

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2126563	(X3) Date Survey Completed 06/25/2025
Name of Provider or Supplier Ariel Precision Medicine	Street Address, City, State 5750 Centre Avenue, Suite 270, 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 lack of documentation and interviews with the Laboratory Director (LD), Chief Science Officer (CSO) and the Chief Executive Officer (CEO), the laboratory failed to establish and follow procedures to assess the competency of 1 of 1 clinical consultant (CC) for their responsibilities as CC in 2023 and 2024. Findings Include: 1. On the day of survey, 06/2//2025 at 01:30 pm, the laboratory could not provide a procedure for assessing the competency for the responsibilities of the clinical consultant position. 2. The laboratory could not provide competency assessment documentation for 1 of 1 CC (CMS 209 personnel #2) from 07/11/2023 to 06/25 /2025. 3. The CEO confirmed the finding above on 06/25/2025 at 01:30 pm.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, record, review and interviews with the Laboratory Director (LD), Chief Science Officer (CSO) and the Chief Executive Officer (CEO),</p>

the laboratory failed to follow established procedures to assess the competency of 1 of 2 testing personnel (TP) for their testing responsibilities in 2023 and 2024. Findings Include: 1. The laboratory's Personnel Competency Assessment Standing Operation Procedure states: " The Laboratory Directory, or the Director's designee, will perform annual competency assessments for all laboratory testing personnel. The competency assessment will be documented on the Annual Competency Assessment form." 2. On the day of survey, 06/25/2025 at 01:30 pm, the laboratory could not provide the annual competency assessment for 1 of 2 TP (CMS 209 personnel #2) for their testing responsibilities in 2023 and 2024. 3. The CEO confirmed the finding above on 06/25 /2025 at 01:30 pm.