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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D1103654 | (X3) Date Survey Completed 07/11/2025 |
| Name of Provider or Supplier Skin And Cancer Associates Llp | Street Address, City, State 2925 Ne 199 Street, Ste 205, 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 |
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| D0000 | An announced CLIA recertification survey was conducted at SKIN AND CANCER ASSOCIATES LLP from 07/02/2025 to 07/11/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5400 CFR 493.1250 Condition: Analytic Systems. |
| D5400 | <p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and Staff interview, the Laboratory failed to stop using expired reagents in Histopathology testing. Refer to D5417.</p> |
| 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 expired reagent in use: 1 bottle of Eosin Y Stain Solution, 1 % expired on 02/21/2025 and 2</p> |

bottles of Hematoxylin Solution Gill III one expired on 03/13/2024 and the second one expired on 05/25/2025, both solutions used for the Hematoxylin and Eosin (H&E) stain. This is a repeated deficiency from the recertification survey completed on 11/06/2023. Findings Included: 1-During laboratory tour on 07/02/2025 at 10:30 AM, the surveyor found in the fire safety cabinet the following expired reagents: 1 liter bottle with approximately 800 ml of Eosin Y Stain Solution 1 %, lot number 2304107 expired since 02/21/2025 and labeled as Waste, two one-liter bottles of Hematoxylin Solution Gill III, also marked as Waste, one with Lot number 2206912 expired on 03/13/2024 and the volume left was approximately 100 ml and the second bottle was unopened with lot number 2311814 expired on 05/25/2025. 2-Review of reagent log for 2023, 2024 and 2025, revealed that the reagents registered matched the ones found in the fire cabinet. The laboratory had no other record of Eosin and Hematoxylin solutions. 3-Patient log review revealed that the laboratory performed H&E stain in the following dates: 03/04/2025 (9 patients), 03/05/2025 (7 patients), 03/21/2025 (5 patients), 04/25/2025 (14 patients), 05/30/2025 (6 patients), 06/20/2025 (11 patients) for a total of 52 patients that were tested using expired reagents. 4-During an interview on 07/02/2025 at 10:40 am with the Laboratory Consultant, she confirmed that the laboratory used the expired reagents listed above and they notified the office, no purchase documentation was available.