

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0978532	(X3) Date Survey Completed 03/25/2026
Name of Provider or Supplier Skin & Cancer Associates Llp	Street Address, City, State 7800 Sw 87th Ave Ste 300c, Miami, 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 SKIN & CANCER ASSOCIATES LLP from 03/19/2026 to 03/25/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory used an expired Bio SB Mohs Mouse/Rabbit Poly Detector Plus DAD HRP Brown Detection System in (Melanocytic Marker Immunohistochemistry (IHC stain) MART-1 for cryostat sections since November 2025. Findings included: 1-During the laboratory tour on 03/19/2026 at 11:30 AM, the surveyor found that the laboratory had in refrigerator two boxes of Bio SB Mohs mouse/Rabbit Poly Detector Plus DAD HRP Brown: Box#1 in use with lot number 03555 TWJ 24 and expiration date 07/25 and Box#2 not in use with lot number 03550PH045 and expiration date 08/01/2027. 2- Review of Manufacturer Instructions (MI) for the Mohs Mouse /Rabbit Poly Detector Plus DAD HRP Brown Detection System, revealed that in the "Stability "section stated "This product is stable up to the expiration date on the product label. Do not use after expiration date listed on the package label." 3-Patient record review revealed that the laboratory tested two patients with the expired Box#1 in the following dates: P#1 (11/14/2025) and P#2 (01/16/2026). 4-During an Interview on 03/19/2026 at 11:450 AM, the consultant confirmed that the laboratory used the expired kit to test two patients in the dates listed above.</p>

D5601**HISTOPATHOLOGY**

CFR(s): 493.1273(a)(f)

(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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have documentation of the acceptability of the positive and negative Quality Control (QC) slides for Melanocytic Marker Immunohistochemical (IHC) stain (MART-1) since 03/14/2025 and for 6 patients. Findings included: 1-The laboratory used the "Melanoma Quality Control Slides" (MQCS) log to record the acceptability of the daily IHC stain (positive and negative controls). Review of the MQCS log for 2025 revealed that the log was not signed by the Mohs surgeon. There was no record for MCQS log for 2026. 2-Review of "MOHS LOG" for 2025 and 2026 revealed the following testing dates and patients tested with MART-1 IHC stain: 03/14/2025 (one patient), 04/11/2025 (one patient), 05/23/2025 (one patient), 07/18/2025 (one patient), 11/14/2025 (one patient) and 01/16/2026 (one patient). 3-During an interview on 03/19/2026 at 11:50 AM the Office Consultant confirmed that the laboratory failed to have records of the acceptability of the positive and negative controls for the staining days that the laboratory used MART-1 stain and that the laboratory tested 6 patients with no documentation of the acceptability of the positive and negative control for MART-1.