

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2126563	(X3) Date Survey Completed 07/15/2021
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 review of laboratory procedure manuals and interview with the Laboratory Director (LD) and Vice President of Operations (VPO), the laboratory failed to follow and establish a complete competency assessment procedure to assess 1 of 2 clinical consultant (CC) for their regulatory responsibilities in 2019 to the day of survey. Findings include: 1. The Lab Personnel Competency Assessment procedure states: "a) Quality control i) During on boarding for all new laboratory hires. ii) 6 month post-start and at 1 year post-start date of new laboratory hires. iii) Annually for laboratory personnel with >1 year at Ariel." 2. On the day of survey, 07/15/2021, the laboratory could not provide the following 2019 competency assessment records: - The 6 month competency assessment for TP #3. - The annual competency assessment for TP #2. 3. The laboratory could not provide a complete policy to assess the competency of 1 of 2 CC (#2) for their regulatory responsibilities in 2019, 2020 and 2021. 4. The CC#2 was not assessed for competency in 2019, 2020 and 2021. 5. The LD and VPO confirmed the findings above on 07/15/2021 around 10:45 am.</p>