

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0870989	<b>(X3) Date Survey Completed</b>  11/04/2019
<b>Name of Provider or Supplier</b>  Kathleen Hutton Md, Inc	<b>Street Address, City, State</b>  1441 Avocado Ave, Ste 309, Newport Beach, 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 review of the laboratory's records for evaluation of proficiency testing performance, and interview with the laboratory personnel, it was determined that the laboratory failed to, at least twice annually, document and verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. The laboratory performed histopathology for skin biopsy testing. b. The histopathology is not included in subpart I of 42 CFR part 493. c. The laboratory failed to document the evaluation of proficiency testing performance for histopathology in 2018.</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 review of the laboratory's records for evaluation of proficiency testing performance, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory performed histopathology for skin biopsy testing and</p>

failed to document the evaluation of proficiency testing performance for histopathology, see D-5217.