

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2131822	(X3) Date Survey Completed 03/15/2022
Name of Provider or Supplier South Texas Skin Cancer Center	Street Address, City, State 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on 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 2021. The findings were: 1. A review of the laboratory's records from 2021 revealed the laboratory failed to have documentation of performing the accuracy assessments semiannually in 2021. Slides for the 2021 were evaluated on 03/08/2022. i) January - June 2021 case: 2021-CV-001 case: 2021-CV-048 case: 2021-CV-090 case:2021-CV-V-8 evaluated: 03/08 /2022 ii) July - December 2021 case: 2021-CV-180 case: 2021-CV-114 case: 2021-CV-208 case: 2021-CV-V-009 evaluated: 03/08/2022 2. The laboratory was asked to provide documentation of performing the evaluation semiannually. No documentation was provided. 3. An interview with the facility manager on 10/22/2020 at 0950 hours in the break room - after his review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 10/22 /2020</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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</p>

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 January 2021 to March 1, 2022, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of evaluating stain quality for 5 of 41 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 January 2021 to March 1, 2022 revealed the laboratory failed to have documentation of the acceptability of stain quality for 5 of 41 test days. The days without the required documentation were: April 21, 2021 May 19, 2021 June 30, 2021 August 11, 2021 February 10, 2022 3. A review of patient test records revealed the following number patients tested on the identified days: a) April 21, 2021 9 patients b) May 19, 2021 9 patients c) June 30, 2021 8 patients d) August 11, 2021 9 patients e) February 10, 2022 6 patients 4. An interview with facility manager on 03/15/2022 at 0950 hours in the break room - after his review of the records- confirmed the finding. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 10/22/2020.