

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2002261	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Overlook Pain And Recovery	Street Address, City, State 160 Overlook Avenue, Suite 1a, Hackensack, NJ	
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 surveyor review of the Procedure Manual (PM), lack of Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy and reliability of Toxicology testing twice a year from 6/4/19 to the date of survey. The finding includes: 1. BA was not performed on, Alprazolam, Sufentanil, Norbuprenorphine, Norfentanyl, Normeperidine, a-Hydroxyalprazolam, Clonazepam, Codiene, Diazepam, Flunitrazepam, Fulrazepam, Hydromorphone, Lorazepam, MDA, MDEA, Meprobamate, Midazolam, Morphine, Naloxone, Naltrexone, Nordiazepam, Norpropoxyphene, Oxazepam, Oxymorphone, Temazepam, Tapentadol, D-tapentadol, Butalbital, Pheobarbital, Secobarbital on the Toxicology tests list above twice a year. 2. The LD confirmed on 9/23/21 at 1:30 pm that the laboratory did not verify the accuracy of Toxicology twice a year.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the</p>

Laboratory Director (LD), the laboratory failed to follow their PM policy for "Proficiency Testing" from 6/4/19 to the date of survey. The finding includes: 1. The PM stated "When proficiency testing specimens are not available from an approved Proficiency Testing program, split sample testing with another laboratory or instrument manufacturer will be arranged. Quality assurance checks on non-regulated analytes may be performed by PT enrollment or split specimen testing with another laboratory ." 2. There was no documented evidence that when proficiency testing specimens are not available from an approved Proficiency Testing program, split sample testing with another laboratory or instrument manufacturer was arranged. 3. The LD confirmed on 9/23/21 at 2:00 pm that the above mentioned procedure was not performed.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on the surveyors review of the Eppendorff Research Plus Pipette User Guild (UG) and interview with the Laboratory Director (LD), the laboratory failed to perform and document maintenance as stated by the manufacturer from 6/9/19 to the date of the survey. The findings include: 1. The UG states "Compliance with regard to error limits must be checked by the user under the control of inspection, measuring and test equipment or analytical quality assurance at least once a year". 2. There was no documented evidence that the above procedure was performed on the following: a) Eppendorf Research Plus Pipette (ERPP) Serial Number (SN) 034291C 1000ul b) ERPP SN P16398C 200ul c) ERPP SN P27066C 20ul 3) The LD confirmed on 9/23 /21 at 2:45 pm that the UG was not followed.