

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2138383	(X3) Date Survey Completed 08/04/2022
Name of Provider or Supplier Lab Rx Llc	Street Address, City, State 92 Thomas Johnson Dr, Suite 250, Frederick, MD	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of sample shipping stability studies and interview with the technical supervisor (TS) and laboratory director (LD), the laboratory failed to evaluate the potential impact on patient results for drug analytes that did not meet the acceptability criteria for shipping stability for urine drug confirmation testing. Findings: 1. The laboratory performed a shipping stability study that mimicked the ambient shipping conditions that patient samples underwent during transport to the laboratory. 2. The "Ambient Sample Shipping Stability Summary" (summary) stated that "2 negative samples and 6 positive samples" spiked with known concentrations of 58 drug analytes were tested. 3. The acceptability limits were defined as "A minimum of 75% (6/8) of the lab result comparisons for each analyte should be within +/- 25.0%." 4. Two drug analytes did not meet the acceptability requirements. Bupropion had three of eight samples (62.5%) test outside the acceptability limits and Lorazepam had five of eight samples (37.5%) test outside the acceptability limits. 5. The summary stated "The study verifies that ambient sample transport temperature is acceptable for the indicated analytes with the exception of bupropion and lorazepam." 6. There was no indication of the potential impact on or the corrective actions that should be taken for patient specimen results indicating the presence of bupropion or lorazepam drug analytes (either above or below the cut-off values). 7. During the survey on 08/04/2022 at 2:30 PM, the TS and LD confirmed that there was no evaluation of the</p>

potential impact of transport conditions on patient results for the drug analytes that did not meet the acceptability criteria for the ambient sample shipping stability study.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

I. Based on review of the procedure manual, the "LCMS [liquid chromatography-mass spectrometry] Batch Evaluation and QC [quality control] Documentation Record" worksheet and interview with the testing person (TP), the laboratory's procedure manual failed to include written instructions for investigating and reporting patient samples that were flagged to be repeated or reprocessed prior to releasing the test results. Findings: 1. The "LCMS Batch Evaluation and QC Documentation Record" worksheet dated 07/10/22 was reviewed. 2. Four patient sample identification (ID) numbers were written in the section labeled "List patient samples to be repeated or reprocessed." They were listed on the worksheet due to QC failures noted in the "Analytical: Batch QC Acceptability" section of the worksheet. The TP was asked to show the surveyors the batch worksheet on which the specimens were repeated. 3. When the TP checked the next batch that was tested in the lab, the four ID numbers were not listed as having been repeated. The TP checked two of the four ID numbers and confirmed that the patients' histories showed that they had been positive the last time they were tested at the lab for the drug that had failed the QC criteria. The TP stated that the results from the 07/10/22 batch had been released based on the patients' previous histories for positivity for that drug. 4. When interviewed, the TP confirmed that the step-by-step procedures for interpreting the patient test results did not include verifying the patient's previous positivity prior to releasing the test results when there was a QC failure. The procedures did not include written instructions for how to document that a patient specimen had been repeated or reprocessed prior to reporting the test results when there was a QC failure. 5. During the survey on 08/04/22 at 1:45 PM, the TP confirmed that there were no written instructions for verifying the patient's previous positivity prior to releasing the test results and how to document that a patient specimen had been repeated or reprocessed prior to reporting the test results when there were QC failures. 43123 II. Based on review of the procedure manual and interview with the technical supervisor (TS), the laboratory failed to have

a procedure for the calibration of pipettes used for urine drug confirmation testing on the liquid chromatography tandem mass spectrometry analyzer (LC/MS/MS). Findings: 1. The laboratory's procedure manual did not include a procedure for the maintenance and calibration requirements for the pipettes used for toxicology testing on the LC/MS/MS analyzer. 2. During the survey on 08/04/2022 at 2:30 PM, the TS confirmed that the pipettes had recently been sent to an outside company for calibration and there was no procedure defining the pipette maintenance and calibration requirements.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on review of the "LCMS [liquid chromatography-mass spectrometry] Batch Evaluation and QC [quality control] Documentation Record" worksheet and interview with the testing person (TP), the TP did not ensure that the "Review Patient Results" and "List patient samples to be repeated or reprocessed" sections of the worksheet included documentation of the investigation of the patient samples to be repeated or reprocessed. Cross refer to Tag D5403 for details.