

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2093889	(X3) Date Survey Completed 10/30/2018
Name of Provider or Supplier Kingdom Pathways	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5435	<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 establish a function check procedure and perform functions checks on all ancillary laboratory equipment. Findings are as follows: 1. One digital thermometer and two dial thermometers were observed in use in laboratory refrigerators during a tour the laboratory on 10/30/18 at 1:00 p.m. Manufacturer calibration labels were not present on the thermometers. 2. Laboratory refrigerators contained patient specimens, testing reagents and quality control materials. 3. A function check procedure for the thermometers was not found in the laboratory's established procedure manuals. Documentation of function checks for this equipment was not found in laboratory records. The laboratory was unable to provide a function check procedure or documentation of function checks for the thermometers upon request. 4. In an interview on 10/16/18, at 1:55 p.m., the General Supervisor confirmed the above finding.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

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 calibrations for Chemistry (Toxicology) testing with the frequency established by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry (Toxicology) testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/30/18 at 1:00 p.m. 2. A Mindray BS 200 chemistry analyzer was observed as present and available for use during the tour of the laboratory. Analytes tested on this analyzer were as follows: cannabinoids and alcohol. 3. The Kingdom Pathways Operations Manual procedure located in the Laboratory Procedure Manual established calibration performance frequency for the analytes as every 2 weeks. The LD approved the procedure on 12/13/17. 4. The laboratory exceeded the 2 week calibration interval (Cal.) on one occasion in the time period reviewed; May 2017 through October 2018. See below Previous Cal. Subsequent Cal. Elapsed time 05/03/17 07/10/17 2 months, 7 days 5. Laboratory records indicated 211 patient specimens were tested between 05/18/17 and 07/10/17. 6. In an interview on 10/30/18 at 3:30 p.m., the GS confirmed the above finding.
This is a repeat finding from the 05/17/17 survey