

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0107659	<b>(X3) Date Survey Completed</b>  01/23/2018
<b>Name of Provider or Supplier</b>  Biogenetics Corp, Lab Services	<b>Street Address, City, State</b>  187 Mill Lane, Mountainside, 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 General Supervisor (GS), the laboratory failed to have a written procedure for preparing Quality Control (QC) material for semen analysis from 10/6/17 to the date of survey. The GS confirmed on 1/23/18 at 11:45 am that the procedure mentioned above was not in the PM.</p>