

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311776	(X3) Date Survey Completed 06/13/2018
Name of Provider or Supplier Lakeway Dermatology Associates, Pc	Street Address, City, State 400 E Economy Road, Ste 8, Morristown, TN	
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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(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;</p> <p>This STANDARD is not met as evidenced by: _____ Based on 3 of 3 testing personnel listed on the CMS-209 form "Laboratory Personnel Report (CLIA)" who perform KOH (potassium hydroxide) testing, lack of policy for monitoring testing personnel performing KOH testing, lack of competency documentation for 3 of 3 testing personnel performing KOH testing and interview with the Laboratory Director, the laboratory director failed to ensure a policy was in place to monitor testing personnel performing KOH testing for 2016, 2017 and 2018. The findings include: 1. Three testing personnel listed on the CMS-209 form who perform KOH testing. 2. Lack of policy for monitoring testing personnel performing KOH testing. 3. Lack of competency documentation for 3 of 3 testing personnel performing KOH testing for 2016, 2017 and 2018. 4. Interview at approximately 12:30 p.m. June 13, 2018 with the Laboratory Director confirmed there was no policy or competency documentation for monitoring 3 of 3 testing personnel listed on CMS-209 form who performed KOH testing since 2016. _____</p>