Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1088909	03/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Tru-Skin Dermatology	2 St Marks Place Suite 140, La Grange, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, accuracy assessment records, and interview, the laboratory failed to perform twice annual accuracy assessments for Mohs histopathology in 2020 and 2019. Findings follow. 1. Review of the laboratory's policy titled ANNUAL PEER TO PEER REVIEW PROTOCOL (tru-skin) dated 04/04/2017 stated "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 2019. Additional peer reviews were requested but not provided. 3. Interview with the clinical manager on March 17, 2021 at 1030 hours in the breakroom confirmed there were no other peer reviews for Mohs procedures conducted in 2019 and 2020 available for review.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially

	available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policies and procedures, annual service records, maintenance logs, observation, and interview, the laboratory failed to perform annual and monthly maintenance, and failed to document daily maintenance performed as defined by the manufacturer using the Avantik Cryostat used to cut frozen sections for Mohs testing. Findings follow. I. Annual Service 1. Review of the Avantik QS11 Instruction Manual, 387779, under 5-3 Cleaning and Care of the Microtome stated, "NOTE: For the examination and readjustment of the microtome a routine maintenance should be performed by trained service technician once a year." 2. Annual service reports were requested but not provided. 3. Interview with the clinical manager on March 17, 2021 at 1045 hours in the breakroom confirmed annual service had not been performed. II. Air filter 1. Review of the Avantik QS11 Instruction Manual, 387779, under 5-4 Cleaning the Cooling Lamella stated, "open the cleaning opening via the attached tool (fig 29.1)... Remove the dust from the cooling lamella by means of a commercially available vacuum cleaner. NOTE: Carry out this cleaning in regular intervals. Thus extending the lifetime of the compressor." 2. Review of the Equipment Quality Control - Cryostat Maintenance Record from Jan - Dec 2020 did not have a column for cleaning the cooling lamella on the form. 3. Surveyor observation on March 17, 2021 at 1050 hours in the laboratory the cooling lamella on the cryostat was visibly dirty. 4. Interview with the histotechnologist on March 17, 2021 at 1045 hours in the breakroom confirmed she does not perform that maintenance. III. Oil/grease 1. Review of the Avantik QS11 Instruction Manual, 387779, under 5-3 Cleaning and Care of the Microtome stated, "after each shutting-off or cleaning of the cryostat, the cross roller bearing should be lubricated. By means of a pipette (fig 27.3) the cross roller bearings (fig 27.4) can be reached from an angle from behind below the housing (fig 27.1). Fill the pipette with a small amount of cryostat oil. Put one or two drops into the space (fig 27.2) of the cross roller bearings. The specimen clamping should be in the lower position. Also slightly lubricate the horizontal cylinder guide behind the specimen clamping." 2. Review of the laboratory's policy and procedure titled Daily Routine and Laboratory Daily Maintenance did not include oiling/greasing the cryostat. 3. Review of the Equipment Quality Control - Cryostat Maintenance Record from Jan - Dec 2020 did not have a column for oiling or greasing the cryostat. 4. Interview with the histotechnologist on March 17, 2021 at 1055 hours in the breakroom confirmed she does not document when she oils or greases the cryostat.
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 stain quality control records, and interview, the laboratory failed to verify the intended negative and positive reactivity for the Hematoxylin and Eosin (H&E) stain at least once each day of use. Findings follow. 1. Review of the laboratory's stain quality control record from 03/27/2020 - current, the laboratory initialed in the column for stain quality as documentation of H and E staining acceptability. 2. Additional documentation for H and E stain quality to ensure predictable staining was requested, but not provided. 3. Interview with the histotechnologist on March 17, 2021 at 1105 hours in the breakroom confirmed the physician was putting his initials instead of the stain quality of the control slide.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, quality assurance forms, and interview, the laboratory failed to follow their own policy for an ongoing mechanism to monitor, assess, and correct problems in the analytic systems. Findings follow. 1. Review of the laboratory's policy and procedure titled Quality Assurance stated, "Annually, the tech will check off the Quality Assurance Checklist. This will cover the quality assessment program for the procedures used in the office. The checklist is used to evaluate General Laboratory Systems, Pre-Analytic Systems, Analytic Systems, and Post-Analytic Systems. Any discrepancies found in the checklist during the annual check will be documented on a lab error form and kept in the manual..." 2. Review of the Annual Quality Assurance Checklist for 2019 and 2020 was requested but not provided. 3. Interview of the clinical manager on March 17, 2021 at 1130 hours in the breakroom confirmed Quality Assurance was not performed in 2019 and 2020.