

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0685111	(X3) Date Survey Completed 05/08/2025
Name of Provider or Supplier Skin And Cancer Associates Llp	Street Address, City, State 20601 E Dixie Hwy Ste 300, Aventura, 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 validation survey was conducted at SKIN AND CANCER ASSOCIATES LLP on May 08, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records and staff interview, the Laboratory failed to follow the laboratory policy for review of the slide stain quality control since March 2024. The findings included: 1-Review of the CMS-209 form signed by the Laboratory Director (LD) on 05-08-2025 revealed that there were six (TP1 (LD), TP2, TP3, TP4, TP5, and TP6) testing personnel. 2-Review of the daily QC records showed that the documentation had been signed by the technicians for all days of testing in March 2024 and 05/01/2025, 05/02/2025, 05/5/2023, 05/06/2023, 05/07/2025, 05/08 /2025. 3-Review of the procedure QC Monitoring of Quality Control Testing stated, "The Quality Control process is documented on the stain Quality Control Log and signed by the Laboratory Director or designee." 4-Interview on 05/08/2025 at 2:43 PM with the Laboratory Director, confirmed that the daily QC records were signed by the designee, who was not a pathologist.</p>