

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2163917	(X3) Date Survey Completed 08/16/2019
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 7535 State Ave, Kansas City, KS	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure and interview with the Quality Assurance Supervisor on 8/16/19 at 10:15 am, it was determined that the laboratory's procedure did not include criteria to determine acceptable control results as required by 493.1251 (b)(7). Findings include: Review of NC-EQUIPQC-006 for Refractometer Quality Control (QC) procedure did not include criteria to determine acceptable control results. Interview with the Quality Assurance Supervisor confirmed that the laboratory failed to define criteria to determine acceptable control results.</p>