

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311776	(X3) Date Survey Completed 10/10/2024
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
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 a review of the laboratory's procedure manual and staff interview, the laboratory failed to establish a written policy for assessing testing personnel competency on the survey date (10.10.2024). The findings include: 1. A review of the laboratory's policy and procedure manual revealed no written policy for testing personnel competency assessments for the surveyor to review on the survey date (10.10.2024). 2. An interview with the Laboratory Director on 10.10.2024 at 10:50 a. m. confirmed that the laboratory did not have a written policy for testing personnel competency assessments.</p>
D5217	<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 observation of the laboratory, review of patient records, lack of documentation, and staff interview, the laboratory failed to verify the accuracy of the Hematoxylin and Eosin (H&E) stain twice a year in 2023. 1. Observation of the laboratory on 10.10.2024 at 8:45 a.m. revealed H&E reagents used for staining tissue removed during dermatology surgical procedures. 2. Patient record review revealed</p>

the use of H&E stain reported on 02.03.2023 for patient number LDA23-0363 and on 02.06.2023 for patient number LDA23-0403. 3. There was no documentation that the laboratory verified H&E stain for accuracy twice a year in 2023. 4. An interview with the Laboratory Director on 10.10.2024 at 10:50 a.m. confirmed the laboratory did not send H&E slides for twice-a-year verification of accuracy in 2023.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory procedure manual and staff interview, the laboratory failed to establish a written policy or procedure defining the quality activities used to monitor, assess, and correct problems in the laboratory's testing systems on the survey date (10.10.2024). The findings include: 1. A review of the laboratory procedure manual revealed no policy or procedure defining the laboratory's quality assessment activities used to monitor, assess, and correct problems in the laboratory's testing systems for the surveyor to review on the survey date (10.10.2024). 2. An interview with the Laboratory Director on 10.10.2024 at 10:50 a.m. confirmed the above survey findings.

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 observation of the laboratory, review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (Form CMS-209), review of personnel records, and staff interview, the technical consultant failed to perform an annual competency assessment for one of one testing personnel who performed potassium hydroxide (KOH), scabies, and Tzanck smear patient testing in 2023. The findings include: 1. Observation of the laboratory on 10.10.2024 at 8:45 a.m. revealed a microscope on the counter used for KOH, scabies, and Tzanck smear patient testing. 2. A review of Form CMS-209 revealed one testing personnel (TP) who perform moderately complex patient testing. 3. A review of personnel records revealed no documentation of annual competency assessment for TP3, as listed on Form CMS-209 in 2023. 4. Interview with the Laboratory Director on 10.10.2024 at 10:50 a.m. confirmed the above survey findings.