

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2173105	(X3) Date Survey Completed 08/29/2024
Name of Provider or Supplier Arete Family Care, Llc	Street Address, City, State 2741 Debarr Road, Ste 307, Anchorage, AK	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the laboratory director, the laboratory failed to have a written procedure for qualitative semen analysis. Findings include: 1. A request was made to review the procedure for qualitative semen analysis and documentation could not be provided. 2. An on-site interview conducted with the laboratory director on 8/26/2024 at 13:30 PM confirmed the laboratory did not have written procedure for qualitative semen analysis. 3. The laboratory reports performing less than five qualitative semen analysis annually.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a lack of documentation and an interview with the laboratory director, the laboratory failed to verify the performance specifications for accuracy, precision, reportable range, and reference range for urine microalbumin on the Alere Afinion 2 analyzer received on 7/6/2023, prior to reporting patient results. Findings include: 1. A request was made to review the verification of performance specifications for urine microalbumin on the Alere Afinion 2 analyzer, and documentation could not be provided. 2. The laboratory started testing patients on 7/8/2024. 3. An on-site interview conducted with the laboratory director on 8/26/2024 at 13:30 PM confirmed the laboratory did not have the verification studies for accuracy, precision, reportable range, and reference range for urine microalbumin on the Alere Afinion 2 analyzer. 4. The laboratory reports performing approximately 1650 microalbumin test annually.