

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2108845	<b>(X3) Date Survey Completed</b>  01/29/2020
<b>Name of Provider or Supplier</b>  Octapharma Plasma, Inc	<b>Street Address, City, State</b>  2985 S State Hwy 360, Ste 102, Grand Prairie, 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 Center Director and Quality Assurance Supervisor were at the entrance conference conducted 01/29/2020. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the Center Director and Quality Assurance Supervisor on 01/29/2020. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Association of Bioanalysts (AAB) instructions, AAB proficiency testing(PT) records, and confirmed in interview, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 3 chemistry events in 2018 (Event 2). 1. Review of the laboratory's PT policy revealed: "5.7. Complete online submission of proficiency testing results... 5.7.11. CLIA Director reviews, signs and dates submission form." 2. Review of AAB general instructions revealed: "REPORTING RESULTS ... The attestation statement on the Centers for Medicare and Medicaid Services (CMS)-scored analytes forms must be signed for each analyte by the analyst performing the procedure. In addition to the analysts' signatures, the director or the director's designee must sign only once for each reporting form..." 3. Review of chemistry PT records for Event 2 in 2018 revealed the laboratory director failed to sign the attestation</p>

statement. 4. During an interview on 01/29/2020 at 10:10 am, the quality assurance supervisor confirmed the above findings.

**D2015**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, American Association of Bioanalysts (AAB) proficiency testing(PT) records, and confirmed in interview, the laboratory failed to retain a copy of all chemistry PT records for 1 of 3 events in 2018 (Event 2). Findings: 1. Review of the laboratory's PT policy revealed: "5.13. Quality Review of Proficiency Testing... 5.13.4. File proficiency testing documentation. 5.13.4.1 File proficiency testing documentation and all applicable attachments." 2. Review of AAB PT records revealed the laboratory failed to retain a copy of the following records for chemistry event 2 in 2018: AAB original forms Test records 3. During an interview on 01/29/2020 at 10:10 am, the quality assurance supervisor confirmed the above findings.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, American Association of Bioanalysts (AAB) proficiency testing(PT) records, and confirmed in interview, the laboratory failed to review and evaluate the results obtained on proficiency testing for 1 of 3 chemistry events in 2018 (Event 2). Findings: 1. Review of the laboratory's PT policy revealed: "5.13. Quality Review of Proficiency Testing... 5.13.3. Review of proficiency testing results. 5.13.3.1. Verify that results have been reviewed, signed and dated by the Donor Center Director/Designee. 5.13.3.2. Verify that results have been reviewed, signed and dated by the CLIA Laboratory Director." 2. Review of chemistry PT records revealed the laboratory director failed to review and evaluate the results obtained on proficiency testing in 2018 for Event 2. 3. During an interview on 01/29/2020 at 10:10 am, the quality assurance supervisor confirmed the above findings.