

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2076002	<b>(X3) Date Survey Completed</b> 06/20/2024
<b>Name of Provider or Supplier</b> Suzanne L Berkman Md Inc	<b>Street Address, City, State</b> 8920 Wilshire Blvd, Ste 545, Beverly Hills, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures and interview with the office manager (OM); it was determined that the laboratory failed to have an established written policies and procedures for KOH, scabies, and dermatopathology. The findings included: 1. On the day of the survey on June 20, 2024, at approximately 12:00 p.m., the laboratory failed to provide written policies and procedures for KOH, scabies, and dermatopathology testing. 2. For seven (7) out of 7 randomly selected patient test results for KOH, scabies, and dermatopathology performed in the lab, no policies and procedures were available at the time of survey. 3. The OM affirmed on June 20, 2024 at approximately 12:00 p.m. that the laboratory did not have an established written policies and procedures available for performance of KOH, scabies, and dermatopathology testing. 4. Based on the annual testing declaration submitted on June 20, 2024, the laboratory performed of 1,030 tests.</p>
<b>D5793</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:  
Based on the lack of policies and procedures manual, interview with the office manager (OM), and review of seven (7) randomly chosen patient records; it was determined that the laboratory failed to perform and document preanalytic, analytic and postanalytic systems for quality assessment necessary to prevent recurrence of problems. The findings include: 1. Based on the survey last June 20, 2024, at approximately 12:00 p. m., no records of quality assurance/assessment were found at the time of survey consisting of QC review, Test Tracking, Communication, Compliance Assessment, etc. 2. For 7 out 7 patient records reviewed, no policies and procedure were found at the time of survey for KOH, scabies and dermatopathology tests. 3. The OM confirmed on June 20, 2024, at approximately 12:00 p. m. that the laboratory failed to perform and document quality assurance/assessment activities. 4. According to laboratory testing declaration submitted on June 20, 2024, the laboratory performed and reported approximately 1,030 tests annually for KOH, scabies, and dermatopathology.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(14)

The laboratory director must 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 interview with the office manager on June 20, 2024, at approximately 12:00 p.m., the laboratory director failed to ensure that an established, approved, signed, and dated procedure manual reflecting the current practice is available to all personnel responsible for any aspect of the testing process. Findings include: See D5401 and D5793.