

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2120545	(X3) Date Survey Completed 08/07/2019
Name of Provider or Supplier May River Dermatology, Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on August 07, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: A review of laboratory personnel records and an interview with the laboratory director, revealed that the laboratory director failed to provide annual Competency Assessment for ALL its testing personnel. Findings include: 1. A review of testing personnel records revealed there were no competency evaluations for testing personnel (TP#s 4 and 5 CMS 209) in 2018 and 2019. 2. An interview with the laboratory director on August 07, 2019 at 12:45 PM in the review room confirmed that there were no annual competencies performed on testing personnel #s 4 and 5 on (CMS 209).</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:

Based on documents review, laboratory tour and an interview with the Laboratory director, it was determined that the laboratory failed to document weekly maintenance as written in the laboratory procedure manual. Findings include: 1.) Laboratory tour and maintenance documents review revealed no weekly change documented on slide staining solutions in the specialty of Histopathology in 2018 and 2019. 2.) An interview with the Laboratory director at approximately 12:15 pm on August 7, 2019 in the review room confirmed weekly changing of staining solutions were not documented in 2018 and 2019 in the specialty of Histopathology.