

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0107659	<b>(X3) Date Survey Completed</b> 02/05/2020
<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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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: Based on surveyor review of the Competency Assessment (CA) records and interview with the Technical Supervisor (TS), the laboratory failed to perform the CA correctly for two out of two Testing Personnel (TP) from 1/23/18 to the date of the survey. The finding includes: 1. The laboratory did not document assessment of problem solving skills on two of two TP. 2. The TP confirmed on 2/5/20 at 10:30 am that the CA was not performed correctly.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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), Work Records (WR) and interview with the General Supervisor (GS), the laboratory failed to follow the procedure for semen analysis from January 2019 to the date of survey. The findings include: 1. The PM stated that if duplicate sperm counts had &gt; 10% difference a third count should be performed. 2. A review of ten patient WR revealed five of ten</p>

duplicate sperm counts had a > 10% difference but there was no documented evidence a third count was performed. 3. The GS confirmed on 2/5/20 at 10:00 am that the laboratory did not follow the procedure stated above.