Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2264975	05/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Micro Path Laboratories, Inc	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 initial survey was conducted at Micro Path Laboratories Inc. on 05/08/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the laboratory failed to have a procedure manual, which included the procedure for specimen acceptance and rejection, control procedures for hematoxylin and eosin stain, immunohistochemical stains, and special stains for histopathology and cytology slides, and procedures for

	reporting normal and imminently life-threatening results, from the date testing started through the date of the initial survey (03/06/23 to 05/08/23). Findings Included: The laboratory was not able to provide a procedure manual for review when requested. On 05/08/23 at 10:50 AM, the Chief of Operation Officer of Laboratory Services confirmed the pathology "read only" laboratory did not have a procedure manual.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the Laboratory Directory failed to ensure that the laboratory had an approved procedure manual for the histology and cytology testing performed in the laboratory from the date testing began through the date of the initial survey (03/06/23 to 05/08/23). Findings included: The laboratory was not able to provide a procedure manual for review when requested. On 05/08/23 at 10:50 AM, the Chief of Operation Officer of Laboratory Services confirmed the Laboratory Director had not approved a procedure manual for the pathology "read only" laboratory.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on lack of documentation, review of personnel files, review of the Laboratory Personnel Report (Form CMS-209) and interview, the Laboratory Director failed to specify in writing, the responsibilities and duties for 5 out of 5 Testing Personnel (#B, #C, #D, #E, #F) from the time testing began to the date of the initial survey (03/06/23 to 05/08/23). Findings included: Review of Form CMS-209 revealed the laboratory has 5 Testing Personnel (#B-#F) performing high complexity testing. Review of the personnel records for Testing Personnel #B-#F revealed no evidence of written job responsibilities and duties. On 05/08/23 at 10:50 AM, the Chief of Operation Officer of Laboratory Services confirmed the Laboratory Director had not specified in writing, the responsibilities and duties of Testing Personnel.