

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2132947	(X3) Date Survey Completed 01/06/2020
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 2930 Sw 59th St, Oklahoma City, OK	
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	The recertification survey was performed on 01/06/20 The findings were reviewed with the center director, quality assurance supervisor, and quality assurance technician at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the quality assurance supervisor and quality assurance technician, the laboratory failed to ensure analyzers were stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the quality assurance supervisor stated the following to the surveyor: (a) Total Protein testing was performed using 7 Reichert TS analyzers (serial #: 10925-0817, 10938-0817, 10943-0817, 10932-0817, 10941-0817, 10933-0817, 10939-0817); (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for the Reichert TS analyzer which required a humidity of less than 80%; (3) The surveyor reviewed laboratory records from July 2019 through December 2019. There was no evidence that the humidity, where the analyzers were maintained, had been monitored; (4) The surveyor asked the</p>

quality assurance supervisor and quality assurance technician if the humidity, where the analyzers were maintained, was being monitored. The quality assurance supervisor and quality assurance technician both stated the humidity was not being monitored.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of records, policy, and interview with the quality assurance supervisor and quality assurance technician, the technical consultant failed to ensure that persons performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #2 - The initial training for this person was completed on 02/14/18. The 6 months competency assessment was completed on 12/11/18, 10 months after the initial training; (b) Testing Person #6 - The initial training for this person was completed on 10/24/18. The 6 months competency assessment was completed on 08/20/19, 10 months after the initial training; (c) Testing Person #8 - The initial training for this person was completed on 01/04/18. The 6 months competency assessment was completed on 12/11/18, 11 months after the initial training; (d) Testing Person #17 - The initial training for this person was completed on 08/28/18. The 6 months competency assessment was completed on 04/18/19, 8 months after the initial training. (2) The surveyor reviewed the policy titled, "Training Policies - NexLynk" which required a semiannual competency be performed at 6 months; (3) The surveyor reviewed the records and policy with the quality assurance supervisor and quality assurance technician. Both stated there were no records to prove the above testing persons had been evaluated at 6 months according to laboratory's policy.