

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D1107252	<b>(X3) Date Survey Completed</b>  03/15/2018
<b>Name of Provider or Supplier</b>  May River Dermatology	<b>Street Address, City, State</b>  7 Arley Way, Suite 101, Bluffton, SC	
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>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: During an onsite recertification survey on 03/15/2018, based on procedure manual review, lack of documentation, and testing personnel interview, it was determined that the laboratory failed to document daily stain acceptability for hematoxylin and eosin stains performed for seventeen out of eighteen months reviewed (April 2016 through March 2018). Findings include: 1. The procedure manual stated that stain quality and acceptability for hematoxylin and eosin stains performed in house will be documented on each day of testing. 2. Review of the laboratory's stain quality control records revealed that documentation of daily stain acceptability for hematoxylin and eosin stains performed was unavailable for review for seventeen out of eighteen months reviewed (April 2016 through March 2018). A monthly stain acceptability had been documented by the laboratory for the reviewed time period. 3. Testing personnel confirmed during an onsite interview on 03/15/2018 at 1:00 pm that the daily stain quality for hematoxylin and eosin stains performed was not documented for seventeen out of eighteen months reviewed (April 2016 through March 2018).</p>