

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0683673	(X3) Date Survey Completed 08/13/2021
Name of Provider or Supplier Calais Dermatology Assoc	Street Address, City, State 5220 Flanders Dr, Baton Rouge, LA	
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 performed on August 13, 2021 at Calais Dermatology, CLIA ID # 19D0683673. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 with personnel, the laboratory failed to have a complete policy for competency assessments for testing personnel who perform Histopathology testing. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director performs Histopathology testing and a testing personnel for KOH. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a written policy detailing the use of following six (6) procedures to establish competency: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on August 13, 2021 at 10:30 am, the laboratory personnel confirmed that the laboratory uses outside verification of</p>

cases to verify competency of the laboratory director's Histopathology reading but the policy did not detail annual competency assessment. Further, the laboratory personnel confirmed competency for KOH was also not detailed in the procedure manual.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel.

Refer to D5209.