

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2007541	(X3) Date Survey Completed 12/12/2024
Name of Provider or Supplier Histopath Inc	Street Address, City, State 6130 Parkway Drive, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>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 the five testing personnel performing Histopathology procedures in 2023 and 2024. The findings included: 1. Review of the policies and procedures found in the purple notebook found no policy 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 the five testing personnel performing histopathology procedures. 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.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>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 13 of 13 policies and procedures were approved, signed</p>

and dated by the current laboratory director. The findings included: 1. Review of the 13 policies and procedures included in the purple notebook found 13 procedures. Review of these procedures found no documentation available that the current laboratory director had approved these procedures for use. 2. During interview of the Histotechnologist conducted December 12, 2024 at 9:36 AM, she confirmed the laboratory director had not approved, signed and dated the procedures in use since becoming the laboratory director on October 1, 2024.

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.