladium IHC stain), and Vimentin (Mesenchymal Cells IHC stain). During an interview on 7/30/18 at 10:50 AM, the</p>

consultant confirmed that they did not record the negative reactivity for IHC controls slides.