

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2126563	(X3) Date Survey Completed 07/11/2023
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the Chief Executive Officer (CEO), Technical Supervisor (TS), and Laboratory Director LD), the laboratory failed to perform and document maintenance as defined and with the frequency specified by the manufacturer on 1 of 1 thermometer used to monitor Room Temperature (RT) from 07/15/2021 to the day of the survey. Findings Include: 1. On the day of the survey, 07/11/2023 at 03:53 PM, an observation of the laboratory revealed that the following thermometer used to record RT for the Genotyping samples processing expired on 06 March 2022. -Traceable- S/N- 200190858. 2. CEO, TS, and LD confirmed the above findings on 07/11/2023 at 04:00 PM.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p>

This STANDARD is not met as evidenced by:

Based on a review of the Quality Control (QC) documents and interview with the Chief Executive Officer (CEO), Technical Supervisor (TS), and Laboratory Director (LD), the Laboratory failed to provide documentation of the corrective action taken when 3 of 3 QC results did not meet the laboratory's established acceptable criteria for Human Genotyping testing performed using Axion Genotyping Solution system in 2023. Findings Include: 1. On the day of survey, 07/11/2023 at 03:16 PM, a review of QC logs revealed that 3 of 3 failed QC manually changed based on the calculation obtained on the Axion system. 2. According to the laboratory manual, QC is automatically generated by the data received from Eremid laboratory for each patient. 3. The QC log in the computer system did not have corrective action documented for failed QC. 4. CEO, LD, and TS confirmed the findings above on 07/11/2023 at 03:56 PM.