

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0981265	(X3) Date Survey Completed 05/01/2024
Name of Provider or Supplier Internal Medicine Of Arizona Pc	Street Address, City, State 4840 E Indian School Road, Ste 101, Phoenix, AZ	
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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records, review of package insert for the commercially available control material utilized and interview with the technical consultant (TC-1), the laboratory failed to establish the statistical parameters for unassayed control materials used by the laboratory for Apolipoprotein B (APO B) testing. Findings include: 1. The laboratory began patient testing for APO B on the Abbott Architect instrument in February 2024 under the specialty of Routine Chemistry. 2. The laboratory utilizes Biorad Liquid Assayed Multiquel Level 1 and Level 3 for QC testing for the analyte, APO B. The current lot of QC material in use at the time of the survey on 5/1/2024 was Lot# 45981 for Level 1 and Lot# 45983 for Level 3 and were put into use on the analyzer in February 2024. 3. Based on review of the manufacturer's package insert, there were no listed acceptable ranges, means or standard deviations for APO B when utilized on the Abbott Architect instrument. 4. Review of the laboratory's QC records showed the laboratory was utilizing the</p>

following acceptable ranges, means and standard deviations for the control material in use: - Biorad Level 1 (Lot# 45981): range- 41.9 mg/dL-49.9 mg/dL; mean and standard deviation- 45.9 +/- 4 mg/dL. - Biorad Level 3 (Lot# 45983): range- 75.7 mg /dL-87.7 mg/dL; mean and standard deviation- 81.7 +/- 6 mg/dL. 5. No statistical analysis documentation was presented for review to support the laboratory's established acceptable range, mean and standard deviation utilized for the lot numbers indicated above. 6. Interview with the TC-1 on 5/1/2024 at 2:05 PM confirmed the laboratory failed to provide statistical analysis to support the established QC ranges, means and standard deviations indicated above. 7. Approximately 69 patient tests for APO B were performed from the start of patient testing through the date of the survey conducted on 5/1/2024.