

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0900897	(X3) Date Survey Completed 01/04/2023
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
D5317	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)</p> <p>If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS Form 116, patient results, laboratory policies, and confirmed in interview of laboratory personnel, the laboratory failed to have a client service manual to include instructions for patient preparation, collection, labeling, storage and preservation, transportation, processing, acceptability and rejection, and referral for 10 of 10 randomly reviewed laboratory assays reviewed from patients tested on January 3, 2023. The findings included: 1. Review of the laboratory's submitted CMS Form 116 (approved by the laboratory director on January 4, 2023, found the laboratory included the following analytes (not all inclusive): Calcium Carbon dioxide Sodium Potassium Chloride Total Protein Glucose Amylase Lipase Phosphorus 2. Review of the laboratory's policies revealed the laboratory had no client service manual to include instructions for patient preparation, collection, labeling, storage and preservation, transportation, processing, acceptability and rejection, and referral for the above assays. 3. An interview on January 4, 2023, at 10:30 hours with the technical consultant and testing personnel 1 (as listed on Form CMS 209) confirmed the above findings. Key: CMS - Centers for Medicare and Medicaid Services</p>