

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0870439	(X3) Date Survey Completed 09/11/2018
Name of Provider or Supplier Hill Country Dermatology, A Part Of Us	Street Address, City, State 95 East Highway Street, Fredericksburg, 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 policies, quality assurance records from 2016 through 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for MOHS testing in 2017. Findings included: 1. A review of the laboratory's policy titled Protocol for Quality Review of Microscopic Slides found " it is the policy of [name omitted] to send slides out twice a year to fellow MOHS surgeons for review to determine the quality and accuracy of the slide. " 2. A review of the laboratory's MOHS testing accuracy assessment records from 2016 through 2018 revealed the laboratory performed two accuracy assessments in 2016, one accuracy assessment in July 2017 and one accuracy assessment performed on March 27, 2018. The laboratory recorded that 2 cases were sent to a fellow MOHS surgeon on 10/30/2017, however there was no evaluation of the cases sent for review. 3. Interview of the histotechnician conducted on September 11, 2018 at 9:53 AM confirmed that the slides had been sent, but the reviews were not returned. She stated that she called the reviewing MOHS surgeons office when preparing for the inspection and they could not provide her with a copy of the review or find that the review was done.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(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</p>

quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Review of policies and procedures, quality assessment activities and interview of facility personnel found that the laboratory failed to follow its own quality assurance plan to identify and correct problems. Findings included: 1. Review of policies and procedures found that the laboratory had a quality assurance plan. On Page 5 of the quality assurance manual under the heading Quality Assurance Review with Staff - "If the laboratory has employees involved in laboratory testing, the Laboratory Director will discuss with the staff on a monthly basis, the results of the quality assurance reviews and ways in which the laboratory can improve the quality of its work. 2. Review of laboratory records found documentation of quality assurance activities for June 15, 2016 and August 14, 2017. No other quality assessment activities were available for review. 3. Interview of the histotechnician conducted on September 11, 2018 at 09:59 AM confirmed that monthly Quality assurance activities were not documented, or discussed with laboratory personnel.