| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D2059259 | 08/29/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Houston Skin Associates | 1401 Binz St, Suite 200, Houston, 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 |
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| **D0000** | An announced survey of the laboratory was conducted on 08/29/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility 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. |
| **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/procedures, twice annual test accuracy verification (proficiency testing) records and staff interview, the laboratory failed to document evaluation of accuracy for one of one 2022 test accuracy verification reviewed, as per its own policy. Note: The laboratory amended its "Proficiency Testing Policy" through an addendum issued 06/30/2022 to clarify diagnosis comparison. Findings included: 1. Review of the laboratory's Proficiency Testing (PT) policy (last amended 06/30/2022) revealed the laboratory sent out it's slides for verification/evaluation to an outside provider. The following instructions were included on the facility's PT form: "Please check each slide and comment if you "Agree" or "Disagree" with the diagnosis. In the event that the diagnosis does not match, an identical slide will be sent to another outside laboratory or pathologist for |

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| | microscopic examination." 2. Review of laboratory's PT records (cases MB22-015 and MB22-019 sent for evaluation on 07/07/2022) completed on 08/29/2022 revealed there was no comment of "Agree" or "Disagree" for diagnostic interpretation added to the evaluation/verification of test results. No original test interpretation documentation was included. There was no documentation of the Laboratory Director's review of the external assessment to evaluate laboratory's performance or whether corrective actions were needed. 3. In an interview on 08/29/2023 at 0945 hours in the laboratory, the facility's Clinic Manager (as indicated on submitted Survey Entrance Conference document), after review of the data, confirmed the findings. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's quality control (QC) records, reagent shipment logs, policies/procedures, patient test logs, laboratory's test volumes and staff interview, the laboratory failed to document verification of reactivity for each new batch/lot number /shipment for one of one mycology reagents, Potassium Hydroxide (KOH). Findings included: 1. Review of laboratory's quality control (QC) records for 2021 and 2022 revealed the laboratory did not document verification of reactivity of new batch/lot number/shipment of KOH reagents received in the laboratory. 2. Review of laboratory's reagent shipment logs revealed there was no record of when KOH shipments were received or placed in use. 3. Review of laboratory's policy/procedure "KOH Examination" revealed there were no protocols addressing KOH reactivity verification for each new batch/lot number/shipment of the reagent. 4. Review of the KOH patient test logs revealed there was no documentation of lot numbers or expiration dates of the KOH reagent in use, so it was not possible to ascertain when the reagent was placed in use. 5. Review of the laboratory's test volumes reveled the laboratory performed approximately 50 KOH procedures annually. 6. In an interview on 08/29/2023 at 1030 hours in the laboratory, the facility's Clinic Manager (as indicated on submitted Survey Entrance Conference document), after review of the data, confirmed the findings. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of laboratory's quality control (QC) records, patient test records and staff interview, the laboratory failed to document QC for Hematoxylin and Eosin (H&E) stain for one of ten reviewed days H&E stain was in use in 2022. Findings included: 1. Review of 2022 QC records for the H&E stain revealed there was no documentation of QC performance on 04/26/2022, one of ten days H&E stain was used in patient testing. 2. Review of patient test records for 04/26/2023 revealed the following patient's sample was tested without H&E QC documentation: Case number: MB22-017 Surgical site: Left Nasal Sidewall Diagnosis: BCC (basal cell carcinoma) 3. In an interview on 08/29/2023 at 1000 hours in the laboratory, the facility's Clinic Manager (as indicated on submitted Survey Entrance Conference document), after review of the data, confirmed the findings. |
| **D5785** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(3)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's temperature logs, policies/procedures and staff interview, the laboratory failed to document corrective action for out-of-range laboratory defined room temperature for 5 of 12 days reviewed for December 2021 to June 2022. Findings include: 1. Review of laboratory's temperature logs revealed the laboratory defined laboratory's acceptable room temperature range as 68-76F. 2. Further review of the temperature logs revealed the laboratory's room temperature was out of acceptable range on the following days: Date: Temperature: 12/07/2021 67F 12 /21/2021 64F 03/01/2022 65F 03/15/2022 67F 04/19/2022 67F There was no documentation of corrective action for any of the above out-of-range temperatures. 3. Review of laboratory's policies/procedures revealed there were no protocols in place addressing out-of-range room temperatures. 4. In an interview on 08/29/2023 at 1015 hours in the laboratory, the facility's Clinic Manager (as indicated on submitted Survey Entrance Conference document), after review of the data, confirmed the findings. Key: F = Degrees Fahrenheit |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's quality control records, corrective action records and staff interview, the laboratory's quality assurance (QA) failed to identify and correct issues with quality control and corrective actions. Refer to D5471, D5473 and D5785. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9) |

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| | The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's personnel records, personnel competency assessment documents, and staff interview, the Technical Consultant (TC) failed to document competency assessment for potassium hydroxide (KOH) preparations at least semiannually within the first year of employment for one of three testing personnel, Testing Person number three (TP3). Findings included: 1. Review of laboratory's personnel records revealed TP3 was hired in August of 2022. 2. Review of personnel competency assessment documents for 2022 and 2023 revealed TP3 did not have documentation of competency assessment for KOH preparations. 3. Further review of the competency assessment document revealed: "The Technical Supervisor must evaluate 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." And, "Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens." Note: Multiple competency assessment documents completed in 2022 did not have the testing personnel's name, or the test/procedure listed for which the competency was performed. This made it impossible to ascertain who did or did not have their competency assessed. 4. In an interview on 08/29/2023 at 0930 hours in the laboratory, the facility's Clinic Manager (as indicated on submitted Survey Entrance Conference document), after review of the data, confirmed the findings. |
| **D6091** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iii)<br><br>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's test accuracy verification (proficiency testing) records and staff interview, the Laboratory Director failed to ensure proficiency testing results are reviewed/evaluated by appropriate personnel. Refer to D5221. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory's quality control records, temperature logs, corrective action logs, policies/procedures and staff interview, the Laboratory Director failed to ensure laboratory's quality assurance was maintained. Refer to D5791. |