

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1105031	(X3) Date Survey Completed 03/12/2019
Name of Provider or Supplier Coastal Pain & Spinal Diagnostics	Street Address, City, State 6221 Metropolitan St, Ste 201, Carlsbad, CA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, reports, and interview with the laboratory personnel, it was determined that the laboratory failed to verify the accuracy of any test or procedure it performs, at least twice annually. The findings included: a. The laboratory used Thermo Indiko Plus instrument to perform urine drugs screen and report 17 analyte. b. The laboratory failed to verify and ensure the accuracy of the testing procedures at least twice annually. c. The laboratory personnel affirmed (3/12/2019 @ 11:34 AM) that the laboratory failed to verify and ensure the accuracy of the testing procedures for its urine drugs screen testing systems by Thermo Indiko Plus instrument. d. The laboratory used AB Sciex LC/MS/MS to perform drug confirmation plus providing drug concentrations in urine, when detected by screen or directly perform urine drugs testing. e. The laboratory used LC/MS/MS to report 44 drug analyte for its patient samples. f. In order to verify and ensure the accuracy of the LC/MS/MS systems, the laboratory elected to enroll DMPM (Drug Monitoring for Pain Management) with CAP (College of American Pathologists) PT (Proficiency Testing) program, which did not cover all 44 drugs this laboratory offers in its laboratory report. g. The laboratory used split samples and sent out to a CLIA certified laboratory as an alternative method to verify and ensure the accuracy of the drugs not covered by CAP's DMPM program. h. The laboratory failed to evaluate the complete test results from the outside CLIA laboratory, but only the analyte not covered by CAP's DMPM.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</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.

This STANDARD is not met as evidenced by:

Based on observations of the laboratory temperature charts and interview with the laboratory personnel, it was determined that the laboratory failed to familiarize the features of the digital thermometers and monitored and documented appropriately the storage devices. The findings included: a. The laboratory used refrigerators and/or freezers to store their laboratory reagents, supplies, and patient samples. b. The laboratory used digital thermometers to monitor the temperatures of the storage devices. c. The digital thermometer features "current", "Min", and "Max" temperature displays, "Alarm" and etc. When the current temperature outside of the acceptable /optimal temperature ranges for storage matters, the alarm shall be on. d. The laboratory established acceptable/optimal temperature for its refrigerator is between 2 to 8 degree Celsius (oC). e. At the time of survey (3/12/2019 @ 9:50 AM), a 1.87 oC was observed on a digital thermometer in its LC/MS/MS room, which is outside of its laboratory established acceptable storage temperature between 2 to 8 oC. f. No alarm sound was noticed at that time. g. Further interviewed and observed with the testing personnel, a "Min" temperature of 0.74 oC and "Max" temperature of 18.33 oC were noted on that digital thermometer, which indicated that at some time passed, the refrigerator temperature conditions were outside of the acceptable/optimal temperature range for storage purposes, low at 0.74 oC and high at 18.33 oC, outside. h. No action taken or documented for failure to maintain the storage temperature within the acceptable/optimal range. i. The laboratory personnel affirmed (3/12/2019 @9:50 AM) that the laboratory failed to monitor the digital thermometer closely, and to ensure and maintain the storage temperature within the acceptable range, and no action taken to correct the failures.

D5467

CONTROL PROCEDURES

CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on observations of the facility, and review of the laboratory calibrator and quality control preparation records, and interview with the laboratory personnel, it was determined that the laboratory failed to use a different lot numbers to prepare in house working calibrators and quality control materials that used to establish a cut-off value or to calibrate the test system.. The findings included: a. The laboratory purchased certified commercial stock drug materials from Cerillian and prepared its working calibrators and quality controls in house. b. When using calibrator material as

	<p>control material, the laboratory must use calibrator material from a different lot number that used to established a cut off value or to calibrator test system. c. The laboratory personnel affirmed (3/12/2019 @ 12:55 PM) that the laboratory used the same lot number of the stock drug materials to prepare calibrators as well as control materials.</p>
<p>D5781</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observations of the facility, and review of the laboratory records, and interview with the laboratory personnel, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when equipment or methodologies that perform outside of established operating parameters or performance specifications. The findings included: See D-5413</p>
<p>D6022</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on observations of the facility, and review of the laboratory records, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the quality control and quality assessment programs were maintained to identify failures in quality as they occur. The findings included: See D-5217, D-5467, and D-5781</p>
<p>D6024</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>The laboratory director is responsible for the overall operation and administration of 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)(7) Ensure that all necessary remedial actions are taken and</p>

documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on observations of the facility, and review of the laboratory records, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that all necessary remedial actions were taken and documented whenever significant deviations from the laboratory's established performance specifications are identified. The findings included: See D-5781