Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2180046	06/14/2023
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
D0000	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, patient testing log, and interview, the laboratory failed to document the internal controls for the Sekisui OSOM Card Pregnancy Test for 17 of 17 months reviewed. Findings follow. A. Review of the Sekisui OSOM Card Pregnancy Test package insert (rev 3135-1 12/12) under Quality Control stated, "Internal Quality Controls Several procedural controls are incorporated into each OSOM Card Pregnancy Test for routine quality checks. The same labeled conjugate antibody results in the appearance of both the test and the control bands. The appearance of the control band in the results window is an internal positive procedural control which validates the following: Test System: The appearance of the control band assures that the detection component of both the test line and control line is intact, that adequate sample volume was added and that adequate capillary migration of the sample has occurred. It also verifies proper assembly of the Test Device. Operator: The appearance of the control band indicates that an adequate volume of the fluid was added to the sample well for capillary migration to occur. If the control band does not appear at the read time, the test is invalid. The clearing of the background in the results area may be documented as a negative procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light gray and not interfere with the reading of the

	test. The test is invalid if the background fails to clear and obscures the observation of a distinct control band." B. Review of the HCG Dipstick Test Kit Quality Control /Patient Log from 01/03/2022 to 06/13/2023 showed either no results for the Internal Controls or "No" in the results column. Review of the log showed 20 patient tests were performed. C. Interview with the Supervisor on June 15, 2023 at 1400 hours 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: I. Based on review of manufacturer's instructions, testing logs, temperature logs, and interview, the laboratory failed to ensure the temperature was within the operating specifications for the Avantik QS12 cryostat used in Mohs testing for four out of 29 days of testing over a period of four months. Findings follow. A. Review of the Avantik QS12 Instruction Manual, on chapter 2. Introduction under Technical Specifications stated, "Temperature (Recommended Operation) 15 to 30 degrees Celsius (59 to 86 degrees Fahrenheit) Note Performance may deteriorate when operated outside of this range". B. Review of the Mohs Accession Log showed from Jan - April 2023 there were 29 days of Mohs patient testing. C. Review of the Quality Control - Temperature & Humidity Chart showed temperature was not documented on the following dates of testing with the Mohs cases: 1. 01/04/2023 CS23-001 to CS23-009 2. 02/16/2023 CS23-104 to CS23-111 3. 03/16/2023 CS23-159 to CS23- 166 4. 03 /29/2023 CS23-176 to CS23-185 D. Interview with the histotechnologist on June 15, 2023 at 1500 hours confirmed the findings. II. Based on review of manufacturer's instructions, testing logs, humidity logs and interview, the laboratory failed to ensure the humidity was within the operating specifications for the Avantik QS12 cryostat used in Mohs testing for four out of 29 days of testing over a period of four months. Findings follow. A. Review of the Avantik QS12 Instruction Manual, on chapter 2. Introduction under Technical Specifications stated, "Relative Humidity [RH] maximum 60% RH up to 35 degrees Celsius". B. Review of the Mohs Accession Log showed from Jan - April 2023 there were 29 days of Mohs patient testing. C. Review of the Quality Control - Temperature & Humidity Chart showed humidity was not documented on the following dates of testing with the Mohs cases: 1. 01/04/2023 CS23-001 to CS23-009 2. 02/16/2023 CS23-104 to CS23-111 3. 03/16/2023 CS23-159 to CS23- 166 4. 03/29/2023 CS23-176 to CS23-185 D. Interview with the histotech on June 15, 2023 at 1500 hours confirmed the findings.
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 the laboratory's policies and procedures, patient testing logs, quality control (QC) records, and interview, the laboratory failed to document the reactivity of the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for their quality control used in Mohs testing for four out of 29 days of testing over a period of four months. Findings follow. A. Review of the laboratory's policy and procedure titled Bi-Annual Log Review for Quality Assurance, reviewed 01 /11/2023, at 6.3 Microscopic Examination under 6.1.1 stated, "... A quality control slide is the first slide examined each day to ensure quality of the stain." B. Review of the Mohs Accession Log showed from Jan - April 2023 there were 29 days of Mohs patient testing. C. Review of the Quality Control - H&E Daily Control Slide Log showed QC was not documented on the following dates of testing with the Mohs cases: 1. 01/04/2023 CS23-001 to CS23-009 2. 02/16/2023 CS23-104 to CS23-111 3. 03/16/2023 CS23-159 to CS23- 166 4. 03/29/2023 CS23-176 to CS23-185 D. Interview with the histotech on June 15, 2023 at 1500 hours confirmed the findings.