Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0913782	09/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
South Texas Dermatology	4141 South Staples #300, Corpus Christi, 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 at the entrance and exit conferences. The facility representative was 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.
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: Based on review of patient test records, laboratory's test menu, laboratory records, and staff interview, it was revealed the laboratory failed to have documentation performing twice annual accuracy assessments in 2019 for Tzanck testing. The findings were: 1. Review of patient test records (see Patient Alias list) revealed that the laboratory performed and resulted a Tzanck test on February 21, 2019. The result was negative. 2. A review of the laboratory's test menu provided on September 8, 2020 revealed no Tzanck testing was performed by the facility. 3. A review of the laboratory's records revealed the facility failed to have documentation of performing twice annual accuracy assessments in 2019 Tzanck testing. The facility was asked to provide documentation of the required assessments. No documentation was provided.

	4. An interview with Testing Personnel #8 (as listed on the Form CMS-209) on September 8, 2020 at 15:00 hours in the laboratory director's office revealed the laboratory did not perform the required assessments in 2019. He was unaware that the provider performed the testing. Key: CMS - Centers for Medicare and Medicaid Services
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for labeling slides. The findings were: 1. Direct observation on September 8, 2020 found 5 of 5 sets of patient slides labeled with date and case number only (included staging). 2. Review of the laboratory's policy titled, "Specimen handling, Storage, Transport, Preservation and Identification" approved by the laboratory director on June 17, 2020 stated, " ... Slides are labeled with number, full patient name and date, and specimen source (if applicable)." 3. The laboratory failed to follow its own policy to include full patient name. 4. An interview with Testing Personnel #8 (as listed on Form CMS-209) on September 8, 2020 at 15:30 hours confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for proper storage of reagents. The findings were: 1. Surveyor observation on September 8, 2020 at 14:45 hours found the following reagents stored in the tabletop refrigerator. The reading at the time was 32.2 degrees Fahrenheit. a. 1 bottle of Acetone Lot # 0028 b. 4 bottles of IHC Wash Buffer Lot # 0001189 2. Review of the manufacturer's instructions for the Acetone found on the package labeling stated, "Store at Room Temperature." 3. Review of the manufacturer's instructions for the IHC Wash Buffer found on the package labeling stated, "Store at 15-30 degrees Celsius." 4. The laboratory failed to follow the manufacturer's instructions for proper storage of reagents used in the laboratory. 5. An interview with Testing Personnel #8 (as listed on Form CMS-209) at 14:55 hours in the laboratory confirmed the findings. B. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for storage of supplies in

	Patient Surgical Rooms. The findings were: 1. Surveyor observation in Patient Surgical Room #7 on September 8, 2020 at 16:00 hours found no means to monitor the environmental temperature of the room. The following items were observed: a. eSwabs (quantity of 2) Lot # 1916015 Expiration date: 01-31-2021 2. Review of the manufacturer's instructions for the eSwabs located on package labeling stated storage temperature for the swabs is, "5-25 degrees Celsius." 3. The laboratory failed to follow the manufacturer's instructions for storage of eSwabs. 4. An interview with Testing Personnel #8 (as listed on Form CMS-209) on September 8, 2020 at 16:05 hours in the Patient Surgical Room #7 confirmed the findings. Key: IHC - immunohistochemical CMS - Centers for Medicare and Medicaid Services
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. This STANDARD is not met as evidenced by: Based on direct observation and interview with facility personnel, the laboratory failed to label stain reagents with their identification, lot number, and preparation and expiration dates. The findings were: 1. Surveyor observation on September 8, 2020 at 14:45 hours in the laboratory found 21 containers of stain reagents used for tissue staining. The containers were unlabeled. 2. The facility failed to label the containers with their identification, lot number, and preparation and expiration dates. 3. At 14:45 hours, Testing Personnel #8 provided the surveyor a Staining Procedure worksheet that provided information as to what reagent was in each container. The worksheet did not match the containers. There were 22 reagents listed on the worksheet and 21 containers. 4. An interview with Testing Personnel #8 (as listed on Form CMS-209) at 14:55 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 direct observation and confirmed in interview of facility personnel the laboratory failed to ensure expired reagents were not available for patient testing. The findings were: 1. Surveyor observation on September 8, 2020 found the following expired items in the tabletop refrigerator: a. 4 bottles IHC Wash Buffer Lot # 0001189 Expiration date: 08-19-2020 b. 1 bottle 0.9% Sodium Chloride Lot # G116921 Expiration date: 03-2018 c. 1 bottle Toludine Blue Lot # K12261 Expiration date: February 2015 2. Interview with Testing Personnel #8 (as listed on Form CMS-209) on February 8, 2020 at 14:45 hours in the laboratory confirmed the findings. He revealed that the Toludine Blue was not used for patient testing.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of laboratory records, and confirmed in interview of facility, the laboratory's quality assurance plan failed to identify and correct problems in its analytic systems. The findings were: 1. The laboratory's quality assurance plan failed to identify that the laboratory failed to follow its own policy for slide labeling (refer to D5401). 2. The laboratory's quality assurance plan failed to identify that the laboratory failed to follow manufacturer's instructions for storage of laboratory supplies and reagents (refer to D5411). 3. The laboratory's quality assurance plan failed to identify that the laboratory failed to ensure reagent stains are labeled with contents, lot number, preparation and expiration dates (refer to D5415) 4. The laboratory's quality assurance plan failed to identify that the laboratory failed to ensure laboratory supplies are not used past their expiration dates (refer to D5417).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and confirmed in interview of facility personnel, the technical consultant failed to ensure 1 of 3 testing persons received two competency assessments during their first year of patient testing. The findings were: 1. Review of the laboratory's personnel records for Testing Personnel #6 revealed the following: Date of patient testing: July 23, 2018 Date of 1st Competency Assessment: December 7, 2018 Date of 2nd Competency Assessment: August 13, 2019 (21 days late) 2. An interview with Testing Personnel #8 (as listed on Form CMS-209) on September 8, 2020 at 13:45 hours in the laboratory director's office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services