

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2082447	(X3) Date Survey Completed 03/06/2018
Name of Provider or Supplier Interventional Pain Management Services	Street Address, City, State 2730 S St Peters Pkwy, Suite 200, Saint Peters, MO	
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's established criteria for toxicology calibration, calibration records for March 2018 and interview with testing personnel #1, calibration data failed to meet acceptable criteria for five of ten drugs performed on the LCMS toxicology analyzer. Findings: 1. The Data Review Process procedure (TOX001) states, " Review the cal curve ensuring all cals and controls are within twenty percent of the target values; the R2 (R squared calibration curve) value for each drug is greater than .990 and that all blanks and negative controls are negative." 2. Review of calibration records showed, the R2 calibration values for five drugs were less than the laboratory's established criteria for acceptability. The following R2 calibration curves did not meet the criteria of greater than .990. a.) Fentanyl .979 b.) Benzoylcegonine .975 c.) MDPV .987 d) Methadone .970 e.) THC .984 3. Interview with testing personnel #1 on March 6, 2018 at 11:30 AM confirmed, the calibration curves for the five drugs did not meet the laboratory's established criteria for calibration acceptability.</p>

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

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 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 chemistry calibration verification and interview with testing personnel #2 the laboratory failed to perform calibration verification in 2017 on 20 of 20 analytes. Findings: 1. Review of chemistry calibration verification showed no calibration that included a minimal, midpoint and maximum value for 2017 for hemoglobin A1C, albumin, alkaline phosphatase, ALT, AST, BUN, calcium, cholesterol, CO2, creatinine, chloride, direct bilirubin, glucose, HDL, potassium, sodium, phosphate, total bilirubin, total protein and triglycerides. 2. Interview with testing personnel #2 on March 6, 2018 at 12:30 PM confirmed the laboratory failed to perform calibration verification in 2017.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Review of personnel training records for 2016, 2017 and interview with the laboratory director, the director failed to ensure testing personnel had appropriate training for high complexity testing prior to testing and reporting patient results. Findings: 1. Review of training documentation for 2016, 2017 revealed the director failed to have initial training for 1 of 2 testing personnel who started employment September 2016.

2. Interview with the laboratory director on March 6, 2018 at 12:30 PM confirmed, the director failed to ensure each testing person had appropriate training for high complexity testing before testing patient specimens.