

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2002261	(X3) Date Survey Completed 06/04/2019
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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR) and interview with the Laboratory Director (LD), the laboratory failed to ensure that TR included all relevant and necessary information for accurate and reliable testing and reporting in February 2019. The finding includes: 1. A review of TR from February revealed nine of nine did not have the temperature of the specimen recorded. 2. The LD confirmed on 6/5 /19 at 12:50 pm that all relevant and necessary information was not on the TR.</p>
D5313	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR), Requisition Forms and interview with the Testing Personnel (TP), the laboratory failed to ensure that the laboratory accurately recorded the date and time specimens were received for Toxicology tests performed on the Applied Biosystem 4000 Q Trap analyzer from May 2108 to the date of the survey. The finding includes: 1. The laboratory did not record the specimen received date but recorded the sample preparation date as the "Specimen Received Date". 2. The Laboratory Director confirmed on 6/5/19 at 1:30 pm that the laboratory did not ensure that the specimen received date was entered accurately.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of reagents, solutions and interview with the Testing Personnel (TP), the laboratory failed to put new expiration dates on all reagents and solutions used for urine Toxicology tests performed on the Applied Biosystem 4000 Q Trap analyzer on the date of survey. The TP confirmed on 6/5/19 at 1:00 pm the laboratory failed to put new expiration dates on reagents and solutions.</p>
<p>D5467</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Laboratory Director (LD), the laboratory failed to use different lot numbers of standards to make the calibrator, internal standard and controls for Urine Toxicology confirmation tests from May 2018 to the date of the survey. The LD confirmed on 6/5/19 at 2:10 pm the laboratory did not use different lot numbers. .</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units</p>

of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to report Urine Drug confirmatory test results accurately from May 2018 to the date of survey. The findings include: 1. The laboratory performed non Food and Drug Administration cleared tests and there was no statement stating "The performance characteristics of this test were determined by (Laboratory Name)". 2. The FR comment stated "symbol >=Results greater then the upper Limit Of Quantitation (LOQ)" but the column read "Cutoff " not LOQ". 3. The "0" in the Result column was referenced to " = Non Detected" but the LOQ for all drugs on the FR was above zero. 4. The LD confirmed on 6/5/19 at 2:10 pm that Urine Drug confirmatory test results were not reported accurately.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Laboratory Director (LD) the LD failed to ensure that PS were adequate to perform Urine Toxicology tests on the Applied Biosystem 4000 Q Trap system from May 2018 to the date of survey. The findings include: 1. The laboratory failed to have acceptable criteria for PS from clinical scientific literature. 2. There was no source available for cut off points. 3. The laboratory did not establish the lowest limit of detection for analytes. 4. There was no validation performed to establish the expiration date of reagents, working solutions, Internal Standard, controls and calibrators used. 5. The validation of the hydrolysis control did not include validation of: a. Optimal Enzyme Concentration b. Temperature of the Heat Block c. Time on the Heat Block 6. There was no criteria to review chromatography. 7. There was no criteria for manual integration of peaks. 8. Sample stability studies were not performed. 9. Verification of manufacturers instructions for Specimen Collection, handling and rejection were not performed. 10. The laboratory did not perform analytical sensitivity or interfering substances studies. 11. The laboratory did not perform carryover studies. 12. The LD confirmed on 6/5/19 at 2:20 pm that the LD did not ensure the PS were adequate.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the LD failed to ensure that all BA results obtained by performing split sample analysis were reviewed and corrective action was performed by the appropriate staff in January 2019. The findings include: 1. A review of split sample results revealed results were scored incorrectly as follows: a. Flunitrazepam - 1 sample failed but the evaluation was scored as 100%. b. Fentanyl - 3 samples failed but the evaluation was scored as 80%. c. Naltrexone - 1 sample failed but the evaluation was scored as 100%. 2. Fentanyl received a 40% which required corrective action but there was no evidence corrective action was performed. 3. The LD confirmed on 6/5/19 at 1:10 pm that the laboratory did not review and perform corrective action for BA results.