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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>45D2179365      | <b>(X3) Date Survey Completed</b><br>05/04/2022 |
| <b>Name of Provider or Supplier</b><br>Texas Skin Surgery Center   | <b>Street Address, City, State</b><br>3585 National Dr Suite 150, Plano, 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>   |
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| <b>D0000</b>              | An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, 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 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. |
| <b>D5429</b>              | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on direct observation, review of manufacturer's instructions, maintenance records from 03/2022-04/2022 and confirmed in staff interview, it was revealed the laboratory failed to have documentation of performing weekly maintenance on the Leica CM1520 Cryostat for 7 of 8 weeks reviewed in 2022. Findings Included: 1. During a tour of the facility on 05/04/2022, the inspector observed one Leica CM1520 Cryostat currently in use. 2. Review of manufacturer's instructions for the Leica CM1520 Cryostat (Version 1.3) revealed the following: "9.3.1 General maintenance</p>  |

instructions: Weekly: Oil the plastic coupling with a drop of cryostat oil; Lubricate the specimen cylinder" 3. Random review of laboratory maintenance records for the Leica CM1520 Cryostat revealed the following weeks weekly maintenance was not performed: March 2022: Week 1- 03/01/2022 through 03/04/2022 Week 2- 03/07/2022 through 03/11/2022 Week 3- 03/28/2022 through 03/31/2022 April 2022: Week 4- 04/04/2022 through 04/08/2022 Week 5- 04/11/2022 through 04/15/2022 Week 6- 04/18/2022 through 04/22/2022 Week 7- 04/25/2022 through 04/29/2022 4. During an interview on 05/04/2022 at 11:30 a.m. with the histotechnician, the histotechnician confirmed the above findings.

**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 the laboratory's policy, Quality Control (QC) logs, 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 Hematoxylin & Eosin (H&E) stain for 18 of 18 days in March 2022 and 20 of 20 days in April 2022. Findings Included: 1. Review of laboratory policy, "Staining Protocol" (Reviewed by the Laboratory Director on 08/15/2016) revealed the following: "4. The first slide of the day will act as a test slide and will be run through the stainer for (Laboratory Director/Testing Person 2)'s review and approval. If necessary, the reagents will be adjusted." The policy did not define intended reactivity of the H&E stain to ensure predictable characteristics. 2. Review of laboratory QC logs, "Histopathology Quality Control- Daily Test Slide Log" revealed the following: The log had a column for "Stain Acceptable?" and each day QC was documented with a "Yes" in the column. Further review of the QC logs revealed the following days QC was performed and documented with a "Yes": March 2022: 03/01/2022; 03/02/2022; 03/03/2022; 03/04/2022; 03/07/2022; 03/08/2022; 03/09/2022; 03/10/2022; 03/11/2022; 03/21/2022; 03/22/2022; 03/23/2022; 03/24/2022; 03/25/2022; 03/28/2022; 03/29/2022; 03/30/2022; 03/31/2022 April 2022: 04/01/2022; 04/04/2022; 04/05/2022; 04/06/2022; 04/07/2022; 04/08/2022; 04/11/2022; 04/12/2022; 04/13/2022; 04/14/2022; 04/15/2022; 04/18/2022; 04/19/2022; 04/20/2022; 04/21/2022; 04/22/2022; 04/25/2022; 04/26/2022; 04/27/2022; 04/28/2022 The laboratory failed to document the H&E stain for intended reactivity to ensure the predictable staining characteristics. 3. Review of test volume records provided by the laboratory included a total annual volume of 2,210 histopathology tests. 4. During an interview on 05/04/2022 at 11:28 a. m. with the histotechnician, the histotechnician confirmed the above findings.