

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2120545	<b>(X3) Date Survey Completed</b>  02/14/2018
<b>Name of Provider or Supplier</b>  May River Dermatology, Llc	<b>Street Address, City, State</b>  6470 East Johns Crossing, Suite 200, Johns Creek, GA	
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>D0000</b>	Based on an Initial CLIA Survey performed on February 14, 2018, this facility was found to be non-compliant with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on general lab systems document review and staff interview, the laboratory failed to verify, at least twice annually, the accuracy of any non-regulated test or procedure as required. Findings include: 1. General lab systems document review revealed the laboratory failed to perform a twice-yearly verification for Potassium Hydroxide (KOH) testing. 2. An interview with the laboratory director on 2/14/18 in a medical office at approximately 4 p.m. confirmed KOH verification testing was not performed twice annually for 2016 and 2017.</p>
<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:</p>

Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to establish a policy and procedure for all tests, assays, and examinations performed by the laboratory. Findings include: 1. SOP review revealed the laboratory had not established a policy and procedure for twice yearly Potassium Hydroxide (KOH) peer review. 2. An interview with the laboratory director in the laboratory on 2/14/2018 at approximately 4 p.m. confirmed there was not a policy and procedure in the SOP for twice yearly KOH peer review.