Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0502642	12/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Histopath Inc	4455 S Padre Island Drive, Suite 39, Corpus Christi, TX	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based upon review of the policies and procedures, review of personnel files and interview of facility personnel, the laboratory failed to have a written policy to assess the competency of testing personnel performing Histopathology procedures in 2023 and 2024. The findings included: 1. Review of the policies and procedures found in the procedure manual found no policy or procedure for assessing the competency of testing personnel performing histopathology procedures. 2. Review of personnel files found no documentation of competency assessments performed in 2023 or 2024 for five of eight testing personnel performing histopathology procedures in 2023 and 2024. 3. During interview of the practice manager conducted on December 12, 2024 at 12:37 PM, she confirmed there were no competency assessments available for review for the five pathologists performing histopathology procedures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based upon review of policies and procedures and interview of facility personnel, the

	laboratory failed to ensure 94 of 94 policies and procedures were approved, signed and dated by the current laboratory director. The findings included: 1. Review of the 13 policies and procedures included in the policy and procedure manual found 94 procedures. Review of these procedures found no documentation available for review that the current laboratory director had approved these procedures for use. 2. During interview of the practice manager conducted December 12, 2024 at 12:10 PM, she confirmed the laboratory director had not approved, signed and dated the procedures in use since becoming the laboratory director on October 1, 2024.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based upon observations, review of manufacturer's instructions and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for storage for five reagents and stains used in histopathology testing. The findings included: 1. Observations made in the laboratory on December 12, 2024 at 12:27 PM found the laboratory stored the following reagents and stains on open shelving in the laboratory: one gallon Epredia EA-50 two gallons Fisherfinest Clarifier 2 one gallon Harris Hematoxylin one gallon Epredia OG-6 one gallon Eosin Y, Alcoholic with Phloxine B. 2. Review of the manufacturer's storage instructions printed on each of the labels found under the heading STORAGE: "Store locked up." 3. During interview of the Histotechnologist conducted December 12, 2024 at 12:27 PM, she confirmed the laboratory did not store the flammable reagents and stains locked in a flammable cabinet.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based upon review of patient reports and interview of facility personnel the laboratory failed to include the location of the laboratory where tests were performed in five of five histopathology final reports reviewed. The findings included: 1. Review of five final patient reports found the laboratory used a post office box as the address with no

	location of the laboratory where testing was performed. 2. During interview of the practice manager conducted December 12, 2024 at 1:13 PM, she confirmed that the laboratory did not include the location of the laboratory where testing was performed on the final reports.