Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2180046	12/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Austin Skin	1501 B Dorothy Nichols Rd, Smithville, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: I. Based on review of accuracy assessments, patient testing logs, and interview, the laboratory failed to perform twice a year accuracy assessments of its Frozen sections for the dermatopathology interpretations for 19 of 19 months reviewed. Findings follow. A. Accuracy assessments for the dermatopathology interpretations of Frozen sections were requested on December 15, 2021 at 1320 hours but not provided. B. Review of the Frozen Section Patient Log showed from 05/01/2020 - 01/27/2021 there were five cases/patients reported. C. Interview with the histotech on December 15, 2021 at 1320 hours in the laboratory confirmed accuracy assessments for Frozens were not performed. II. Based on review of patient testing logs, the laboratory's policies and procedures, accuracy assessments and interview, the laboratory failed to perform twice a year accuracy assessments of its Mohs testing (accuracy of the map and slides and agreement of clear margins on final stage) for two of three events reviewed. Findings follow. A. Review of patient test logs showed Mohs testing began 02/08/2020. B. Review of the laboratory's policy and procedure titled Dermatology - Mohs Program Laboratory Manual on page 56 under Proficiency Testing stated, "There is no approved proficiency testing program for Mohs Micrographic Surgery. In compliance with Section 493.1709, [Laboratory Director's name redacted] requests a fellowship - accredited Mohs surgeon or board-certified dermatopathologist with a CLIA certified laboratory to review a collection of slides for proficiency testing. Every 50 cases, an extra slide is cut and saved for this proficiency test. The quality of the slide and staining are also reviewed. The results are recorded and compared with [Laboratory Director's name redacted] diagnosis. This review is performed biannually and documentation is maintained in the laboratory Quality Assurance Log. C. Review

	of the Mohs accuracy assessments showed 21 Mohs cases were submitted for peer review 12/09/2021. D. Interview with the histotech on December 15, 2021 at 1300 hours in the laboratory confirmed all the cases were submitted for peer review at the same time and after a review of the findings confirmed twice per year accuracy assessments had not been performed.
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: I. Based on review of the internal temperature of the Avantik QS12, patient logs, and interview, the laboratory failed to document internal temperatures of the Avantik QS12 used to prepare slides for Mohs testing for ten of ten months reviewed. Findings follow. A. Review of the Cryostat QC Equipment Quality Control - Cryostat /Microtome Maintenance Record from Jan - Oct 2021 showed check marks on each day of Mohs testing. The bottom of the page stated "*Acceptable temperature range for thermometers -23 and -27 degrees Celsius, and is indicated by a check." B. Interview with the histotech on December 15, 2021 at 1145 in the laboratory confirmed the laboratory was having refrigeration trouble with the cryostat and it was being serviced. Interview with the histotech on December 15, 2021 at 1235 hours in the laboratory confirmed actual internal temperatures were not documented. C. Review of the Mohs Patient Log showed from Jan - Oct 27, 2021 530 Mohs cases were performed II. Based on review of the laboratory's temperature and humidity charts, patient logs, and interview, the laboratory failed to document the temperature and humidity of the laboratory for eleven of eleven months reviewed for Mohs testing. Findings follow. A. Review of the laboratory's Quality Control - Temperature & Humidity Chart from Jan - Nov 2021 showed check marks on each day of Mohs testing. The bottom of the page stated, "The temperature will be maintained between 65 and 72 degrees Fahrenheit. Humidity between 0-60%. A check mark in the box states that the temperature/humidity was within this range on that date." B. Interview with the histotech on December 15, 2021 at 1225 in the laboratory confirmed actual temperatures and humidity were not documented on the form and agreed there could not be a review of the temperatures and humidity. C. Review of the Mohs Patient Log showed from Jan - Nov 18, 2021 639 Mohs cases were performed.
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, review of manufacturer's instructions, reagent logs, patient logs, and interview, the laboratory failed to ensure reagents were not used beyond their expiration for three of four tissue marking dyes currently in use by the laboratory used in Mohs testing. Findings follow. A. Surveyor observed on December 15, 2021 at 1140 hours on the laboratory counter at the workstation that the following Avantik Tissue Marking Dyes available and in use by the laboratory were expired: 1. Blue, Lot 087417, expiration 09/30/2021 2. Green, Lot 088372, expiration 10/31/2021, 3. Red, Lot 087417, expiration 11/30/2021. B. Review of the Reagent Log titled Mohs lab Media or Stain Receipt Log did not have a column for expiration dates. C. Interview with the histotech on December 15, 2021 at 1215 in the laboratory confirmed the findings and acknowledged he did not know where the expiration dates were found and agreed a review could not be performed to know when previous stains and reagents had expired with the exception of the bottles currently available in the laboratory. D. Review of the Mohs Patient Log showed 171 Mohs cases were performed from 10/05/2021 - 11/18/2021. From Jan - Nov 18, 2021 639 Mohs cases had been performed.
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 internet search, review of quality control (QC) records, and interview, the laboratory failed to include the intended reactivity of the Hematoxylin and Eosin stain to ensure predictable staining characteristics on their quality control log used to document stain quality for Mohs testing for 3 of 3 months reviewed. Findings follow. A. Internet search of the stains used in the laboratory during the survey showed no definitions of staining characteristics of the stain. Further search stated, "the nuclei are stained blue, whereas the cytoplasm is pink". B. Review of the Slide Quality Control/ Daily Quality Assurance Log showed from 08/26/2021 - 11/18/2021 there were check marks in the column of Satisfactory for every day of patient testing. The bottom of the form stated, "The first section cut of the day is designated as a QC slide, and H&E stain is assessed daily by the Surgeon, a check mark indicates the stain was satisfactory that day, and initialed by the Doctor." C. Interview with the histotech on December 15, 2021 at 1245 hours in the laboratory confirmed the staining characteristics were not on the quality control log.
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 the patient test reports, Mohs map, and slides, the laboratory failed to include part of the test report for one of nine Mohs test reports reviewed. Findings follow. A. Review of nine randomly selected Mohs cases showed Mohs case CS21-022 was missing a STAGE in the visit notes which also served as the patient test report. Review of the visit notes for the Mohs Surgery only documented 2 stages: "STAGE 1: The area was prepped with Hibiciens. A rim of normal appearing skin was marked circumferentially around the lesion. The area was infiltrated with local anesthesia. The tumor was first debuked with a curette to remove clinically apparent tumor. An incision at a 45 degree angle following the standard Mohs approach was done and the specimen was harvested as a microscopic controlled layer. Hemostasis was achieved with electrocautery. The specimen was oriented, mapped and placed in 1 block. Each section was then chromacoded and processed in the Mohs lab using the Mohs protocol and submitted for frozen section. Frozen section analysis showed: residual tumor seen. Histology: STAGE 2: The patient was prepped in the same fashion as the first stage. An incision at a 45 degree angle following the standard Mohs approach was done and the specimen was harvested as a microscopic controlled layer. Hemostasis was achieved with electrocautery. The specimen was oriented, mapped and placed in 1 block. Each section was then chromacoded and processed in the Mohs lab using the Mohs protocol and submitted for frozen section. Frozen section analysis showed: No residual tumor seen. Histology: There were no malignant cells seen in the sections examined." B. Review of the Mohs map showed there were 3 stages, STAGE I and II showed a squamous cell carcinoma in situ tumor, STAGE III was clear. C. Review of the case slides showed a total of six slides labeled for STAGE I, II and III and slides A and B for each stage. D. Interview with the clinic supervisor on December 15, 2021 at 1520 hours in the laboratory confirmed the patient note was incorrect based on the Mohs map and slides, and added they would correct the surgery notes.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the competency evaluations and interview, the technical consultant failed to include five of six components in the competency evaluation for two of two testing personnel for one of one event for KOH testing used to identify fungal elements. Findings follow. A. Review of the Annual KOH Competency Assessment for testing personnel #1 & 2, listed on the CMS form 209, completed on 12/01/2021 did not include the following components of a competency evaluation: 1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; 2. Monitoring the recording and reporting of test results; 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. Direct observation of performance of instrument maintenance and function checks; 5. Assessment of problem-solving skills. B. Interview with the clinic manager

	on December 15, 2021 at 1530 hours in the laboratory confirmed after a review of the findings that the competency evaluation was actually a form of accuracy assessment for KOH (required twice a year annually).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of patient testing logs, the laboratory's policies and procedures, accuracy assessments and interview, the Laboratory Director failed to ensure the accuracy of its Frozen sections for the dermatopathology interpretations and Mohs testing (for the accuracy of the map and slides and agreement of clear margins) peer reviews were performed at least twice annually (see D5217 I and II).