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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0695067 | (X3) Date Survey Completed 10/05/2020 |
| Name of Provider or Supplier Ttuhsc Dept Of Dermatology | Street Address, City, State 3601 4th Street Suite 4a100, Lubbock, 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 |
|---------------------------|---|
| 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 patient testing logs, accuracy assessments, and interview, the laboratory failed to ensure accuracy assessments were performed at least twice annually for Tzanck testing for 2 of 2 years reviewed. Findings follow. Review of patient testing logs showed 17 patients were tested for Tzanck from 2018 - 2020: 2 patients in 2020, 4 patients in 2019, and 11 patients since the last survey on Feb 19, 2018. No accuracy assessments for Tzanck testing were available for review at the time of the survey. Interview with the LVN with the initials SH on 10/06/2020 at 1610 hours in the office acknowledged they perform so few Tzanck testing. Interview with the LVN with the initials SH on 10/06/2020 at 1635 hours in the office confirmed accuracy assessments were not done for Tzanck smears. Key: LVN: Licensed Vocational Nurse</p> |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> |

This STANDARD is not met as evidenced by:
 Based on review of manufacturer's instructions, policy and procedures, temperature charts, and interview, the laboratory failed to define the acceptable range for room temperature and humidity. Findings follow. Review of Leica CM1860/CM1860UV - Cryostat Instructions for Use Manual, rev 10/2016, on page 18 stated under Chapter 4. Setting up the Instrument, "The place of installation must meet the following requirements: ... Room temperature consistently 18 degrees C (Celsius) - 35 degrees C... Relative humidity, maximum 60%". Review of the facility's policy and procedure titled Cryo Stat Policy under "Text" stated, "5) Ambient room temperature will be maintained 18 degrees Celsius to 35 degrees Celsius with Humidity less than 60%". No room temperatures were available for review for the Mohs laboratory. Other temperatures were recorded from March 2018-September 2020 but room temperature was not recorded. Humidity was recorded, but the acceptable range was not on the form, and the laboratory exceeded 60% humidity on 2 of 30 days from May through September 2020: June 24, 2020 and Sept 2, 2020. Interview with the LVN with the initials SH on 10/06/2020 at 1650 hours in the reception area confirmed room temperature was not documented on the days for Mohs and the acceptable ranges are not defined on the form. KEY: LVN: Licensed Vocational Nurse

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 observation and interview, the laboratory failed to ensure expired reagents were not used for testing. Findings follow. 1. Surveyor observed on 10/06/2020 at 1525 hours in the laboratory the Marking Dye available and in use for Mohs testing was expired. The Orange Tissue Marking Dye, Lot 063265, had an expiration date of 1/20, the Green Tissue Marking Dye, Lot 066442, had an expiration date of 5/20, the Red Tissue Marking Dye, Lot 066681, had an expiration date of 5/20, the Black Tissue Marking Dye, Lot 065951, had an expiration date of 4/20, the Yellow Tissue Marking Dye, Lot 064984, had an expiration date of 3/20. No other marking dyes were available for use in the laboratory. Interview with the LVN with the initials SH on 10/06/2020 at 1525 hours in the laboratory confirmed the marking dyes were expired. 2. Surveyor observed on 10/06/2020 at 1445 hours next to the microscope, the PMS Fungal/Tzanck Stain currently in use, Lot K18911, expired on 09-30-2020. Review of patient logs showed no patients were tested since its expiration. Interview with the LVN with the initials SH on 10/06/2020 at 1445 hours in the hall verified the stain was expired. 3. Surveyor observed on 10/06/2020 at 1530 hours in the laboratory 4 of 4 bottles of the Tissue Freezing Media Neg-50, Lot 410250, had an expiration of 10/2019. Interview with the histotechnician with the initials CP on 10/06/2020 at 1530 hours in the laboratory acknowledged he hasn't used it in a long time. Key: LVN: Licensed Vocational Nurse

D5805

TEST REPORT
 CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification,

either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview, the laboratory failed to include the facility address on the Mohs reports on 2 out of 3 reports reviewed. Review of the Mohs patient reports showed case #s 20-001 and 19-340 were missing the address of the location where the test was performed. Interview with the LVN with the initials SH on 10/06/2020 at 1715 hours in the office confirmed the test reports were missing the facility address. KEY: LVN: Licensed Vocational Nurse