

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2250212	<b>(X3) Date Survey Completed</b>  10/24/2023
<b>Name of Provider or Supplier</b>  Pinnacle Gastroenterology Sc	<b>Street Address, City, State</b>  3 N Main St, Manteno, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1); the laboratory failed to establish written policies and procedures for histopathology patient testing specimen rejection in 2022 and 2023. Findings Include: 1. Review of the "Pinnacle Gastroenterology Specimen Acceptance Policy" and lack of documentation revealed the laboratory failed to establish written policies and procedures for the rejection of histopathology patient samples. a. "PURPOSE: To provide specimen acceptance guidelines." 2. On 10/24/2023 at 11:29 a.m., an interview with the TP 1 confirmed the above findings.</p>
<b>D6102</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1); the laboratory director failed to ensure that four of four testing personnel (TP 1, TP 2, TP 3, and TP 4) listed on the Laboratory Personnel Report (CLIA) Form CMS - 209 received and demonstrated the appropriate training required prior to performing and reporting high complexity histopathology patient testing in 2022 and 2023. Findings Include: 1. Review of the "Pinnacle Gastroenterology Histotechnician Competency Checklist" forms and lack of documentation for TP1, TP 2, TP 3, and TP 4 revealed the laboratory failed to document training and competency for the histopathology techniques protocol utilized for patient testing in 2022 and 2023. a. "Name of Employee: TP 1" "Date of Hire: 11/29/2022" "Content: Standards-Protocols-Procedure-Practice Guidelines" "Reviewed By: (illegible) Date: 5-1-23" "Employee Signature: TP 1 Date: 11/29/22" b. "Name of Employee: TP 2" "Date of Hire: 11/29/2022" "Content: Standards-Protocols-Procedure-Practice Guidelines" "Reviewed By: (illegible) Date: 5-1-23" "Employee Signature: TP 2 Date: 11/29/22" c. "Name of Employee: TP 3" "Date of Hire: Aug 15, 2023" "Content: Standards-Protocols-Procedure-Practice Guidelines" "Reviewed By: TP 1 Date: 08/24/23" "Employee Signature: TP 3 Date: 08/24/23" d. "Name of Employee: TP 4" "Date of Hire: 11/29/2022" "Content: Standards-Protocols-Procedure-Practice Guidelines" "Reviewed By: TP 1 Date: 11/29/22" "Employee Signature: (illegible) Date: 11/29/22" 2. Review of the "Pinnacle Gastroenterology Grossing Competency Checklist" form and lack of documentation for TP 2, revealed the laboratory failed to document training and competency for the histopathology technique protocol utilized for patient testing in 2022 and 2023. a. "Name of Employee: TP 2" "Date of Hire: 10/1/22" "Content: Standards-Protocols-Procedure-Practice Guidelines" "Reviewed By: (illegible) Date: 11/29/2022" "Employee Signature: TP 2 Date: 11/29/2022" 3. Review of the "Pinnacle Gastroenterology Lab Director Responsibilities" procedures manual revealed the following: a. "(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;" 4. On 10/24/2023 at 11:15 a.m., an interview with the TP 1 confirmed the above findings.