

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1052493	<b>(X3) Date Survey Completed</b>  02/21/2018
<b>Name of Provider or Supplier</b>  Octapharma Plasma, Inc	<b>Street Address, City, State</b>  3144 Louisville Avenue, Monroe, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A RECERTIFICATION SURVEY was performed on February 21, 2018 at Octapharma Plasma, Inc - CLIA #19D1052493 and was found in compliance with 42 CFR 493 Requirements for Laboratories. However, standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual and interview with personnel, the laboratory failed to include criteria required for assessing personnel competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not have a policy and procedure that included the six (6) part criteria required for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with Personnel 12 on February 21, 2018 confirmed the laboratory did not have a Competency Policy and Procedure that included the six (6) required elements.</p>
<b>D5421</b>	<b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b>

CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for five (5) of five (5) new Reichert Refractometers. Findings: 1. Observation by surveyors during the laboratory tour on February 21, 2018 revealed the laboratory utilizes the following five (5) Reichert Refractometers for patient testing of Total Protein (TP): a) Reichert Refractometer - SN 56242 b) Reichert Refractometer - SN 56243 c) Reichert Refractometer - SN 56143 d) Reichert Refractometer - SN 56144 e) Reichert Refractometer - SN 56145 2. Review of the laboratory's "Digital Refractometer Equipment Validation" policy revealed that validation is required after installing of a new digital refractometer at Donor Center, transferring a digital refractometer from Donor Center to Donor Center, or receiving digital refractometer after it has been sent to the manufacturer or third party for repairs or adjustments; However the policy does not include instructions for testing personnel of what to do for studies for accuracy, precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference ranges and the acceptability criteria for each of the studies. 3. Review of the laboratory's data revealed the following studies performed for each new instrument: a) Accuracy b) Simple Precision 4. Further review of the laboratory's data revealed the following information was not included: a) Complete Precision: Day-to-Day and Operator Variance b) Reportable Ranges with data to support ranges in use c) Reference Ranges with data to support ranges in use 5. In interview on February 21, 2018, Personnel 12 confirmed that complete performance specification validation studies were not performed for five (5) of five (5) new instruments. 6. Review of the Tasl 1 & 3 provided by the laboratory revealed the laboratory performs 94,981 tests annually on the Reichert Refractometers.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

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.

**D6030****LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209