

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1084815	(X3) Date Survey Completed 09/01/2022
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 observation of the ABI SCIEX, Q Trap 4500 [SN B122241308] for toxicology testing using LC-MS/MS (Liquid chromatography-tandem Mass spectrometry), review of 2020-2021 CAP "DMPM" (College of American Pathologists, Drug Monitoring for Pain Management) proficiency testing reports and laboratory reports for 49 drugs tested, and interview with the Laboratory Director, it was determined that the laboratory failed to at least twice annually verify the accuracy of testing at the analyte level. Findings included: 1. The laboratory tested and reported results for 49 drugs. 2. The laboratory chose to enroll in CAP's DMPM proficiency testing program as the means to fulfill the requirement to at least twice annually verify the accuracy of testing for drugs. 3. The DMPM reports revealed the following: a. for 2020 i. 20 drugs were not present in both events ii. 16 drugs were only present in one event a. for 2021 i. 24 drugs were not present in both events ii. 23 drugs were only present in one event 4. The Laboratory Director/Technical Supervisor affirmed (8/31/22 at 10:10AM and 9/01/22 at 3PM) the laboratory used no additional method to verify the accuracy of testing in 2020 - 2021; and thus, the laboratory failed to verify test accuracy at least twice annually for 36 out of 49 drugs in 2020, and 47 out of 49 drugs in 2021. 5. For 8 out of 8 reports selected at random from 2020- 2021, as follows, the laboratory reported results as Detected for drugs that were not verified for test accuracy at least twice annually: Date 3/10/20 5/27/20 7/27/20 11/12/20 2/25/21 3/03/21 6/13/21 9/04/21 12/04/21 6. The reliability and quality of results reported as Detected could not be assured for the drugs the laboratory failed to verify at least twice annually. The laboratory reported 49 results per specimen tested for a total of 94,129 toxicology results annually (CLIA Application, 8/24/22).</p>