

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2217304	(X3) Date Survey Completed 04/12/2024
Name of Provider or Supplier Charlotte Dermatology Pa	Street Address, City, State 8208 Devon Court, Ste B, Myrtle Beach, SC	
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 initial survey was conducted at Charlotte Dermatology, PA on 04/12/2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Specific standard level deficiencies cited are as follows:
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient reports, review quality assurance records, and staff interviewed, the laboratory failed to document positive and negative reactivity for 2 of 2 Periodic Acid Schiff (PAS) stained slides. Findings included: 1. During a review of records on 04/12/2024 at 11:45am, the surveyor observed that special stains were reported on patients results: a. Patient #3 under microscopic examination "A PAS stain was performed." b. Patient # 4 under microscopic examination "A PAS stain was performed." There was no documentation of acceptable positive and negative reactivity. 2. Review of the laboratory's quality assurance records revealed no documentation of reactions of the control slide for PAS. 3. During an interview on 04/12/2024 at 12:49 pm, lab manager confirmed that the reaction to PAS stain was not documented on either patient reports or quality control sheet. No documentation provided.</p>