

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1103654	(X3) Date Survey Completed 11/06/2023
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
D0000	A recertification survey conducted on 11/06/2023 found the SKIN AND CANCER ASSOCIATES LLP clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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 interview, the laboratory failed to stop using the following expired reagents: Tissue Freezing Medium and the Liquimount from 01/01/2022 to present. Findings included: During laboratory tour on 11/06/2023 at 10:00 AM, the surveyor found that the laboratory had the following expired reagents in use: - One open bottle and four unopened bottles of Mercedes Scientific Tissue Freezing Medium with Lot 85814 expired since 07/2021. There were no records of the reception and date of initial use of this reagent in the reagent log. - One open bottle of Mercedes Scientific Liquimount cover slipping with Lot 114845 and expired since 01/31/2023. -The laboratory tested 197 patients using the expired reagents since 01/01/2022 to present. -Review of the Quality Control policy from procedure Manual signed by the Laboratory Director on 09/15/2023 revealed that expired reagents will be disposed properly. During an interview on 11/06/2023 at 11:00 AM, the Office Assistant confirmed that the laboratory used the expired reagents for the period of reference.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p>

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document all maintenance activities for 2 out of 26 testing days since 01/01/2022 to present. Findings included: Review of Patient Log for 2022 and 2023 revealed that the laboratory tested 11 patients on 10/07/2022 and 8 patients on 01/13/2023. The laboratory document "H + E Stainer Log", did not have documentation showing the Hematoxylin and Eosin (H&E) stain used was Added, Rotated Up, Filtered or Changed on 10/07/2022 and on 01/13/2023. Review of Logs: Mohs Quality Control for 2022 and Mohs Laboratory Quality Control for 2023, revealed that the laboratory failed to document Daily Cryostat Maintenance on 10/07/2022 and 01/13/2023. During an interview on 11/06/2023 at 11:30 AM, the Office Assistant confirmed that the laboratory failed to have documentation of the daily maintenance of the H&E stain and Cryostat for the days of reference.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for 2 out of 26 testing dates from 01/01/2022 to present. Findings included: The laboratory used the "Quality Control Slide" Log in 2022 and the "Quality Control Staining" Log for 2023 to record the acceptability of the H&E stain. Review of the QC logs revealed that the laboratory had no documentation of the acceptability of the QC slides for 10/07/2022 (11 patients tested) and for 01/13/2023 (8 patients tested) During an interview on 11/06/2023 at 11:30 AM the Office Assistant confirmed that the laboratory failed to document the acceptability of the Daily QC slide for H&E stain on the days listed above.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly,

accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Technical Supervisor (TS) failed to evaluate the competency for five out of five testing personnel (TP) for the two years reviewed. Findings included: -Review of the FORM CMS-209 signed by the Laboratory Director (LD) on 11/03/2023 revealed that the LD, Clinical Consultant (CC), TS, General Supervisor (GS) was also TP#A. The laboratory had five TP (TP#A, TP#B, TP#C, TP#D and TP#E). -Review of personnel records revealed that there were no competencies evaluations performed during 2022 and 2023. During an interview on 11/06/2023 at 11:35 AM with Office Assistant, she confirmed that the TS failed to perform the competencies listed above.