

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D1009875	<b>(X3) Date Survey Completed</b>  02/19/2020
<b>Name of Provider or Supplier</b>  Advanced Dermatology And Skin Surgery, Pa	<b>Street Address, City, State</b>  12 Medical Park Drive, Asheville, NC	
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 review of manufacturer's instructions, review of laboratory's procedure and logs, and interview with the laboratory supervisor 2/19/20, the laboratory failed to check and document negative control reactivity for the Melan-A IHC (immunohistochemical) stain. Findings: The manufacturer's instructions for the Stat Lab Medical Products MART-1/Melan-A, Melanoma Marker states under Storage and Handling, "...Positive and negative controls should be run simultaneously with all patient specimens..." Review of the laboratory's procedures revealed the laboratory began testing the Melan-A IHC stain in April 2018. The Melan-A stain procedure states, "PROCEDURE...2. Add a positive Melan-A control above the patient tissue (Positive control results are recorded on the "Immuno Stain Control Slide Check" form..." Review of the IHC stain log revealed the laboratory only documents positive control reactivity for Melan-A. At approximately 11:20am, the laboratory supervisor confirmed the laboratory only uses a positive control for Melan-A IHC stain. She confirmed that negative control reactivity is not documented.</p>