Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0685911	09/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Skin And Cancer Associates Llp	1460 North University Dr, Coral Springs, 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 AND CANCER ASSOCIATES LLP on September 10, 2025 to September 15, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6168 493.1487 Condition: Testing Personnel
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to store 100% Reagent Alcohol, 10% Formalin Fixative and Xylenes according to Mercedes Scientific product label, and Ammonium Hydroxide 28% according to the EKI CHEM product label since 01/02/2025. The findings included: 1-During a tour of the laboratory on 09 /10/2025 at 10:45 AM, observed 500ML bottle with about 80% fill of Ammonium Hydroxide 28%, 1/4 gallon 100% Reagent Alcohol, 3/4 gallon 10% Formalin Fixative, and one 2/3 gallon Xylenes under the stainer bench cabinet. 2-Review of product labels for four out of six reagents stored under the stainer bench revealed the following: a) Ammonium Hydroxide 28% #1625-500ML stated "STORAGE /DISPOSAL: Store locked up." b) 100% Reagent Alcohol # MER 1200 - 1 Gallon stated "STORAGE: Store locked up." c) 10% Formalin Fixative # MER 44991GL - 1 Gallon stated "STORAGE: Store locked up." d) Xylenes # MER 1250 - 1 Gallon stated "STORAGE: Store locked up." 3-During interview on 09/10/2025 at approximately 10:55 AM, the TP3 admitted the reagents were not locked up after open, since started working in the laboratory full time.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of Histopathology testing at least twice annually for 1 (2024) out of 2 years (2024-2025) reviewed. Findings included: 1. Personnel records reviewed revealed that in the Histopathology section there were three testing personnel TP1 (laboratory director), TP2 (Mohs doctor), and TP3 (histology technician) as per CMS 209 Form. 2. Review of Subpart I, 42 CFR Part 493.901 through 493.959 revealed that there was no approved proficiency testing programs for the interpretation of stained tissues. 3. Review of the laboratory procedure stated in Section 8 Proficiency Testing (PT) "Semi-annually, two cases will be randomly selected by the histotechnologist and will be submitted to a Board-Certified Dermatopathologist/Dermatologist for review." 4. Review of the Quality Assurance (QA) peer review found that peer review for Histopathology was done for TP1 and TP2 on 12/09/2024. 5. During an interview on 09/10/2025 at 1:18 PM, TP3 confirmed there was one QA peer review documented for the year 2024. The Laboratory did not provide documentation for a second PT event in 2024.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have the Technical Supervisor (TS) or a designee document direct observation of patient testing during competency evaluation for the one testing personnel (TP2) for year 2024. Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 08/14 /2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC), TS/General Supervisor (GS) and TP1 for Histopathology subspecialty. The laboratory also had TP2 and TP3. 2-Review of personnel records revealed that annual competency for TP2 (Mohs Surgeon) for the Histopathology subspecialty, with patient testing observed by the LD/GS was last performed on 11/12/2023. 3- During an interview on 09/10/2025 at 12:32 PM, TP3 admitted that the competency assessment for the Histopathology subspecialty have not been performed for 2024.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed perform initial and six-month competency evaluations for one out of three testing personnel (TP) in the Histology laboratory during the first year (2025). Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director on 08/14/2025, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC), TS/General Supervisor (GS) and TP1 for Histology laboratory. The laboratory also had TP2 and TP3. 2-Review of personnel records revealed that there was no initial and no six month competency evaluation for TP3 (Histology Technician) for patient testing observed by the TS. 3- Email from Office Manager on 09/15/20205 at 2:51 PM confirmed that TP3 was trained on the job and started full-time on 01/02/2025. See tag 6171. 4- During an interview on 09/10/2025 at 12:32 PM, TP3 admitted that the competency assessment for the Histopathology subspecialty had not been performed for 2025.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to verify the education of 1 of 3 Testing Personnel (TP) performing the Histopathology testing. See D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

	(b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the education of one out of three testing personnel (TP) since 01/02/2025 until 09/15/2025. Findings included: 1-Review of FORM CMS-209 Laboratory Personnel Report dated and signed by the Laboratory Director on 08/14/2025 listed three TP (TP1, TP2, TP3). 2-Review of employee files revealed that TP3 had a High school diploma from Puerto Rico is Spanish, with no certificate of translation equivalency. Additionally, TP3 had a histology Mohs technician training certificate of completion dated 06/20/2016. 3- Email from Office Manager on 09/15/20205 at 2:51 PM stated that TP3 did not have a state of Florida (technician) license but was trained on the job and started full time on 01/02/2025. 4-During an interview on 09/10/2025 at 1:11 PM with TP3 stated was not aware of the minimum education requirement for high complexity testing.