

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0949953	(X3) Date Survey Completed 02/13/2018
Name of Provider or Supplier Db Biologics, Llc	Street Address, City, State 104 Old Hickory Blvd East, Jackson, TN	
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: Based on observation of the laboratory, review of the document titled "Equipment Qualification-Refractometer" for the Reichert TS Meter Plasma Protein Refractometer, the document titled "TS Meter-DSP Plasma Protein Refractometer User's Guide Reichert Technologies" and interview with the technical consultant, the laboratory failed to verify the upper reportable range for the total protein assay using the Reichert TS Meter in 2017. The findings include: 1. Observation of the laboratory on February 13, 2018 at 1:00 pm revealed Reichert TS Meter Plasma Protein Refractometers in use for patient testing. 2. Review of the document titled "TS Meter-DSP Plasma Protein Refractometer User's Guide Reichert Technologies" page 3 revealed a range of 0.0-14.0 g/100ml for the total protein assay. 3. Review of the documents titled "Equipment Qualification-Refractometer" dated 4-19-17 and 4- 27- 17 revealed that validation of the instrument did not span the high reportable range for eight of eight instruments (equipment id #s 0011110001, 0011110002, 0011110003, 0011110004, 0011110005, 0011110006, 0011110007, 0011110008). Highest level verified for any of the eight instruments was 10.5. 4. Interview with the technical consultant on February 13, 2018 at 3:45 pm confirmed the laboratory began using the</p>

Reichert TS Meter Plasma Protein Refractometer for patient testing beginning May 1, 2017, and failed to verify the upper reportable range for the Reichert TS Meter Plasma Protein Refractometer prior to patient testing in 2017.