

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2138383	(X3) Date Survey Completed 08/01/2018
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessments, interview with the laboratory director, and the testing person, the laboratory did not perform competency assessments on the technical supervisor (TS) Findings: 1. The laboratory begin patient testing in May 2017. The laboratory did not perform an assessment of the TS competency for performing testing on the Liquid Chromatology Mass Spectrophotometer analyzer. 2. The laboratory director and the testing person stated that they were unsure if the TS needed a competency assessment performed.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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:

Based on review of the written procedure manual, interview with the laboratory director, and the testing person, the laboratory did not have written procedures for all areas of the laboratory. Findings: 1. The laboratory performs toxicology testing with a Liquid Chromatography Mass Spectrophotometer analyzer. 2. The laboratory did not have written procedures for processing urine samples for testing. 3. The testing person stated that right now he is the only testing person. 4. The testing person confirmed that urine sample processing procedures were not available.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of corrective action procedures, interview with the laboratory director, and the testing person, the laboratory did not document all steps needed to perform corrective action when the refrigerator temperature was out of range. Findings: 1. The laboratory "front" refrigerator was outside of the 2-8 degrees Celsius range on May 5, 2018. 2. The testing person documented the out of range temperature on the temperature log during morning hours and adjusted the thermometer. 3. The testing person did not retake the "front" refrigerator temperature in the afternoon to ensure that the refrigerator equilibrated between 2-8 degrees Celsius and reagents were not damaged. 4. The testing person confirmed that he did not retake the "front" refrigerator temperature to ensure that the refrigerator equilibrated between 2-8 degrees Celsius and reagents were not damaged.