

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0462788	(X3) Date Survey Completed 12/29/2022
Name of Provider or Supplier Dermatology Clinic, The	Street Address, City, State 5326 O'Donovan Drive, 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 Certification survey was performed at Dermatology Clinic-CLIA ID 19D0462788 on December 29, 2022. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure (1) of eight (8) physicians performing potassium hydroxide (KOH) testing had appropriate training documentation prior to patient testing. Findings: 1. In interview on December 29, 2022 at 9:54 am, Histotech 1 stated Physician 8 was hired on October 1, 2022. 2. Review of personnel records for Physician 8 revealed the laboratory did not have documentation of an initial training for KOH testing. 3. In further interview on December 29, 2022 at 1:20 pm, Histotech 1 and the Technical Consultant confirmed the laboratory did not have documentation of an initial training for KOH testing for Physician 8.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p>

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6054.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, personnel records, and interview with personnel, the Technical Consultants failed to evaluate competency annually in 2021 and 2022 for one (1) of eight (8) physicians performing potassium hydroxide (KOH) testing. 1. Review of the laboratory's policies under the section "Competency" revealed " Annual. The Laboratory Director or designee will perform competency evaluations on all testing personnel every six months for the first year and annually thereafter. The Competency Assessment form should be completed and filed with employee records." 2. Review of personnel records for physicians performing KOH testing revealed Physician 3 did not have documentation of an annual competency assessment for 2021 and 2022. 3. In interview on December 29, 2022 at 1:20 pm Histotech 1 and the Technical Consultant confirmed the laboratory did not have documentation of annual competency assessments for Physician 3 for KOH testing for 2021 and 2022.