

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2093889	<b>(X3) Date Survey Completed</b>  12/31/2020
<b>Name of Provider or Supplier</b>  Kingdom Pathways	<b>Street Address, City, State</b>  426 Oxford Street, Saint Paul, MN	
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>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document function checks (calibration) for 3 of 3 digital thermometers. Findings are as follows: 1. The laboratory performed Toxicology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory on 12/31/20, at 09:05 a.m. 2. The following digital thermometers were observed as in use in the laboratory refrigerators during the tour: Serial #: 181559379 Calibration Expiration Date: 8-30-20 Refrigerator: Sample Storage Serial #: 181616154 Calibration Expiration Date: 9-26-20 Refrigerator: Reagent Storage 1 Serial #: 181559380 Calibration Expiration Date: 8-30-20 Refrigerator: Reagent Storage 2 3. The manufacturer's certificate of calibration for each thermometer was not found in the laboratory's records. Documentation of function checks for this equipment was not found in laboratory records. The laboratory was unable to provide certificate of calibration or function check documentation for the thermometers upon request. 4. In an interview on 12/31/20, at 9:55 a.m., the LD confirmed the above finding. NOTE: This is a repeat citation from previous survey, 10-30-18. .</p>