Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2107608	11/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pacific Spine & Pain Center	5127 W Noble Ave, Visalia, 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
D2115	TOXICOLOGY CFR(s): 493.845(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing records, records from API (American Proficiency Institute), and patients reports; the lack of laboratory documents, and interview with the Testing Person, the laboratory failed to return proficiency testing results to API within the specified time frame. Findings include: a. The laboratory chose to enroll in API's program for testing in Toxicology for Amphetamine, Benzodiazepine, Cocaine, Methadone, and Opiate using the Siemens Viva-E analyzer (serial number 10-2363). b. API stated samples were mailed on 10/15 /18 with the last date of 11/02/18 for reporting results. c. Laboratory records revealed testing was performed on 11/08/18. d. API informed the laboratory that the results were submitted after the required date and would not be graded. e. The Testing person affirmed (11/27/18) the aforementioned failure to report results within API's specified timeframe. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing records, the lack of proficiency

	testing evaluations, and interview with the Testing person, the laboratory failed to verify the accuracy of testing in Toxicology. Findings include: a. The laboratory chose to enroll in API proficiency testing program as the means to satisfy the requirement to at least twice annually verify the accuracy of testing for Amphetamine, Benzodiazepine, Cocaine, Methdadone, and Opiate. b. The laboratory's results for event 2, 2018, were not graded by API. See D2115 c. Laboratory written policy included the form titled "PT Investigation Form"; however, the laboratory failed to provide the document for evaluating the laboratory's results in comparison to API's Participant Data Summary. d. The Testing person affirmed (11/27/18) the aforementioned lack of laboratory document; and thus, the laboratory failed to verify the accuracy of testing. e. The reliability and quality of testing for Amphetamine, Benzodiazepine, Cocaine, Methdadone, and Opiate could not be assured. The laboratory stated reporting 7,000 results during the timeframe July - November 2018. Examples are as follows: Date Number of patients tested ---------- 7/17/18 13 8/23/18 10 9/18/18 26 10/10 /18 20 11/20/18 18 .
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of patients test records and the laboratory procedure manual for the Siemens Viva-E analyzer; and interview with the Testing person, the laboratory procedure manual failed to include specifications for control materials. Findings include. a. The laboratory procedure failed to specify the control materials and frequency of use. b. The Testing person affirmed (11/27/18) the aforementioned specifications were not in the procedure manual. c. The laboratory had tested almost daily, Monday through Thursday, since July 2018.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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--

	At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of testing records, the lack of laboratory documents for QC, and interview with the Testing person, the laboratory failed to include two levels of quatitative Controls each day of testing urine specimen for pH and Creatinine using the Siemens Viva-E analyzer. Findings include: a. The laboratory failed to provide QC results for 4 out of 5 patients tested: Date Patient ID ---------- 7/17/18 PG 8/23/18 KM 9/18/18 DH 11/20/18 SB b. The Testing person affirmed (11/27/18) the failure to include QC materials each day of testing. c. The reliability and quality of chemistry testing could not be assured. The laboratory tested approximately 280 patients during the timeframe July - November 2018. Examples are as follows: Date Number of patients tested ---------- 7/17/18 13 8/23/18 10 9/18/18 26 11/20 /18 18 .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of testing records, the lack of laboratory documents for QC, and interview with the Testing person, the laboratory failed to include a Negative and a Positive Control each day of testing patients. Findings include: a. The laboratory failed to provide QC results for 4 out of 5 patients tested: Date Patient ID ---------- 7/17/18 PG 8/23/18 KM 9/18/18 DH 11/20/18 SB b. The Testing person affirmed (11/27/18) the failure to include QC materials each day of testing. c. The reliability and quality of toxicology testing could not be assured. The laboratory tested approximately 280 patients during the timeframe July - November 2018. Examples are as follows: Date Number of patients tested ---------- 7/17/18 13 8/23/18 10 9/18/18 26 11/20 /18 18 .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on observation of two methodologies for toxicology testing, the lack of laboratory documents and procedure, and interview with the Testing person, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using the TransMed "CSI" drug screening test cup and the Siemens Viva-E analyzer. Findings include: a. The laboratory performed drug screen testing using the Siemens automated analyzer and the TransMed urine cup that requires a visual read and manual recording of test strips results. b. The laboratory failed to provide documents for review and the procedure manual failed to include a way to twice each year compare results between the two methods. c. The Testing person affirmed (11/27/18) performing drug screen testing using the two different methods and the lack of a procedure and process for twice annually comparing results. d. The laboratory stated annually reporting approximately 2,880 results using the manual method and 16,800 results using the automated method.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the numerous deficiencies cited, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory Director was not met. The Laboratory Director was deficient in the practice of providing overall management and direction of the laboratory performing moderate complexity testing. (See D2115, D5217, D5403, D5447, D5449, D5775, D6047) Furthermore, the Laboratory Director failed to ensure the policy and practice of requiring testing personnel to demonstrate the reliable performance of preanalytic, analytic, and postanalytic procedures to provide and report accurate results, prior to testing patients specimen. See D6029. .
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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: Based on review of patients test records, the lack of laboratory document(s), and interview with the Testing person, the Laboratory Director is herein cited for deficient practice in ensuring the Testing person demonstrated preanalytic, analytic, and postanalytic operation of the Siemens Viva-E test system prior to testing patients specimen in July 2018. Findings include: a. Test records revealed that the Siemens Viva-E analyzer was in use for testing patients specimen beginning in July 2018. b. The laboratory failed to provide for review laboratory documents from the Testing

	person demonstrating testing for the Laboratory (Technical Consultant or Laboratory Director), including dated Viva-E instrument printouts (raw data) providing reliable results, prior to testing patients in July 2018. c. The Testing person affirmed (11/27 /18) the aforementioned lack of documents including instrument raw data and printouts demonstrating testing for the Laboratory prior to testing patients in July 2018. d. The Laboratory Director failed to ensure the laboratory had a written policy and practice to ensure that prior to testing patients, each testing person demonstrate the ability to perform all preanalytic, analytic, and postanalytic procedures reliably to provide and report accurate results.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the serious cumulative nature of deficiencies cited, the Technical Consultant is herein cited at the Condition level for failing to provide technical oversight of the laboratory. See D6036. .
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: The Technical Consultant is herein cited for failure in responsibility for the technical and scientific oversight of the laboratory. Findings include: a. The Technical Consultant failed in responsibility for the laboratory returning proficiency testing results within the stated timeframe. See D2115. b. The Technical Consultant failed in responsibility for the laboratory evaluating proficiency testing results to verify the accuracy of testing. See D5217. c. The Technical Consultant failed in responsibility for the laboratory procedures to include specifications and instructions for controls. See D5403. d. The Technical Consultant failed in responsibility for establishing and maintaining daily QC. See D6042. e. The Technical Consultant failed in responsibility for establishing policy and procedure for comparing test results by different methods. See D5775. f. The Technical Consultant failed in responsibility for directly observing testing personnel to assess competency in test performance. See D6047. .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on review of patients test records, the lack of quality control records, and interview with the Testing person, it was revealed that the Technical Consultant failed to establish and maintain a quality control program requiring the testing of Control materials, quantitative and qualitative, with each day of testing patients specimen. See D5447 and D5449.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the laboratory document titled "6 Month Evaluation of Testing Personnel Competency" and the Personnel reports (CMS209, LAB116), the lack of patients test records, and interview with the Testing person, the Technical Consultant failed to Directly Observe the Testing person performing preanalytic, analytic, and postananytic procedures, including operation and maintenance of the Siemens Viva-E. Findings include: a. The competency assessment document stated date of review as 11 /25/18. b. Patients test records revealed no testing and reporting was performed on 11 /25/18. c. The Testing person affirmed (11/27/18) not working in the laboratory on Sunday, 11/25/18, and that the Technical Consultant had not been present during Initial training or all other days of routine testing. d. Only one testing person was included on the Personnel reports. .