

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0952507	(X3) Date Survey Completed 07/23/2025
Name of Provider or Supplier University Pediatrics	Street Address, City, State 615 East University Drive, Edinburg, TX	
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>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (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. (d)(10)(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. (d)(10)(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records from September 2023 to December 2024 and staff interview, the laboratory failed to have documentation of verifying 5 of 7 new lots of quality control material prior to previous lot expiration. The findings included: 1. A review of the laboratory's quality control records from September 2023 to December 2024 identified the following 5 lots of control material that were placed into use without documentation of verifying values prior to use: a) Lot: 22308 Verified: 09/22/2023 Previous lot expired: 09/21/2023 (Lot 22305) b) Lot: 22311 Verified: 12/23/2023 Previous lot expired: 12/22/2023 (Lot 22308) c) Lot: 22405 Verified: 06/25/2025 Previous lot expired: 06/24/2025 (Lot 22402) d) Lot: 22402 Verified: not verified e) Lot: 22411 Verified: 12/24/2024 Previous lot expired: 12/23/2024 (22408) 2. The technical consultant confirmed the findings by phone on 07/22/2025 at 0938 hours.</p>