

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D2090589	<b>(X3) Date Survey Completed</b>  08/13/2019
<b>Name of Provider or Supplier</b>  Toxperts, Llc	<b>Street Address, City, State</b>  400 Venters Lane, Ste 200, Pikeville, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 08/13/2019, the laboratory failed to verify the reportable range of test results using a minimal, mid-point, and maximum values for the urine creatinine analyte on the Beckman Coulter AU 480 chemistry analyzer. Findings include: 1. Review of the Standard Operating Procedure #6.1 entitled "Periodic Calibration, Calibration Verification (AMR)and Assay Correlations" stated "Calibration Verification and validation of the analytical</p>

measurement range (AMR) are required to substantiate the continued accuracy of the test method. The test specimens must have analyte values that, as a minimum, are near the low, mid-point, and high values of the AMR." 2. Review of the package insert for the Thermo Scientific DRI Creatinine-Detect Test used for the quantitative determination of creatinine in human urine included an assay range of 0.78 mg/dl to 420 mg/dl. 3. Review of calibration verification records for urine creatinine on 06/19/2018, 12/17/2018, and 07/22/2019, revealed the test specimens used for calibration verification had values of 1.3 mg/dl, 7.5 mg/dl, and 23.0 mg/dl. 4. The General Supervisor acknowledged in an interview at 11:30 AM on 08/13/2019, the laboratory failed to follow their policy to use test specimens covering the analytical measurement range when performing the calibration verification for urine creatinine.