

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1098041	(X3) Date Survey Completed 10/20/2020
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 7006 University Avenue Unit13, Lubbock, TX	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Review of the proficiency testing records, corrective action, training records, and interview, the laboratory failed to test samples in the same manner as it tested patient specimens in 4 of 5 events reviewed. Findings follow. 1. Review of the American Association of Bioanalysts (AAB) Chemistry proficiency testing (PT) records from 2019 and 2020 (three testing events per year); from the 1st, 2nd, and 3rd events of 2019 and the 1st and 2nd events of 2020, found: A. In the 1st testing event of 2019 the laboratory received an unsatisfactory score of 60% for Total Protein (satisfactory score is 80% or higher). B. The Attestation Statements from the events in 2019 and 2020 signed by Testing Personnel and the Laboratory Director stated, "The undersigned analyst attests that samples were tested in the same manner as patient samples." 2. Review of the corrective action "Deviation" dated March 12, 2019 the laboratory stated, "On 28Feb19 while reviewing results for Q1 2019 Proficiency Testing it was discovered by Quality Assurance Supervisor (MM) that the donor center received a score of 60. Deviation was initiated as required by PC-QA-021 Proficiency Testing." Continued review of the Correct & Prevent record stated under Task 3, "Performed documented training with Center Leadership of new center policy that a member of Management or Quality must be present when staff is performing</p>

testing for center submission to ensure the vials are verified and correct reading is documented for correct vial." 3. Review of the Document Review/Training Record showed training was conducted on March 25, 2019. The title of the training stated, "This training record is to inform you of a new center policy that a member of Management or Quality must be present when employee performs proficiency testing for center submission to ensure that vials are tested and documented concurrently and correctly and to ensure that vial numbers are verified when documenting the result." 4. Interview with the Quality Assurance supervisor with the initials DM on 10/20/2020 at 0915 hours in the office confirmed training was performed and implemented after the 1st event of 2019 and confirmed patient testing was not routinely observed by Management or Quality personnel.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, quality control records and interview, the laboratory failed to have control procedures that monitor the accuracy and precision for Total Protein tested by refractometer to include the statistical parameters of mean, standard deviation, and coefficient of variation. Findings follow. 1. Review of the package insert for the KOVA Refractrol SP Serum Protein Reference Control found under "Intended Use" stated, "KOVA Refractrol SP ... is intended to monitor the accuracy and precision of total serum protein values measured by digital and analog refractometer procedures." 2. Random review of the quality control records from June 28 - Aug 2 2018, June 1 - July 4 2019, Dec 19 2019 - Jan 17 2020, June 1-30 2020, and Aug 4 - Sept 4 2020 showed the daily quality control data points and a graph (not a Levy-Jennings chart) of the points. Statistical data, ie. mean, standard deviation, and coefficient of variation were not calculated to determine the accuracy and precision of each refractometer for Total Protein. 3. Statistical data was requested at 1430 hours but not provided. 4. Interview with the Quality Assurance Supervisor with the initials DM at 1455 hours confirmed the statistical data is not calculated and the graph is all they have.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as

required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records, corrective action, training records, and interview found that the Laboratory Director failed to ensure the laboratory tested Proficiency Testing (PT) samples in the same manner as it tested patient specimens (see D2006).

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, quality control records and interview, the Laboratory Director failed to ensure the quality control program monitored the accuracy and precision for Total Protein over time (see D5441).