

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2008154	(X3) Date Survey Completed 03/10/2020
Name of Provider or Supplier Comprehensive Dermatology & Dermatologic Surgery	Street Address, City, State 201 N Lakemont Ave Ste 100, Winter Park, FL	
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	A recertification survey was conducted on March 10, 2020. Comprehensive Dermatology and Dermatologic Surgery clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish a written policy on training and competency assessment, and failed to document the training and competency assessment for Testing Personnel B from July 2018 to March 8, 2020. Findings: 1. Review of the procedure manual signed by the Laboratory Director on July/2018 showed that the manual did not contain a policy on personnel training and competency assessment. During an interview on 3/10/2020 at 11:30 AM, the Laboratory Director stated that they did have have a policy on training and competency. 2. Review of the Laboratory Personnel Report (CMS 209), signed and dated by the Laboratory Director on 3/10/2020, showed that there are two testing personnel. Review of personnel records for the histology technologist (Testing Personnel B) showed a competency evaluation was performed on March 9, 2020. No other documentation of training or competency assessments were available for review at the time of the survey. During an interview on 3/10/2020 at 10:40 AM, the Histology Technologist stated that no competency assessments were performed.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain at least twice annually in 2018 and 2019, and failed to verify the accuracy of the Potassium Hydroxide (KOH) testing at least twice annually in 2018. Findings: 1. The laboratory used peer review to verify the accuracy of the reading and interpretation H&E stains. Review of the laboratory's records for 2019 showed that there were only five peer review cases that were signed and dated by the reviewing dermatopathologist on 2/8/19. No peer review records were available for review at the time of the survey for 2018. During an interview on 3/10/20 at 10:44 AM, the Mohs Technician stated that peer review was performed only once during 2019. During an interview on 3/10/20 at 11:25 AM, the Mohs Technician stated she did not know where the peer review was located for 2018. 2. The laboratory is enrolled in proficiency testing (PT) with American Proficiency Institute (API) for KOH. API provides samples for PT three times a year for KOH. No documentation of PT for KOH was available for 2018. During an interview on 3/10/20 at 11:34 AM, the Laboratory Director stated they had shipping problems in 2018 and did not do any proficiency testing for KOH in 2018.