Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2131822	10/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
South Texas Skin Cancer Center	813 Paris Street, Castroville, 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 the laboratory's procedures, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for biopsies and Mohs specimens twice annually in 2018, and 2019. The findings were: 1. A review of the laboratory's Quality Assurance procedure under the section titled "9.0 Quality Assurance" revealed: "A. Semiannual Audit Procedure for Proficiency... 1) On a semiannual basis, Mohs cases will be pulled at random and submitted for review by a member of the American College of Mohs Surgery, or by a board certified dermatopathologist... C. Semiannual Audit Procedure for Proficiency - Biopsies 1) On a semiannual basis, biopsies will be pulled at random and submitted for review by a member of the American College of

	Mohs Surgery, or by a board certified dermatopathologist." 2. A review of the laboratory's records from 2018 and 2019 revealed the laboratory failed to have documentation of performing the audit semiannually in 2018 and 2019. Slides for the second half of 2018 and all of 2019 were sent and evaluated on 10/20/2020. Evaluations were documented as being performed on the following days: A) Mohs i) January - June 2018 case: 2018-CV-119 evaluated: 10/29/2018 case: 2018-CV-093 evaluated: 10/29/2018 ii) July - December 2018 case: 2018-CV-162 evaluated: 10/20 /2020 case: 2018-CV-118 evaluated: 10/20/2020 ii) January - June 2019 case: 2019-CV-093 evaluated: 10/20/2020 case: 2019-CV-029 evaluated: 10/20/2020 iii) July - December 2019 case: 2019-CV-180 evaluated: 10/20/2020 case: 2019-CV-134 evaluated: 10/20/2020 B) Biopsies i) January - June 2018 case: 2018-CV-003 evaluated: 10/29/2018 case: 2018-CV-V-002 evaluated: 10/29/2018 ii) July - December 2018 case: 2018-CV-VII, VI evaluated: 10/20/20 ii) January - June 2019 case: 2019-CV-V7, VI evaluated: 10/20/20 iii) July - December 2019 case: 2019-CV-V10, VI evaluated: 10/20/2020 3. The laboratory was asked to provide documentation of performing the evaluation semiannually. No documentation was provided. 4. An interview with the histotech on 10/22/2020 at 0950 hours in the break room - after her review of the records- confirmed the findings.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's slide quality control records from June 2020 to October 2020 (as of the day of the survey), review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of evaluating stain quality for 2 of 11 days of testing. The findings were: 1. Review of the laboratory's quality assurance procedure under the section titled "8.0 Quality Control" revealed: "A quality control slide will be the first slide of the day produced. The quality control slide will be reviewed by the Mohs surgeon and the Quality Control Slide Log will be annotated." 2. A review of the laboratory's Quality Control Slide Log from June 2020 to October 22, 2020 revealed the laboratory failed to have documentation of the acceptability of stain quality for 2 of 11 test days. The days without the required documentation were: October 7, 2020 October 21, 2020 3. A review of patient test records revealed the following number patients tested on the identified days: a) October 7, 2020 9 patients b) October 21, 2020 8 patients 4. An interview with Mohs histotech on October 22, 2020 at 0950 hours in the break room - after her review of the records- confirmed the finding.