

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1024988	(X3) Date Survey Completed 05/05/2026
Name of Provider or Supplier Us Path Labs Llc	Street Address, City, State 4910 Communication Ave Suite 175, Boca Raton, FL	
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
D0000	An announced CLIA recertification survey was conducted at US Path Labs LLC on May 5, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard level deficiencies cited are as follows:
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to have a reagent log of the chemicals used in the Vacuum Infiltration Processor (VIP) and autostainer from 02/28/2024 to 05/05/2026. Findings Included: 1. Review of the US Path Labs Pegasus log revealed, the laboratory used the following reagents in their VIP: Formalin, Alcohol and Xylene. 2. Review of the Sakura Autostainer Quality Control (QC) log revealed, the laboratory used the following reagents in their H&E stain: Hematoxylin, Eosin, Alcohol, Xylene, and Acidic Alcohol. 3. Review of the laboratory's QC logs revealed, the laboratory did not have a log of the chemicals used in their VIP or autostainer. 4. During an interview on 05/05/2026 at 9:48 AM, the Vice President of Operations stated they did not have a log of the chemicals used.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of</p>

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of personnel records, and interview, the Technical Supervisor (Laboratory Director) failed to document competency evaluations for seven (B - H) of eight Testing Personnel (A - H) in 2024, 2025, and 2026. Findings included: 1. Review of the personnel records for Testing Personnel B revealed there was no documentation of an initial competency in November 2024, and a sixth month competency evaluation in 2025. 2. Review of the personnel records for Testing Personnel C revealed the initial competency evaluation performed on 09/30/2025 and the sixth month competency evaluation performed on 04/02/2026 were not performed by the Technical Supervisor. 3. Review of the personnel records for Testing Personnel D revealed the initial competency evaluation performed on 10/31/2025 and the sixth month competency evaluation performed on 04/02/2026 were not performed by the Technical Supervisor. 4. Review of the personnel records for Testing Personnel E revealed the initial competency evaluation performed on 04/02/2026 was not performed by the Technical Supervisor. 5. Review of the personnel records for Testing Personnel F and G revealed the annual competency evaluations performed on 03/08/2026, 04/01/2025, and 4/02/2026 were not performed by the Technical Supervisor. 6. Review of the personnel records for Testing Personnel H revealed the initial competency evaluation performed on 10/08/2025 and the sixth month competency evaluation performed on 04/02/2026 were not performed by the Technical Supervisor. 7. During an interview on 05/05/2026 at 11:30 AM, the Vice President of Operations revealed there was no competency on the second Dermatopathologist (Testing Personnel B), and she reviewed and signed the competency evaluations for Testing Personnel C - H.