

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2023248	<b>(X3) Date Survey Completed</b>  08/07/2018
<b>Name of Provider or Supplier</b>  Cosmetic And Dermatologic	<b>Street Address, City, State</b>  719 N Beers St, Holmdel, NJ	
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 surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have an accurate procedure for biannual assessment from 6/27/16 to the date of survey. The findings include: 1. CLIA regulation states "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." (D5217) 2. The PM stated, "proficiency testing is done annually". 3 The TP confirmed on 8/7 /18 at 1:00 pm that the laboratory did have an accurate procedure for BA.</p>