

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2019934	(X3) Date Survey Completed 03/10/2021
Name of Provider or Supplier Tru-Skin Dermatology	Street Address, City, State 3101 Hwy 71 East Suite 203, Bastrop, 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
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, quality assurance records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS histopathology in 2020. Findings included: 1. Review of the laboratory's own policy titled ANNUAL PEER TO PEER REVIEW PROTOCOL (tru-skin) dated 04/04/2017 found: " annually, the tech or Lab Director will select a total off two mohs cases from one of the following clinics: Bastrop, LaGrange, Kerrville or Austin. They will choose one stage 1 case and one stage 2 case for submission within the current year. A completed case submission form, slides and a copy of the original mohs map will be submitted to Dr. [name omitted] or Dr. [name omitted] for final review. Once the Mohs surgeon has reviewed and signed off on the two cases, copies of both reports will be placed in each clinics PEER TO PEER REVIEW binder and recorded in the PEER TO PEER REVIEW calendar." 2. Review of peer review records found one case for the assessment of accuracy of results for the Mohs testing performed in 2020. Additional peer reviews were requested but not provided. 3. Interview of the practice manager conducted on March 10, 2021 at 11: 37 confirmed there were no other peer reviews for MOHS procedures conducted in 2020 available for review.</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when</p>

applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on observation, review of the instructions manual and interview, the laboratory failed to have the correct instructions manual for the Avantik QS12 Cryostat used for cutting specimens for Mohs testing and in use in the laboratory. Findings follow. Surveyor observed on March 10, 2021 at 1020 hours in the laboratory the cryostat being used was the Avantik QS12. The Instructions Manual provided to the surveyor and available in the laboratory for use was for the previous Cryostat, Leica CM1800 located in the Cryostat Quality Control Log Bastrop binder. Surveyor requested the Avantik QS12 operator's guide and one was printed during the survey. Interview with the Clinical Manager on March 10, 2021 at 1045 hours in the breakroom confirmed the Instructions Manual available to laboratory staff was for the previous Cryostat. Interview with the Practice Administrator on March 10, 2021 at 1115 hours in the breakroom confirmed the Avantik Cryostat was installed December 2018.

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 manufacturer's instructions, temperature charts, and interview, the laboratory failed to define the acceptable room temperature and humidity using the Avantik QS12 Cryostat used for cutting specimens for Mohs testing. Review of the Instruction Manual for the Avantik QS12 Cryostat, 04/2017, on page 2 under Technical Specifications stated for Temperature "41 to 95 degrees Fahrenheit" and Relative Humidity of "maximum 60% ". Review of the Room and Equipment Quality Control-Temperature Log Sheet from Jan - Dec 2020 showed the acceptable Room Temperature and Humidity was not defined. Interview with the Clinical Manager on March 10, 2021 at 1100 hours in the breakroom confirmed the acceptable criteria for room temperature and humidity were not defined.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	<p>This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to label their Cryostat oil vial, used to oil the microtone blade on the Cryostat used for cutting specimens for Mohs testing, lacked the identity of the solution, lot number, pour over date, and expiration, as applicable. Findings follow. Surveyor observed on March 10, 2021 at 1015 hours in the laboratory a vial containing a blue colored solution located in the cabinet. Interview with the Clinical Manager on March 10, 2021 at 1015 hours in the laboratory acknowledged the vial was cryostat oil and confirmed it was missing a label with the required information.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the test report in the patient chart, and interview, the laboratory failed to ensure the Mohs maps were attached to the patient's chart for 1 of 8 Mohs maps reviewed. Findings follow. Review of the Mohs maps in the patient chart showed B19-040 was missing the Mohs map test report. Interview with the Clinical Manager on March 10, 2021 at 1210 hours in the breakroom confirmed the Mohs map was not in the patient's chart and they were coming up with another procedure to store the Mohs map.</p>
<p>D6127</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least semiannually during the first year the individual tests patient specimens for one of two testing personnel performing Mohs procedures. The findings included: 1. Review of personnel files found no records of competency assessment performed at least semiannually in the first year of performing Mohs surgery for testing person two (hired 08/2019). 2. Interview of the practice manager conducted on March 10, 2021 at 11:12 AM confirmed there were no semiannual competency assessments available for review.</p>