

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D1097614	<b>(X3) Date Survey Completed</b>  03/02/2022
<b>Name of Provider or Supplier</b>  Octapharma Plasma Inc	<b>Street Address, City, State</b>  2102 S Michigan St, South Bend, IN	
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>D2089</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the laboratory failed to participate in one of three proficiency testing (PT) events (2nd event 2021) for total protein. Findings: 1. Review of the "CMS Cumulative Scores" document from the American Association of Bioanalysts (AAB) indicated that AAB received no submissions for total protein for the 2nd event of 2021, resulting in a "0" score. 2. On 03/02/2022 at 9:37 AM, SP4 (quality assurance supervisor) confirmed that the 2nd PT event for total protein in 2021 had a score of "0". 3. On 03/02/2022 at 10:24 AM, SP3 (quality assurance technician) confirmed that the laboratory missed the submission deadline for the 2nd PT event in 2021. At 10:29 AM, SP3 added that the results for this event were never submitted. 4. The annual testing volume for Routine Chemistry is approximately 60,934.</p>
<b>D6019</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on interview and record review, the laboratory director failed to ensure that a policy for proficiency testing (PT) corrective action was followed after the laboratory had unsuccessful performance for one of three PT events (2nd event 2021) for total protein. Findings: 1. Review of the "CMS Cumulative Scores" document from the American Association of Bioanalysts (AAB) indicated that AAB received no submissions for total protein for the 2nd event of 2021, resulting in a "0" score. 2. The "Deviation Detail" report "DEV-2021-6024", dated June 10, 2021, read, "Proficiency Testing for Quarter 2 was not completed or submitted by the required date of 28MAY21." "DEV-2021-6024" additionally indicated that SP4 manually graded and forwarded results to SP2 (laboratory director) for review. 3. Review of "Proficiency Testing" policy, effective February 21, 2022, not signed by the laboratory director, stated that the CLIA Laboratory Director is responsible for "[Approving] investigation and corrective and preventative action ...for Proficiency Testing scores that are less than 100%." 4. 03/02/2022 at 12:31 PM, SP1 (assistant manager) indicated that the laboratory director had not signed off on corrective actions for the failed PT submission from 2021. 5. The annual testing volume for Routine Chemistry is approximately 60,934.