

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1096437	<b>(X3) Date Survey Completed</b>  08/04/2022
<b>Name of Provider or Supplier</b>  Carol N Abalihi Md Pa	<b>Street Address, City, State</b>  12350 Paseo Nuevo Dr, El Paso, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records for Thyroid Stimulating Hormone (TSH) patient test records and interview of facility personnel found the laboratory tested ten patient specimens without at least two acceptable quality control results, The findings included: 1. Review of the quality control procedure found on page 6 under the heading Quality Control Procedures: "15. The NHANES guideline declares a system "out of control" if any one of the following events occur for any one of the quality control materials: A. The mean from a single control falls outside the 99% (3SD) confidence limits. B. The means from two controls fall outside the 95% (2SD) confidence limits. C. The daily means of one control from eight successive runs lie either all above +1SD or all below -1SD. 16. PLEASE DO NOT RUN PATIENT SAMPLES UNTIL QC PASSED." 2. Reviw of quality control records found on June 13, 2022 the laboratory failed to obtain acceptable results for BIO RAD Immunoassay levels 2 and 3. a. BIO RAD Immunoassay level 2 - The laboratory obtained a value of 4.3 uIU/ml with an acceptable result 4.39- 5.72 uIU/ml. b. BIO RAD Immunoassay level 3 - The laboratory obtained a value of 27.19 uIU/ml with an acceptable result 28.28-39.65 uIU/ml. 3. Review of patient test records found the laboratory tested the following patient specimens on June 13, 2022 without at least 2 levels of acceptable quality control: Accession 24363 Accession 24746 Accession 32054 Accession 21151 Accession 45518 Accession 26401 Accession 47998 Accession 26371 Accession 23920 Accession 47979 4. Interview of testing personnel conducted August 4, 2022</p>

confirmed the laboratory did not obtain at least two levels of acceptable quality control before testing patient specimens.