

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2054123	(X3) Date Survey Completed 11/19/2024
Name of Provider or Supplier Southeastern Dermatology Group Pa	Street Address, City, State 2505 Harrison Ave, Panama City, 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 recertification survey was conducted at Southeastern Dermatology Group PA in Panama City, FL on 11/19/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on interviews and review of records and procedures, it was determined the laboratory failed to, for each day of use, verify test staining materials for intended reactivity to ensure predictable staining characteristics for two of two years (2023-2024). The findings include: The Laboratory Policy and Procedure manual approved by the Laboratory Director on 1/9/2024 included Quality Control Policies and Documentation which stated "stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is recorded on a QC (Quality Control) log." A review of QC logs for 2023-2024 failed to document approval of QC slide reactivity by one of one personnel, Testing Personnel #A (the physician). The Histology Tech on 11/19/24 at 10:50 am and Laboratory Administrator on 11/19/2024 at 10:55 am confirmed the failure to document the intended reactivity each day of use by Testing Personnel #A for 2023-2024.</p>