

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2081491	(X3) Date Survey Completed 10/29/2018
Name of Provider or Supplier Endocrinology Consultants, Pc	Street Address, City, State 221 Engle Street, Englewood, NJ	
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>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-- Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Manufacturer's Package Inserts (MPI) and interview with the Technical Consultant (TC), the laboratory failed to establish the criteria for acceptability of QC material used for Unsaturated Iron-Binding Capacity (UIBC) tests performed on the Architect Plus ci4100 analyzer from 10/4/16 to the date of the survey. The finding includes: 1. The MPI for Biorad QC for UIBC stated that the laboratory must establish the criteria for acceptability but the laboratory did not have records to show that the ranges were established. 2. The TC confirmed on 10/29/18 at 11:45 am that acceptable QC ranges were not established.</p>