

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2094986	<b>(X3) Date Survey Completed</b>  09/09/2020
<b>Name of Provider or Supplier</b>  Coastal Hills Dermatology	<b>Street Address, City, State</b>  600 Corporate Dr Ste 100, Ladera Ranch, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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 the surveyor's review of the laboratory's records for evaluation of proficiency testing performance and an interview with laboratory personnel (LP) on 9/9/2020 between 10 am and 11:30 am, it was determined that the laboratory failed to at least twice annually, document their quality assurance/proficiency testing. Findings include: 1. On 9/9/2020, an inspection was conducted between 10 am and 11:30 am. 2. During a review of the laboratory documentation, it was noted at approximately 10:45 am that the laboratory failed to document proficiency testing for MOHS Histopathology in 2018 and 2019. The LP recognized that this documentation was missing. 3. An administrative procedure approved by the director did exist indicating that two times per year, 5 MOHS cases would be pulled for a peer review; with results posted to a worksheet for review. This procedure was not followed during 2018 and 2019.</p>
<b>D6094</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's records for evaluation of proficiency testing</p>

performance for MOHS reporting, and an interview with laboratory personnel (LP) on 9/9/2020, it was determined that the laboratory director failed to ensure that the quality assessment programs were provided and maintained. 1. Activities to assess and monitor quality and accuracy were not performed (see D-5217).