

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0557210	(X3) Date Survey Completed 07/03/2024
Name of Provider or Supplier Skin And Beauty Center - West Hills	Street Address, City, State 7345 Medical Center Dr, Ste 310, West Hills, CA	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory tour and interview with the laboratory's Mohs technician (MT) and laboratory staff (LS); it was determined that the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. The findings include: 1. The laboratory failed to provide a written procedure for laboratory safety. 2. On the day of the survey July 3, 2024, at approximately 1:00 p.m. the surveyors observed that the laboratory lacked an eyewash and spill kits in the area where tissue samples are processed. The surveyor also observed used gloves in the regular trash can. 3. The MT and LS affirmed the lack of safety procedures, eyewash, and spill kits in the testing area. The MT and LS also affirmed presence of the gloves in the regular trash can in the laboratory. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 06/21/2024, the laboratory processes and reports approximately 300 samples annually.</p>
D5401	<p>PROCEDURE MANUAL 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>

This STANDARD is not met as evidenced by:
 Based on the lack of laboratory written policies and procedures for potassium hydroxide (KOH) and preparation for the detection of *Sarcoptes scabiei* (scabies) and interviews with the laboratory staff (LS) it was determined that the laboratory failed to have available and follow written procedures for mycology and parasitology test performed in the laboratory. The findings included: 1. On the day of the survey on July 3, 2024, at approximately 11:30 a.m. the laboratory failed to provide written policies and procedures for mycology and parasitology test performed in the laboratory. 2. The LS confirmed on 07/03/2023 at approximately 11:30 a.m. that the laboratory did not have written policies and procedures available for mycology and parasitology tests performed in the laboratory. 3. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 06/21/2024, the laboratory processes and reports 50 mycology and parasitology samples annually.

D6011

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(2)

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)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:
 Based on direct observation during the tour of the laboratory and interviews with the Mohs technician and the laboratory personnel; it was determined that the laboratory director failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards. See D3011.

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 laboratory personnel on the day of the survey (July 3, 2024), the laboratory director failed to ensure that an 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: D5401.