| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D2170188 | 03/21/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Texas Skin Center Kingwood | 350 Kingwood Medical Dr Ste 220, Kingwood, TX | |

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** | The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The laboratory was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. |
| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's observations and staff interview, it was determined the laboratory failed to ensure the safety of the laboratory by incorrect storage of 1 of 6 reagents (Alcohol) used in Mohs testing. Findings included: 1. Surveyor observations on 03/21 /2023 at 10:25 hours in the laboratory revealed the following Alcohol reagent stored in an under the counter cabinet in the laboratory: Mercedes Scientific 100% Reagent Alcohol Lot number: 2210920 Expiration date: 2024-10-25 2. Review of the label of the of the above alcohol reagent revealed: "Highly flammable liquid and vapor." And, "STORAGE... Store locked up in a well ventilated place. Keep cool" 3. In an |

| | |
|---|---|
| | interview on 03/21/23 at 10:25 hours in the laboratory, the laboratory's Testing Person number 2 (as described on submitted Form 209) confirmed the above findings. |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and procedures, review of laboratory's documentation for twice annual accuracy verification for Mohs testing for 2021 and 2022, and staff interview, it was determined the laboratory failed to document, per laboratory policy, singoff of evaluation by the laboratory director for 3 of 4 reviewed twice annual accuracy verification events in 2021 and 2022. Findings included: 1. Review of laboratory's policy "Quality Assurance and Training for the Texas Skin Center" (last reviewed on 07-14-2021) revealed: "Outside QA The verification of internal laboratory results will be accomplished by utilizing an outside Quality Assurance review process to validate case results... Twice per calendar year the histotechnologist in the laboratory will prepare a validation packet for review..." And, "Acceptable Review Scores The laboratory will consider any period review with a final score BELOW 70% as a FAILED QA Validation Review. A passing QA Validation total will be notated to the records from the period, and the results stored in the Laboratory Manual. The histotechnologist will have the Laboratory Director sign the review and it will be considered completed." 2. Review of the laboratory's documentation for twice annual accuracy verification for Mohs testing for 2021 and 2022 revealed the following 3 of 4 reviewed accuracy verification events did not have laboratory director's signoff of the event's evaluations, as per its own policy: Event 2 of 2021 (Period 21 B) Cases included: TSCKW2021-140 TSCKW2021-162 TSCKW2021-187 TSCKW2021-224 TSCKW2021-263 TSCKW2021-291 Score: Not calculated There was no documentation of a passing QA Validation total (final score) or evaluation's signoff by laboratory director. Event 1 of 2022 (Period 22 A) Cases included: TSCKW2022-228 TSCKW2022-257 TSCKW2022-294 TSCKW2022-322 TSCKW2022-359 TSCKW2022-410 Score: Not Calculated There was no documentation of a passing QA Validation total (final score) or evaluation's signoff by laboratory director. Event 2 of 2022 (Period 22 B) Cases included: TSCKW2022-022 TSCKW2022-048 TSCKW2022-075 TSCKW2022-136 TSCKW2022-153 TSCKW2022-193 Score: Not calculated There was no documentation of a passing QA Validation total (final score) or evaluation's signoff by laboratory director. 3. In an interview on 03/21/23 at 10:25 hours in the laboratory, the laboratory's Testing Person number 2 (as described on submitted Form 209) confirmed the above findings. |