

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2131822	(X3) Date Survey Completed 06/13/2018
Name of Provider or Supplier South Texas Skin Cancer Center	Street Address, City, State 813 Paris Street, Castroville, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. 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. 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.
D5217	<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 laboratory's policies, review of the laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for Histology stains in 2017. The findings were: 1. A review of the laboratory's policy titled "MOHS Histopathology quality Assurance" revealed: "Histologic test will be reviewed by an independent reviewer. Cases will be selected that occur at six(6) month intervals...The reviewer will look at the biopsy specimen and record a diagnosis...The reviewer will look at the Mohs specimens and record a diagnosis while reviewing histologic quality, to include: adequate staining, adequate thickness, epidermal presence on the first stage, and visible dye on cut margins." 2. A review of the laboratory's records revealed the</p>

laboratory had documentation of the following accuracy assessments performed June 12, 2018: a) Biopsy case: 2017-CV-V-01 case: 2017-CV-V-02 case: 2017-CV-V-04 case: 2018-CV-V-3 case: 2018-CV-V-5 case: 2018-CV-V-06 b) Mohs case: 2017-CV-013 case: 2017-CV-27 case: 2017-CV-36 case: 2018-CV-03 case: 2018-CV-12 case: 2018-CV-39 3. The laboratory was asked to provide documentation of performing accuracy assessments for histology stains in 2017. No documentation was provided. 4. An interview with the administrator on 06/13/2018 at 1111 hours in the office revealed the laboratory had not performed accuracy assessments in 2017. This confirmed the findings.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, review of the laboratory's temperature records, and staff interview, it was revealed the laboratory failed to: A) monitor the cryostat temperature defined by its policy, and B) have documentation of monitoring room temperature and humidity levels for the laboratory in 2017. The findings were:
A) Cryostat 1. A review of the laboratory's policy titled "Equipment Maintenance Protocols" revealed the laboratory's defined acceptable temperature range for the operation of the cryostat was -17 degrees C to -22 degrees C. 2. A review of the laboratory's cryostat temperature monitor records from June 2017 to June 2018 revealed the laboratory monitored the following range for the cryostat: - 17 degrees C to -27 degrees C 3. Further review revealed the following days were the documented cryostat temperature was outside the laboratory's acceptable range as stated in its policy: Date Temp 06/28/17 -23C 08/20/17 -23C 09/13/17 -24C 09/22/17 -24C 10/25/17 -24C 11/15/17 -25C 11/29/17 -24C 12/13/17 -23C 01/10/18 -23C 01/30/18 -23C 02/14/18 -23C 02/28/18 -23C 03/28/18 -23C 04/20/18 -23C 05/09/18 -23C 05/30/18 -23C 06/23/18 -23C 4. An interview with the administrator on 06/13/2018 at 950 hours in the office - after her review of the records- confirmed the findings. B) Room temp and humidity 1. A review of the laboratory's room temperature and humidity monitoring from June 2017 to June 2018 revealed the laboratory failed to have documentation of monitoring the environmental conditions in 2017. Testing was performed on the following days in 2017: 06/28/2017 08/20/2017 08/30/2017 09/13/2017 09/27/2017 10/25/2017 11/15/2017 11/29/2017 12/13/2017 2. The laboratory was asked to provide documentation of monitoring the room temperature and humidity in 2017. No documentation was provided. 3. An interview with the administrator on 06/13/2018 at 955 hours in the office - after her review of the records- confirmed the findings.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of supplies currently in use in the laboratory, and staff interview, it was revealed the laboratory failed to ensure expired supplies were not available for use. The findings were: 1. Surveyor observation of supplies currently in use by the laboratory on 06/13/2018 at 1045 hours identified the following expired supplies: 1 bottle Orange Tissue Marking Dye Lot: 051438 expiration: 01/2018 2. An interview with the histotechnologist on 06/13/2018 at 1103 hours in the laboratory revealed the expired bottle of orange dye was currently in use. This confirmed the findings.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, review of the laboratory's cryostat maintenance records, and staff interview, it was revealed the laboratory failed to have documentation of performing required maintenance. The findings were: 1. A review of the laboratory's policy titled "Equipment Maintenance Protocols" revealed the laboratory required daily, monthly, and yearly maintenance be performed on the cryostat. 2. A review of the laboratory's maintenance records from June 2017 to June 2018 revealed the laboratory revealed the laboratory documented the cryostat had been "cleaned" on the following days: 08/11/17 09/14/17 11/16/17 01/17/18 02/15/18 03/29/18 05/10/18 The records did not indicate if it was daily, monthly or yearly maintenance that had been performed. 3. Further review revealed the following days when testing was performed but maintenance was not documented: a) Daily 06/28/17 08/10/17 09/13/17 10/25/17 11/15/17 11/29/17 12/13/17 01/10/18 01/30/18 02/14/18 02/18/18 03/28/18 04/11/18 05/09/18 05/30/18 b) monthly June 2017 October 2017 December 2017 April 2018 4. The laboratory was asked to provide documentation of performing the missing maintenance. No documentation was provided. 5. An interview with the administrator on 06/13/2018 at 950 hours in the office - after her review of the records- confirmed the findings. 4. An interview with the administrator on 06/13/2018 at 0950 hours in the office - after her review of the records- confirmed the findings.