

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2000885	(X3) Date Survey Completed 12/07/2021
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 3342 Broadway Blvd Suite 110, Garland, 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
D0000	<p>The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1412 Condition: Testing personnel; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was 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>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's quality control records and staff interview, it was revealed the laboratory failed to have documentation of verifying new lots of control material prior to use. The findings include: 1. A review of the laboratory's quality control records from 2020 and 2021 revealed the following lot number in use for total protein testing on the refractometers: a) low control K303250 K303959 K304829 K304831 b) normal control K303960 K304604 K303959 K384913 2. The laboratory was asked to provide documentation of verifying each lot of control prior to it being placed into service. No documentation was provided. 3. An interview with the field quality manager on 12/07/2021 at 1045 hours in the conference room revealed the laboratory did not verify new lots of control material, nor did it have a policy to address this requirement. This confirmed the findings.

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 review of the laboratory's submitted CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 17 testing personnel (refer to D6065).

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 CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 17 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 17 testing personnel. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of education to qualify 1 of 17 testing personnel. a) Testing personnel # 9 Bachelor of Arts degree from a foreign country The foreign credentialing listed his education comparable to a bachelor of arts degree in the US. There was no mention of the equivalence for a high school diploma or bachelor of science degree. 3. The laboratory was asked to provide documentation of the required education/equivalency. No documentation was provided. 4. An interview with the

field quality manager on 12/07/2021 at 9:30 am in the conference room - after her review of the records- confirmed the findings.