

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0327278	<b>(X3) Date Survey Completed</b>  06/11/2019
<b>Name of Provider or Supplier</b>  Affiliated Dermatology Surgery Center	<b>Street Address, City, State</b>  650 Shawan Falls Dr, Dublin, OH	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on manual review and an interview with the Laboratory Director (LD), the laboratory failed to have a written policy and procedure available to and followed by the laboratory personnel for the test accuracy verification of Mohs specimens. All Mohs patient testing performed in this laboratory had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manuals titled "AD Histology Procedure Manual" and "AD Histology Policy Manual" provided on the date of the inspection, did not find a policy and procedure for Mohs test accuracy verification. 2. The surveyor requested the laboratory's test accuracy verification policy and procedure for Mohs from the LD. The LD stated the laboratory did not have a test accuracy policy and procedure for Mohs testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 06/11/2019 at 10:30 AM.</p>