

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1084815	(X3) Date Survey Completed 11/19/2025
Name of Provider or Supplier Pain & Rehabilitative Consultants	Street Address, City, State 1335 Stanford Ave, Emeryville, 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 written procedure for "PRCGM Alternative Proficiency Testing" and laboratory reports for 2023, 2024, and 2025; and interview with the Laboratory Director, it was determined that the laboratory failed to verify the accuracy of High complexity testing in Toxicology for 11-nor-9-carboxy-THC (THC metabolite), Meprobamate (Carisoprodol metabolite), Amphetamine, Methamphetamine, and O-desmethyltramadol (tramadol metabolite). Findings included: a. The laboratory implemented an alternative method procedure as an additional means for verifying the accuracy of their laboratory-developed-test utilizing LC-MS/MS (Liquid Chromatography-Tandem Mass Spectrometry methodology), as follows: "Twice a year, the 3 calibrators (CAL 0, CAL 25, CAL1000) will be run in duplicate as unknown proficiency testing samples. The results will be reviewed to ensure that no analytes are detected in the CAL 0 and all analytes in the method are detected in both the CAL25 and CAL 1000." b. The laboratory reported unacceptable results, Not detected, for CAL25, as follows: . . . EVENT ANALYTE NOT DETECTED ----- 2023_A_01 THC X Meprobamate X 2023_A_02 THC X Meprobamate X Amphetamine X Methamphetamine X 2023_B_01 THC X Meprobamate X 2023_B_02 THC X Meprobamate X 2024_A_01 THC X Meprobamate X 2024_A_02 THC X Meprobamate X 2024_B_01 THC X Meprobamate X 2024_B_02 THC X Meprobamate X 2025_A_01 THC X Meprobamate X 2025_A_02 THC X Meprobamate X 2025_B_01 THC X Meprobamate X o-desmethyltramadol X Amphetamine X Methamphetamine X 2025_B_02 THC X Meprobamate X o-</p>

desmethyltramadol X Amphetamine X Methamphetamine X c. The Laboratory Director affirmed (11/19/25 at 3:00 PM) the aforementioned results reported for CAL25. d. It was determined that the results reported as "Not detected" failed to meet the laboratory's criteria requiring All analytes to be Detected in the CAL25; and thus, the laboratory failed to verify the accuracy of testing. e. The reliability and quality of results reported for the aforementioned analytes during the aforementioned timeframes could not be assured during this Survey. The laboratory reported a total annual tests volume of 36,845 (CMS116 CLIA Application, 11/05/25). Laboratory reports of patients' tests results randomly selected for review are, as follows: Print Date Patient Provider ----- . 2/22/23 H, K Dr. BJ 8/30 /23 J, J Dr. BJ 5/28/24 M, L Dr. BJ 8/27/24 P, P Dr. BM 3/04/25 H, V Dr. BM 5/22 /25 T, T Dr. NK 8/19/25 GM, J Dr. NK .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on the deficiency cited, review of a laboratory written procedure and records titled, "PRCGM Alternative Proficiency Testing Results Summary" for 2023-2025, the lack of records, and interview with the Laboratory Director, it was determined the laboratory failed in it's responsibility to the providers and patients to follow it's wriitten policy/procedure to identify testing failures, investigate, and resolve problems. Findings included: a. The laboratory written procedure for it's alternative proficiency testing program stated, as follows: 1. That All analytes are detected in the CAL 25, calibrator material used as the unknown proficiency testing sample. 2. "Any proficiency testing failures will be investigated, documented, and reviewed by the laboratory director. If necessary, corrective actions will be implemented before patient testing is resumed. All proficiency testing documentation will be maintained as QA records." b. The laboratory reported "Not detected" test results. See D5217. c. The 2023-2025 laboratory records titled, "PRCGM Alternative Proficiency Testing Results Summary", incorrectly stated for CAL 25 Results as "all compounds detected" and Graded as "Acceptable". d. The laboratory failed to have records identifying and investigating the unacceptable "Not detected" results; and resolving the error. e. And thus, the laboratory failed to follow it's written procedure. f. The reliability of the laboratory to comply with it's own policies and procedures to assess and ensure quality could not be assured during this Survey. .