

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D2093889	<b>(X3) Date Survey Completed</b> 04/08/2025
<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>D0000</b>	. The Kingdom Pathways laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on April 8, 2024. The following standard-level deficiencies were cited: 493.1236 Evaluation of proficiency testing performance 493.1413 Technical consultant responsibilities .
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:                      . Based on document review and interview with laboratory personnel, the laboratory failed to review proficiency testing (PT) results for three of four PT events completed in 2023 and 2024. Findings are as follows: 1. The laboratory performed ethyl alcohol and cannabinoid testing under the Toxicology subspecialty as confirmed by the Technical Consultant and Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on 04/08/25. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. Laboratory director review of proficiency testing scores was required when each event was graded by API as established in the Proficiency Testing procedure found in the Proficiency Testing manual. 4. The results from the following PT events were not found in the laboratory records on the day of survey. 2023 1st Chemistry miscellaneous event 2023 2nd Chemistry miscellaneous event 2024 1st Chemistry miscellaneous event The laboratory was unable to provide evidence of documented PT result review for these events upon request. 5. In an interview at 11:10 a.m. on 04/08/25, the LD confirmed the above findings. .</p>
<b>D6054</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p>

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

. Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess Toxicology testing competency at least annually for one of two testing personnel (TP) in 2023 and one of three TP in 2024. Findings are as follows: 1. The laboratory performed ethyl alcohol and cannabinoid testing under the Toxicology subspecialty as confirmed by the Technical Consultant (TC) and Laboratory Director during a tour of the laboratory at 10:05 a.m. on 04/08/25. 2. A Mindray BS-200 chemistry analyzer and a ThermoFisher Scientific Indiko Plus chemistry analyzer were observed in the laboratory during the tour. The laboratory performed testing on the Indiko Plus analyzer beginning in June 2024. The Mindray analyzer was in use prior to June 2024. 3. Ethyl alcohol and cannabinoid testing competency assessments were required annually as established in the Employee Training Competency and Assessment procedure found in the Safety & Employee Policies Manual. 4. Annual competency assessment documentation for the following TP was not found during review of laboratory records as indicated below. 2023 TP1 2024 TC 5. The laboratory was unable to provide the missing records upon request. 6. In an interview at 10:30 am. on 04/08/25, the TC confirmed the above finding.