

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2018576	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Columbia Pain And Spine Institute	Street Address, City, State 689 Nw Burnside Rd, Gresham, OR	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's specimens stability and viability validation results for specimens stored at 2-8 degree centigrade and interview with the General Supervisor (GS) and Technical Supervisor (TS), the laboratory failed to discard specimens kept in the refrigerator for confirmatory testing since 06/10/2022. Findings include: 1. The Shimadzu LCMS analyzer is down since 06/10/2022 awaiting turbo parts. The urine specimens for confirmatory testing since 06/10/2022 were stored in the refrigerator at 2-8 degrees centigrade awaiting testing when the LCMS is up and running. 2. The specimens stability and viability validation study shows specimens stored at 2-8 degree centigrade are good between 21 to 48 days depending on what drug analytes that requires confirmation testing. 3. The laboratory failed to discard the specimens that exceeded the stability and viability as established by the laboratory stability determination for confirmatory testing. 4. The laboratory performs 25,000 to 50,000 urine drug testing annually. 5. Interview with the GS and TS on 09/13/2022 @ 10:30 AM concur with the findings.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on random inspection of reagents and controls from the laboratory's refrigerator and discussion with the General Supervisor (GS) and the Technical Supervisor (TS), the laboratory failed to discard expired reagents and controls. Findings include: 1. Potassium hydroxide for THC hydrolysis expired in 2021. The laboratory performs 25,000 to 50,000 urine drugs testing annually, approximately 2000 to 4000 THC hydrolysis annually. 2. UTAK Urine controls expired 06/2022. 3. Buffers for LCMS expired 06/2022. 4. Discussion with the GS and TS on 09/13/2022 @ 12:45 PM confirmed the presence of expired reagents listed above.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of preventive maintenance records and interview with the Technical Supervisor (TS), the laboratory failed to perform preventive maintenance of the six MLA pipettes used in the laboratory. Findings include: 1. The MLA pipettes calibration and preventive maintenance were due 02/2022. 2. The MLA pipettes are use to aliquot exact amount of specimens and buffers solutions when processing urine specimens. 3. The laboratory performs 25,000 to 50,000 urine drug testing annually. 4. Interview with the TS on 09/13/2022 @ 1245 concur with the findings.