

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2108295	<b>(X3) Date Survey Completed</b>  10/06/2020
<b>Name of Provider or Supplier</b>  Octapharma Plasma Inc	<b>Street Address, City, State</b>  9203 Stella Link Rd, Houston, TX	
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>	<p>The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing results from 2020 first event, and confirmed in interview with facility staff, the laboratory failed to achieve successful score of 80% for the analyte total protein in Chemistry. The findings were: 1. A review of the laboratory's AAB proficiency testing results from 2020 first event, revealed the laboratory failed to achieve a successful score of 80% for the analyte total protein in chemistry. Total Protein 2020 - First event: 60% AAB Specimen Result Expected result 4.2 3.3 - 4.0 (unacceptable) 2. An interview with facility staff on October 06, 2020 at 1410 hours in the office, confirmed the findings.</p>

**D2093**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing records it was revealed that the laboratory failed to return all proficiency testing results to the proficiency testing program within the time frame specified by the program for the specialty of chemistry result. unsatisfactory performance. Findings were: 1. Review of the American Association of Bioanalysts 2018 revealed the results of the second testing event for the speciality of chemistry was not returned to the proficiency testing program within the specified time frame. The failure to return the results caused a score of "0" on the testing event resulting in unsatisfactory performance for the specialty of chemistry. 2. An interview with the facility personnel on 10/06/2020 at 1410 hours in the office confirmed the above findings, the laboratory failed to return the proficiency testing records in the time frame specified.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview of laboratory personnel, it was revealed that the laboratory director failed to ensure that prior to testing patients' specimens, all personnel had the appropriate education and training required to perform moderate complexity testing, demonstrated that they were competent to perform testing and failed to ensure that the credentials submitted by personnel were verified. Findings were: 1. A review of the facility's personnel records revealed that credentials submitted by personnel were not verified resulting in 2 of 73 testing personnel having no documentation, at the time of the survey, of proof of a high school diploma or equivalent. (Refer to D6065) 2. A review of the facility's personnel records revealed that 2 of 73 personnel with a high school diploma had no documentation of training appropriate to the Houston facility testing menu prior to performing testing. (refer to D6066) 3. A review of personnel records revealed the laboratory director failed to ensure that prior to patient testing 2 of 73 testing personnel (Personnel 43 and 59) demonstrated the skills required for proper performance of preanalytic, analytic, and post analytic phases of testing for Total Protein. a. A review of the facility "Moderate Complexity Assessment" form (TR-Form-028 Rev:06 Effective Date: 16 Sep 2019 12:00AM) page 2 revealed a statement: Trainee " is authorized to independently perform moderate complexity

specimen testing for Total Protein, test performance, result reporting and the following moderate complexity testing responsibilities..." Below the authorization statement was an area for "Laboratory Director Approval" b. A review of personnel records for testing personnel number 43 revealed he was hired 1/22/2018 and transferred to the Houston location on 7/1/2019. c. A review of the Houston competency for Testing personnel number 43 revealed a competency assessment and authorization to independently perform testing dated 3/03/2020. d. In an interview of the training coordinator on 10/06/2020 at 1119 hours in the training room, he stated that when the testing person transferred to the Houston he was considered fully trained and was allowed to start testing. e. In an interview of the manager on 10/06/2020 in the training room, he stated that testing personnel number 43 performed testing between 7/1/2020 and 3/3/2020, but he was unable to print a report of the testing because the testing person was terminated [on 4/19/2020]. f. A review of personnel records for Testing personnel number 54 revealed he was hired 9/10/2019 and transferred to the Houston location on 4/20/2020. g. A review of the Houston competency for Testing personnel number 54 revealed a competency assessment and authorization to independently perform testing dated 8/22/2020. h. A review of the employee efficiency statistics for testing person 54 revealed he performed 134 screenings between 4/20/2020 and 8/20/2020. i. In an interview of the manager on 10/06/2020 at 1530 hours in the training room he confirmed that the 134 screening completed would include the moderate complexity Total Protein testing. j. In an interview of the training coordinator on 10/06/2020 at 1111 hours in the training room, he stated that testing persons are not allowed to begin testing until the laboratory director performs the first competency assessment.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on a review of the Laboratory's Listing of Facility Personnel form, personnel records and staff interview, it was revealed that the 4 of 73 testing personnel did not have the appropriate education credentials and training required to perform moderate complexity testing (refer to D6065, D6066).

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted Listing of Facility Personnel form review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 73 testing personnel to perform moderate complexity testing. The findings were: 1. A review of the laboratory's submitted Listing of Facility Personnel form revealed the laboratory identified 73 testing personnel from January 2018 to October 2020. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify 2 of 73 testing personnel. They were listed on the Listing of Facility Personnel form. Testing personnel number 7 No proof of High School graduation or GED Testing personnel number 49 High School transcript indicated no graduation 3. The laboratory was asked to provide documentation of education to quality the identified testing personnel. No documentation was provided. 4. An interview with facility staff on 10/06/2020 at 1410 hours in the office - after review of the personnel records- confirmed the findings.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's test menu, personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 2 of 73 testing persons with a high school diploma to qualify them to perform moderate complexity Total Protein testing. (Testing persons 43 and 54.) The findings were: 1. A review of the facility's test menu revealed the laboratory performed moderate complexity Total Protein testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training at the laboratory for 2 of 73 testing personnel with a high school diploma to qualify them to perform moderate complexity testing for Total Protein. They were (as documented on the Listing of Facility Personnel (15 Sep 2020)): Testing personnel number 43 Testing personnel number 54 3. A review of personnel records for testing personnel number 43 revealed he was hired 1/22/2018 and transferred to the Houston location on 7/1 /2019. His personnel records included proof of a high school diploma. a. A review of the Houston training documentation for Testing personnel number 43 revealed no documentation of training for the Houston location. c. In an interview of the training coordinator on 10/06/2020 at 1119 hours in the training room, he stated that when the testing person transferred to the Houston he was considered fully trained and was allowed to start testing. He confirmed there was no documentation of training at the Houston facility. In addition, he stated that normally testing persons are authorized to begin testing when the laboratory director completes their first competency assessment. (refer to D6029) 4. A review of personnel records for Testing personnel number 54 revealed he was hired 9/10/2019 and transferred to the Houston location on 4/20/2020. His personnel records included proof of a high school diploma. a. A review of the Houston training documentation for Testing personnel number 54 revealed no documentation of training for the Houston location. b. In an interview of the (manager) on 10/06/2020 at 1500 hours in the training room, he confirmed there was no documentation of training at the Houston facility. c. A review of the employee

efficiency statistics for testing person 54 revealed he performed 134 screenings between 4/20/2020 and 8/20/2020. d. In an interview of the manager on 10/06/2020 at 1530 hours in the training room he confirmed that the 134 screening completed would include the moderate complexity Total Protein testing.