

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1089660	<b>(X3) Date Survey Completed</b>  03/04/2021
<b>Name of Provider or Supplier</b>  Universal Pain Management	<b>Street Address, City, State</b>  819 Auto Center Dr, Palmdale, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2109</b>	<p>TOXICOLOGY CFR(s): 493.845(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of second quarter event in 2019 (Q2-2019) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in the Urine Adulteration panel. The findings included: 1. The API reported for Q2-2019, an unsatisfactory proficiency testing score of 67% for Creatinine analyte tested on the Indigo Plus screening for urine adulterants. 2. For two (3) out of three (3) random patient sampling test results reviewed covering period from 2/12/2019 to 06/25/2020, the laboratory analyzed and reported Creatinine analyte during the time the laboratory received an unsatisfactory proficiency testing score. 3. The TS affirmed on March 4, 2021 at approximately 11:00 a.m. that the laboratory received the above unsatisfactory proficiency test score.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:  
Based on the surveyor's observation, lack of maintenance protocol and documentation, and interview with the laboratory technical supervisor (TS); it was determined that the laboratory failed to establish and document a maintenance protocol for the Chemical Safety Cabinet, vortex, heating block, sonicator and thermometers that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. The laboratory uses a LABCONCO chemical cabinet for processing urine samples and preparation of chemical, and small equipment such as sonicator, heat block, vortex, weight balance (Intelligent Lab brand) and thermometers for various procedures used in the laboratory. 2. Based on surveyor observation during tour of the laboratory on March 4, 2021 at approximately 11:00 a.m. the equipment described above used in the laboratory had no records of maintenance. 3. The TS affirmed that the laboratory failed to establish a maintenance protocol for the chemical cabinet and small equipment described in 1. 4. Based on the laboratory's monthly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 388,800 Toxicology samples annually.

**D6095**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, lack of preventive maintenance records, random patients, proficiency testing records, and interview with the technical supervisor; it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance. See D2109 and D5433.