

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0900897	(X3) Date Survey Completed 04/01/2025
Name of Provider or Supplier Valley Regional Diagnostics	Street Address, City, State 502 South Closner, 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 chemistry quality control records from October 2024 to March 2025, review of the laboratory's endocrinology quality control records from October 2024 to March 2025, and staff interview, the laboratory failed to have documentation of verifying 7 of 7 lots prior to use. The findings included: 1. A review of the laboratory's chemistry quality control records from October 2024 to March 2025 identified the following control material were placed into use: a) BioRad Liquichek Multiquel Control Lot: 45930 b) BioRad Liquichek Urine Chemistry Control Lot: 97470 c) BioRad Liquid Assayed Multiquel Control Lot: 48010 d) BioRad Liquid Assayed Multiquel Control Lot: 45980 2. A review of the laboratory's endocrinology quality control records from October 2024 to March 2025 identified the following control material were placed into use: a) BioRad Lyphocheck Diabetes Control Lot: 85890 b) BioRad Liquichek Specialty Immunoassay Control Lot: 1003720 c) BioRad Liquichek Immunoassay Plus Control Lot: 1003900 3. The laboratory manager confirmed the laboratory did not verify the controls identified prior to putting them into use in an interview conducted on 04/01/2025 at 1330 hours in the conference room.</p>