Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2009046	09/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Histopathology Services	15012 Red Hill Ave, Ste 8h, Tustin, 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 Beckman AU400e chemistry analyzer [serial 4062941] and the two Agilent LC/MS test systems [serial numbers SG16067302, SG15207305], review of 2021-2023 laboratory records, and interview with the Technical Supervisor, the laboratory failed to verify the accuracy of test results reported for analytes in Toxicology drug confirmatory testing. Findings included: 1. Toxicology is a sub-specialty of Chemistry, for which accuracy of testing must be verified for each test /analyte. 2. The laboratory screened urine specimen for drugs using the Beckman AU400e and followed up with confirmatory testing for 86 analytes using the Agilent LC/MS (CMS116 CLIA Application, 8/31/23; LAB144A Laboratory Testing Declaration, 8/31/23). 3. Urine Drug Screen: Beckman AU400e ---------- a. The laboratory participated in API (American Proficiency Institute) proficiency testing program, EtG, as the means to satisfy the requirement to at least twice annually verify the accuracy of testing for Ethyl glucuronide. b. For Event 1: 2022, EtG i. API reported the laboratory's unsatisfactory score of 67% for reporting Negative (*), when the intended result was Positive, as follows: PT sample ID Lab result Intended ---------- ETH-01 Negative* Positive ETH-02 Negative Negative ETH-03 Negative Negative ii. The laboratory failed to provide for review records documenting alternate means of verifying accuracy of testing for EtG on the Beckman AU400e during this timeframe. iii. The Technical Supervisor affirmed (9/08/23 at 3pm) the aforementioned findings. iv. The accuracy, reliability, and quality of Urine Drug Screen testing for EtG in January - May 2022 was not assured. 4. Urine Drug Confirmation: Agilent LC/MS

	---------- a. In 2021, the laboratory validated and established the accuracy of the LC/MS drugs confirmation system for 86 analytes prior to June 2021. i. The laboratory performed split sample testing with another laboratory in December 2021, as the means to satisfy the requirement to verify the accuracy of testing at least twice annually in 2021. The records for December 2021 verified the accuracy of detecting 9 analytes present in the samples. ii. The Technical Supervisor affirmed (9/08/23 at 3pm) the aforementioned records. iii. The accuracy, reliability, and quality of test results for the remaining 77 drugs was not assured in 2021. b. In 2022, the laboratory participated in the Urine Toxicology (LC/MS) proficiency testing program by CAP (College of American Pathologists) and performed split samples testing as the means to at least twice annually verify the accuracy of testing for 86 drug analytes. i. Records documented 23 drugs were present and verified accuracy of testing at least twice. ii. Records documented 48 drugs were present only once, and thus accuracy failed to be verified at least twice. iii. Records documented 16 drugs were Not detected in any of the samples or PT program; and thus, accurate testing for the presence of the drugs could not be verified, as follows: 6-Acetylmorphine Norketamine Diazepam PCP Ketamine Phentermine MDA Propoxyphene MDMA Cyclobenzaprine MDPV Desipramine Mephedrone EDDP Methylphenidate Phenobarbital iv. The accuracy, reliability, and quality of results reported as Not detected/Negative for 64 drugs were not assured in 2022. 5. The laboratory tested for 86 drugs and reported 1,187,000 Toxicology results annually (CMS116-CLIA Application, 8/31/23). .
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the deficiency cited, the laboratory is herein cited for failing to establish written policy and procedures for an ongoing process to monitor and assess activities verifying the accuracy of testing for 86 drugs at least twice each calendar year, January to December 31, and correct problems when identified. See D5217. .