

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2282024	(X3) Date Survey Completed 05/14/2026
Name of Provider or Supplier Vital Total Health Lab	Street Address, City, State 180 E Leland Rd Ste D, Pittsburg, 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	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 observation of the SciEx Triple Quad 6500+ LC-MS/MS analytic system (Liquid Chromatography- Mass Spectrometers, serial number DZ245082207), review of laboratory records, the lack of records, and interview with Testing Person /Technical Supervisor-2, it was determined the laboratory failed to verify the accuracy of confirmatory drug testing in 2024. Findings included: 1. The laboratory's list of drugs confirmed by LC-MS/MS method included 34 analytes (CMS116- CLIA Application, 5/14/26), as follows:. 6- MAM alpha-hydroxyalprazolam Alprazolam Benzoylecgonine Buprenorphine Carisoprodol Codeine EDDP (Methadone metabolite) Fentanyl Hydrocodone Hydromorphone MDMA (Ecstasy) Meprobamate Methadone Amphetamine Methamphetamine Morphine Oxycodone Oxymorphone PCP Propoxyphene Tapentadol THC-COOH Tramadol EtG (Alcohol metabolite) EtS (Alcohol metabolite) Meperidine Clonazepam Norfentanyl Temazepam (continued) Lorazepam Diazepam Oxazepam Nordiazepam 2. Four laboratory reports of confirmatory drug test results were selected from the timeframe February to December 2024, as follows, for this survey: Date Reported Accession # ----- 2/04/24 100079 2/05/24 100160 8/08/24 100678 12/10/24 101105 3. The laboratory failed to have records verifying the accuracy of confirmatory testing for drugs in 2024. 4. Technical Supervisor/ Testing Person-2 affirmed (5/14/26 at 3:00 PM) the aforementioned findings; and thus, for 4 out of 4 laboratory reports the laboratory failed to verify the accuracy of confirmatory drug testing in 2024. .
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 review of the laboratory list of drugs confirmatory tests, 2025 laboratory records for CAP proficiency testing, the lack of records, and interview with Testing Person/Technical Supervisor-2, it was determined the laboratory failed to establish an ongoing policy and process for monitoring and assessing its program for at least twice annually verifying the accuracy of confirmatory testing for each Analyte. Findings included: 1. The laboratory listed confirmatory testing for 34 analytes. See D5217. 2. The laboratory chose to participate in the 2025 CAP (College of American Pathologists) proficiency testing program, DMPM, Drug Monitoring for Pain Management, as the means to fulfill the requirement at 493.1236(c)(1). See D5217. 3. Review of the 2025 DMPM Evaluations of intended responses for Events A and B revealed specific drugs were not included, as follows: EDDP PCP Propoxyphene Tapentadol EtG EtS Meperidine Clonazepam Temazepam Lorazepam 4. Review of the 2025 DMPM Evaluations of intended responses for Events A and B revealed specific drugs were included in only one out of two events, as follows: alpha-hydroxyalprazolam Alprazolam Carisoprodol Hydrocodone Hydromorphone MDMA Meprobamate Amphetamine Methamphetamine Morphine (continued) Oxycodone Norfentanyl Diazepam Oxazepam Nordiazepam 5. The laboratory had no other written policy/procedure or records for alternate methods for verifying the accuracy of confirmatory testing. And thus, the laboratory failed to verify the accuracy of confirmatory testing for the aforementioned analytes at least twice annually in 2025. 6. Three laboratory reports from the timeframe April to December 2025, included results of confirmatory drug tests, as follows: Date Reported Accession #
----- 4/07/25. 101550 10/27/25 102319 12/15/25 102790 7. Testing Person/Technical Supervisor-2 affirmed (5/14/26 at 5:00 PM) the aforementioned findings. For 3 out of 3 reports of confirmatory testing, the laboratory lacked a process for monitoring and assessing the effectiveness of the CAP program, and thus, the failure to identify the issues and implement corrective action. .

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the survey findings of noncompliance, the Laboratory Director is herein cited at the standard level for deficient practice in monitoring and ensuring the quality and accuracy of confirmatory drug testing. See D5217 and D5791.