

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2252604	<b>(X3) Date Survey Completed</b>  01/25/2024
<b>Name of Provider or Supplier</b>  Pathology Services, A Professional	<b>Street Address, City, State</b>  18316 Murdock Circle, Unit 106, Port Charlotte, FL	
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>D0000</b>	An on-site announced CLIA recertification survey was conducted at Pathology Services, A Professional on 01/09/2024 to 01/25/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
<b>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to ensure quality control (QC) for hematoxylin and eosin (H&amp;E) stains were documented and acceptable before reporting patient results from the date of the last survey, 04/13/2022 through 01/09/2023. Findings included: Hematoxylin and eosin quality control records were not provided to the surveyor when requested on 01/09/2022. Review of the laboratory procedure for hematoxylin and eosin revealed the procedure did not include instructions for Hematoxylin and Eosin quality control documentation. Record review of four out of four patient test results revealed the report did not contain Hematoxylin and Eosin quality control documentation. On 01/09/2024 at 01:05 PM, the Laboratory Manager confirmed that the laboratory did not have Hematoxylin and Eosin quality control documentation.</p>