

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1031713	(X3) Date Survey Completed 07/14/2020
Name of Provider or Supplier Genesis Medical Laboratory	Street Address, City, State 8150 Perry Highway Suite 102, Pittsburgh, PA	
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
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: Based on review of the competency records and policy & interview with the Laboratory Director, Technical Supervisor, and General Supervisor, the Technical Supervisor failed to establish written policies and procedures to assess competency for 1 of 1 Technical Consultants, 2 of 2 Technical Supervisors, and 1 of 1 General Supervisor from (05/08/2018) through the date of the survey (07/14/2020). Findings: 1. At the time of the survey, the Laboratory could not provide written policies and procedures to assess Technical Consultant, Technical Supervisor, & General Supervisor competency. 2. A review of the competency assessment records revealed there was no documentation of supervisor competency assessment from (05/08/2018) through the date of the survey (07/14/2020). 3. From (05/08/2018) through the date of the survey (07/14/2020), 40927 toxicology specimens were run. 4. During the survey at (15:30 07/14/2020), the Technical Supervisor #1 confirmed, the above findings.</p>