

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2163800	(X3) Date Survey Completed 08/23/2019
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 2148 O'Neal Lane, Baton Rouge, LA	
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
D0000	An initial certification survey was conducted at Octapharma Plasma-CLIA ID # 19D2163800 on August 23, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
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, record review and interview with personnel, the laboratory failed to verify complete performance specifications for Total Protein testing. Findings: 1. Observation on August 23, 2019 revealed the laboratory utilized six (6) refractometer for total protein testing. 2. Review of the manufacturer instructions revealed the reportable range of the manufacturer listed as 0-15%. 3. Review of the laboratory's validation records revealed the laboratory tested samples between 3-10%. 3. Interview with Personnel 2 and 3 on August 23, 2019 at 9:45 am revealed the laboratory uses total protein to determine whether a donor meets the FDA criteria of 6-9%. Personnel 2 confirmed the validation did not specifically access the manufacturer's reportable range of the refractometers.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.