

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0958465	<b>(X3) Date Survey Completed</b>  09/20/2018
<b>Name of Provider or Supplier</b>  Essentia Dermatology	<b>Street Address, City, State</b>  402 East Second Street, Duluth, MN	
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 document review and interview with laboratory personnel, the Mohs Surgeon failed to document the acceptability of the Quality Control (QC) slide each day of patient specimen testing. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty of Histopathology as confirmed by the Anatomic Pathology Supervisor during a tour of the laboratory on 09/20/18 at 10:05 a.m. 2. Daily QC slide performance requirements were established in the Frozen Sections - Handling, Sectioning, and Staining in the Dermatology Laboratory procedure located in the Mohs Laboratory Manual. The procedure indicated the Mohs Surgeon evaluated the QC slide for staining acceptability. 3. QC slide acceptability documentation was not found during review of laboratory records from January 2017 to date of survey, 09/20/18. The laboratory was unable to provide documentation of daily QC slide evaluation for this time period upon request. 4. In an interview on 09/20 /18 at 12:00 p.m., Testing Personnel 1 confirmed the approval of the daily QC slide had not been documented.</p>