

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0893887	(X3) Date Survey Completed 02/02/2023
Name of Provider or Supplier Genetic Diagnostic Laboratory	Street Address, City, State 560 Clinical Research Bldg, 415 Curie Blvd, Philadelphia, 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 laboratory's competency assessment records and interview with Laboratory Director (LD), the laboratory failed to have a porcedure to assess the competency of 1 of 1 General Supervisor (GS) for their supervisory responsibilities from 08/04/2022 to the date of survey. Findings include: 1. On the day of survey, 02 /02/2023 at 11:40 am, the LD could not provide a competency assessment procedure to assess the competency of the 1 of 1 GS (on CMS 209, listed as personnel #2) from 08/04/2022 to the date of survey. 2. The LD could not provide competency assessment records for 1 of 1 GS (on CMS 209, listed as personnel #2) for their supervisory responsibilities from 08/04/2022 to 02/02/2023 3. The LD confirmed the findings above on 02/02/2023 around 01:20 pm.</p>
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Genetic Diagnostic Laboratory Quality Assurance and</p>

Internal Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory director (LD) failed to ensure that all PT reports were reviewed by the appropriate staff in 2022. Findings Include: 1. On the day of survey, 02/02/2023 at 12:30 pm, review of the PT attestation statements revealed, the LD did not sign the following attestation forms in 2022: - FOP - X-inact - BWS - RSS - CHI L1 - Twist - OVG - LYM - Agilent aCGH - UM Chr 3,6,8 - MCC - RB FFPE Comprehensive tumor, no B - F8 inversion 2. The LD confirmed the findings above on 02/02/2023 around 01:20 pm.