

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0991904	(X3) Date Survey Completed 05/16/2018
Name of Provider or Supplier Southern Medical Group	Street Address, City, State 211 East Stadium, Magnolia, AR	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the new instrument validations, which were performed on 04/11/2016, for the Vitros ECI Immunoassay Analyzer, and Vitros 350 Chemistry Analyzer, a review of the Ortho-Diagnostic Measurement Data Reports, as well as interviews with staff, it was determined the laboratory failed to validate the reportable range established by the manufacturer for four of seven Immunoassays validated on the Vitros ECI and seven of twenty-one Chemistry assays validated on the Vitros 350. As evidenced by: A. A review of the validation documentation for the Vitros ECI Immunoassay revealed the following manufacturer's analytical ranges for the analytes listed: Vitamin B12 (159 to 1000); Ferritin (0.29 to 1000); Testosterone (4.903 to 2163) and Vitamin D (12.8 to 126). B. A review of the Ortho-Diagnostic Measurement Data Report for the Vitros ECI Immunoassay revealed the following ranges validated by testing standards: Vitamin B12 (159 to 898.00); Ferritin (0.29 to 949.5); Testosterone (4.903 to 1870) and Vitamin D (12.8 to 111). The laboratory did not validate the full analytic range established by the manufacturer. C. A review of the validation documentation for the Vitros 350 Chemistry analyzer revealed the following manufacturer's analytical ranges for the listed analytes: Chloride (CL) (50 to 175); Alanine Aminotransferase (ALT) (6 to 1000); Aspartate Aminotransferase (AST) (3 to 750); Triglycerides (TRIG) (10 to 525); Total Bilirubin (TBILI) (0.1 to</p>

27); Iron (Fe) (10.1 to 600) and Glucose (GLU) (20 to 625). D. A review of the Ortho-Diagnostic Measurement Data report for the Vitros 350 Chemistry revealed the following ranges validated by testing standards: CL (50 to 141); ALT (6 to 848); AST (3 to 722); Triglycerides (TRIG) (10 to 455); Total Bilirubin (TBILI) (0.1 to 18); Iron (Fe) (10.1 to 585) and GLU (20 to 608). The laboratory did not validate the full analytic range established by the manufacturer. E. In an interview at 13:20 on 05/16 /2018, technical consultant (as listed on the form CMS-209) confirmed the laboratory did not validate the full reportable range claimed by the manufacturer for the Vitros 350 Chemistry and the Vitros ECI Immunoassay analyzers.