Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2170193	08/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Texas Skin Center Pearland	3609 Business Center Dr #124, Pearland, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control records for June 2021 and July 2021, review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation available for review to ensure the negative and positive reactivity of Hematoxylin and Eosin stain was acceptable each day of patient testing between June 3, 2021 and June 25, 2021. Findings include: 1. A review of the laboratory's quality control records for the Hematoxylin and Eosin (H and E) stain found no documentation of the stain acceptability for 4 of 4 days between June 3, 2021 and June 25, 2021. 2. A review of patient test records revealed the following patient's specimens were tested on days between June 3, 2021 and June 25, 2021:

	PATIENT ID: TSCPL2021-051 Processed: 6/3/21 PATIENT ID: TSCPL2021-052 Processed: 6/4/21 PATIENT ID: TSCPL2021-053 PATIENT ID: TSCPL2021-054 Processed: 6/11/21 PATIENT ID: TSCPL2021-055 PATIENT ID: TSCPL2021-056 PATIENT ID: TSCPL2021-057 PATIENT ID: TSCPL2021-058 PATIENT ID: TSCPL2021-059 Processed: 6/25/21 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/4/21 at 10:43 in the laboratory, stated that he was not sure where the testing personnel had been documenting the stain acceptability. This confirmed the above 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: Based on a review of the laboratory's policies, a review of the 'Lab Daily Log Sheets', a review of patient test records, and staff interview, it was revealed that the laboratory failed to document the temperature of the Cryostat for 7 of 63 days from October 2019 to May 2021 when patient's specimens were processed. Findings include: 1. A review of the laboratory's policy titled 'Tissue Processing Protocol for Mohs Micrographic Surgery' revealed the following: "At the start of the day the technician will record the temperature of the cryostat, as determined by the red readout on the machine, in the cryostat temperature log located in the logbook in the lab or on the bulletin board/ wall board posted in the lab. The operational temperature for cold-section processing in this lab is regarded as -19 to -24 degrees Celsius." 2. A review of the 'Lab Daily Log Sheets' from October 2019 to May 2021 revealed the following 7 days when the temperature of the Cryostat was not documented: 12/5/19 4/23/20 5 /21/20 9/25/20 10/2/20 1/22/21 4/22/21 3. A review of the laboratory's patient test records revealed the following patient's specimens were processed on the above listed dates: PATIENT ID: TSCPL2019-008 Processed: 12/5/19 PATIENT ID: TSCPL2020-013 Processed: 4/23/20 PATIENT ID: TSCPL2020-020 Processed: 5/21/20 PATIENT ID: TSCPL2020-039 Processed: 9/25/20 PATIENT ID: TSCPL2020-042 Processed: 10/2/20 PATIENT ID: TSCPL2021-007 Processed: 1/22/21 PATIENT ID: TSCPL2021-035 Processed: 4/22/21 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/4/21 at 10:45 a.m. in the laboratory, after review of the records, confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, a review of patient test records, and staff interview, it was revealed the laboratory director failed to ensure documentation of site-specific training for 3 of 3 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the the laboratory identified 3 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. 2. A review of the laboratory's personnel records revealed testing person #1, testing person #2, and testing person #3 failed to have documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) to perform high complexity testing- grossing of histology specimens for MOHS testing. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/4/21 at 10:25 a.m. in the laboratory, after review of the records, confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, and staff interview, it was revealed that the laboratory failed to have documentation of the technical supervisor performing competency assessments at least semiannually during the first year of testing in 2020 and 2021, on 2 of 3 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 3 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical supervisor performing competency assessments at least semiannually during the first year of testing for the following 2 testing personnel performing high complexity testing: Testing person # 2 - start date 3 /2/20 - missing 2 competency assessments within the first year of testing Testing Person # 3 - start date 7/2/20 - missing 2 competency assessments within the first year of testing 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/4/21 at 10:30 a.m. in the laboratory, after review of the records, confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, and staff interview, it was revealed that the laboratory failed to have documentation of the technical supervisor performing a competency assessment in 2020 on 1 of 3 testing personnel performing high complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 3 testing personnel performing high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical supervisor performing a competency assessment in 2020 for testing person #1. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/4/21 at 10:30 a.m. in the laboratory, after review of the records, confirmed the above findings.