

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2057071	<b>(X3) Date Survey Completed</b>  06/11/2021
<b>Name of Provider or Supplier</b>  Texas Dermatology And Skin Cancer Center	<b>Street Address, City, State</b>  5757 Warren Parkway, Suite 330, Frisco, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS (Center for Medicaid &amp; Medicare Services) 116 form, laboratory proficiency testing records, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures at least twice annually for 1 of 2 testing events in 2020. Findings: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed KOH procedures. 2. Review of the laboratory's proficiency testing records for 2020 revealed the laboratory performed proficiency testing for KOH on 03/10/2020. There were no other documented proficiency testing events in 2020. The laboratory failed to verify the accuracy of KOH procedures at least twice annually in 2020. 3. During an interview on 06/17/2021 at 10:05 am, the histotechnician was asked for documentation of twice annual accuracy for KOH procedures in 2020. The histotechnician stated there was only one KOH accuracy assessment performed in 2020, confirming the above findings.</p>

**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 review of laboratory policy, CMS (Center for Medicaid & Medicare Services) 116 form, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain. Findings: 1. Review of laboratory policy "Histopathology-Mohs Surgery" revealed: "6. Quality Control 6.1.1 All slide and reports are available for review by laboratory accrediting agencies. 6.1.2 Reports for cases sent for consultation are maintained as part of the patient record. 6.1.3 The laboratory participates in reciprocal reading of slides with "XX", M.D., dermatopathologist." The procedure failed to define the staining characteristics for intended reactivity for the H&E stain. 2. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory had an annual test volume of 200 histopathology cases. 3. During an interview on 06/11/2021 at 11:15 am, the histotechnician confirmed the above findings.