Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2264975	(X3) Date Survey Completed 02/18/2025
Name of Provider or Supplier Micro Path Laboratories, Inc	**Street Address, City, State** 2000 Osprey Blvd Ste 204 Room P1, Bartow, 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 Micro Path Laboratories, Inc. on 2/18/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on review of records and interview, the laboratory failed to ensure documentation of test staining materials for the intended reactivity for one (7/18/24) of three test days (07/18/24, 1/22/25, and 2/3/25) days of patient Hematoxylin and Eosin (H&E) Histopathology testing reviewed. Findings include: 1. Patient report #1 documented H&E stain was performed on 7/18/2024. The acceptability of H&E Stain Control log for July 2024 included columns to document the acceptability of stain control and for the doctor to initial.. There was no documentation of H&E stain acceptability documented on 7/18/24. 2. The Procedure Manual, approved by the Lab Director 1/24/2025, included a section titled Quality Control. The Quality Control procedure showed "Each day the pathologist marks the H&E stain control log for acceptability." 3. The Chief Operating Office (COO) of Lab Services confirmed on 02 /18/25 at 11:00 AM there was no documentation of expected reactivity of H&E staining performed on 7/18/25.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review and interview, the Lab Director failed to ensure the quality control (QC) and quality assessment (QA) programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred for 2024. Findings include: 1. The Quality Policy, approved by the Lab Director 1/24/25, revealed the QA program was limited to to review of comparisons. There was no written laboratory QA program to include the General, Pre-Analytic, Analytic, and Post-Analytic laboratory testing process to identify failures as they occurred. 2. The Laboratory Director failed to ensure the laboratory QC and QA program identified the laboratory had not documented test staining materials for the intended reactivity for one (7/18/24) of three test days (07/18/24, 1/22/25, and 2/3/24)) days of patient Hematoxylin and Eosin (H&E) Histopathology testing reviewed. (See D5473). 3. The Laboratory Director failed to ensure the laboratory QC and QA program identified the Technical Supervisor failed to evaluate the initial competency of five Testing Personnel (TP) B, C, D, E, and F of six Testing Personnel for 2024. (See D6120) 4. The Chief Operating Office (COO) of Lab Services confirmed on 02/18/25 at 11:15 AM there was no written laboratory QA program to include the General, Pre-Analytic, Analytic, and Post-Analytic laboratory testing process to identify failures as they occurred, and the QA program had not identified the failures as cited at D5473 and D6120.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (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 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 record review and interview, the Technical Supervisor failed to evaluate the initial competency of five Testing Personnel (TP) B, C, D, E, and F of six Testing Personnel for 2024. Findings included: 1. Review of the Laboratory Personnel Report signed by the Laboratory Director on 1/27/25, showed six TP-A B, C, D, E, and F. Testing Personnel A was listed as the Laboratory Director, Technical Supervisor, and General Supervisor. 2. Personnel records for TP- B, C, D, E, and F documented annual competencies were performed and signed by TP-D. 3. Policy for Laboratory Personnel Descriptions approved by the Lab Director on 6/7/23 stated the Technical Supervisor was responsible for evaluating the competency of all testing personnel. 4. On 02/18/25 at 10:30 AM, the Chief Operating Office (COO) of Lab Services confirmed the lack of documentation of competency for TP- B, C, D, E, and F for 2024 by the Technical Supervisor.