Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1046365	02/22/2022
Name of Provider or Supplier	**Street Address, City, State**	
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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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: I. Based on review of laboratory policy, the laboratory's twice annual accuracy assessments for MOHs testing, and confirmed in staff interview, the laboratory failed to have documentation of evaluating the results of the peer reviews to determine accuracy for 1 of 2 events in 2021 and 1 of 1 events in 2022. Findings: 1. Review of the laboratory's policy manual stated: "Quality Assurance Program ... Comparison of Test Results: Twice annually, slides from randomly chosen Mohs and in-house biopsy specimens will be sent to a dermatopathologist for evaluation of slide adequacy and second opinion of results from the Mohs surgery procedure. A request will be made

for consulting slides to be returned to XX [laboratory director] and accompanying reports will be filed in the Mohs laboratory as part of the quality assurance record." 2. Review of the laboratory's twice annual accuracy assessment for 2021 and 2022 revealed the following: 05/05/2021 Accession number: 21-275AC "I have evaluated sections 21-275 A-C from your patient XX for quality assurance, and the following are my evaluations: 1. The thickness of the section is adequate to provide histologic interpretation of the sections. There are no processing artifacts that would obscure critical findings. The staining is of excellent quality demonstrating contrast between the epithelium and connective tissue. 2. The sections are oriented in a fashion that allows complete assessment of the entire specimen from the epidermis of subcutaneous fat, which is the goal of Mohs micrographic surgery. The ink is present on all appropriate margins, and there are no significant holes. 3. The sections demonstrate sebaceous hyperplasia with scar and no residual neoplasm, which presumably is the interpretation that was rendered in this case. In summary, the sections are of excellent quality and do accomplish the goals of micrographic surgery." The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the laboratory director (who also served as technical supervisor) for accuracy. Note: The laboratory failed to perform a second twice annual accuracy assessment in 2021. Refer to D5217, II. 02/15/2022 Accession number: 22/0028 A-C "I have evaluated sections from your patient for quality assurance, and the following are my evaluations: 1. The thickness of the section is adequate to provide histologic interpretation of the sections. There are no processing artifacts that would obscure critical findings. The staining is of excellent quality demonstrating contrast between the epithelium and connective tissue. 2. The sections are oriented in a fashion that allows complete assessment of the entire specimen from the epidermis of subcutaneous fat, which is the goal of Mohs micrographic surgery. The ink is present on all appropriate margins, and there are no significant holes. 3. The sections demonstrate scar and no residual neoplasm, which presumably is the interpretation that was rendered in this case. In summary, the sections are of excellent quality and do accomplish the goals of micrographic surgery." The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the laboratory director (who also served as the technical supervisor) for accuracy. The laboratory failed to have documentation of evaluating the results of the peer reviews to determine accuracy for the above-mentioned testing events. 3. During an interview on 02/22/2022 at 9:45 am, the Histotechnician confirmed the above findings. II. Based on review of laboratory policies, Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology (MOHs) procedures at least twice annually for 1 of 2 testing events in 2021. Findings: 1. Review of the laboratory's policy manual stated: "Quality Assurance Program ... Comparison of Test Results: Twice annually, slides from randomly chosen Mohs and in-house biopsy specimens will be sent to a dermatopathologist for evaluation of slide adequacy and second opinion of results from the Mohs surgery procedure. A request will be made for consulting slides to be returned to XX [laboratory director] and accompanying reports will be filed in the Mohs laboratory as part of the quality assurance record." 2. Review of the CMS-116 form submitted on the day of the survey by the laboratory revealed the laboratory performed histopathology (MOHs) procedures. 3. Review of the laboratory's proficiency testing records for 2021 revealed the laboratory failed to verify the accuracy of histopathology (MOHs) procedures for 1 of 2 events in 2021. 4. During an interview on 08/26/2021 at 9:45 am, the Histotechnician was asked for documentation of twice annual accuracy histopathology procedures for 2021. The Histotechnician stated that there was only one event for histopathology (MOHs) in

	2021, confirming the above findings.