

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2119317	(X3) Date Survey Completed 01/15/2018
Name of Provider or Supplier Octapharma Plasma, Inc	Street Address, City, State 5330 Walzem Road, Suite 108, San Antonio, 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>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable</p>

limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's verification records, review of the laboratory's calibration and quality control records, review of the laboratory's calibration records, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verification every six months on 8 of 8 refractometers. The findings were: 1. A review the laboratory's verification records revealed the laboratory performing the required studies in October 2016 on 8 of 8 Reichert refractometers used by the laboratory. The instrument identification numbers were: 53510 53511 53512 53513 53514 53515 53516 53517 Thus, calibration verification was due by April 2017 and October 2017. 2. A review of the laboratory's calibration and control records revealed the laboratory performed a 1-point calibration daily and tested two levels of control daily. Thus calibration verifications was required. 3. A review of the laboratory's calibration verification records revealed the laboratory had documentation of performing the verifications at the following times: ID number Date elapsed months 53510 07/2017 9 months 53511 08/2017 10 months 53512 08/2017 10 months 53513 08/2017 10 months 53514 08/2017 10 months 53515 07/2017 9 months 53516 07/2017 9 months 53517 08/2017 10 months 4. The laboratory was asked to provide documentation of performing calibration verification every six months as required. No documentation was provided. 5. An interview with the quality supervisor on 01/15 /2017 at 1100 hours in the conference room revealed the laboratory was unaware calibration verification was required at least every six months. This confirmed the findings.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control records from November 2016 to December 2017, and staff interview, it was revealed the laboratory failed to have documentation of verifying new lots of control material prior to placing it into use. The findings were: 1. A review of the laboratory's quality control records from November 2016 to December 2017 revealed the laboratory placed the following lot numbers of control material into use: a) High Level Control Lot number: K301432

(Tested once a month) b) Normal Level Control Lot number: K301003 Lot number: K301818 (Tested daily) c) Low Level Control Lot number: K301008 Lot number: K301822 (Tested daily) 2. The laboratory was asked to provide documentation of verifying each lot of control material prior to placing it into use. No documentation was provided. 3. An interview with the center director on 01/15/2018 at 1110 hours in the conference room revealed the laboratory did not verify lots of control material prior to placing it into use. This confirmed the findings.