

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2144307	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Skin And Beauty Center (Sbc)	Street Address, City, State 2220 N Screenland Dr, Ste 101, Burbank, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's examination of laboratory reagents and interview with the laboratory's manager (LM) and the laboratory operation director (LOD); the laboratory failed in not using reagents when they have exceeded their expiration date. The findings include: 1. Based on the surveyor's examination, the laboratory stored the following expired reagents: a. Red Dye, Lot # 1155867, Expiration Date: 02/28 /2023 and b. Light Green for AFB, Lot #176389 Expiration Date:08/31/2024 No other Red Dye or Light Green for AFB was available for replacement. 2. The LM and LOD affirmed on June 26, 2025, at approximately 1:30 p.m., that the laboratory only had at the time of the survey, expired Red Dye and Light Green reagents used for sample staining for microscopic examination. 3. Based on the laboratory's submitted testing declaration test volume, the laboratory stained and tested and reported approximately 18,000 samples for Histopathology microscopic examination for some of which they might have used expired staining reagents.</p>
D5815	<p>TEST REPORT CFR(s): 493.1291(h)</p> <p>(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.</p>

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies and procedures, patient test records review from 6/14/2024 to 05/14/2025, and interview with laboratory manager (LM); the laboratory failed to have a policy for turn-around time (TAT) for all histopathology tests performed in the laboratory. 1. The laboratory failed to provide TAT of testing for six (6) out of six (6) randomly selected patients at the time of the survey (June 26, 2025). The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory manager on June 26, 2025, at approximately 1:15 p.m. affirmed that the laboratory did not have a TAT policy to notify any delay on testing to the submitters. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/30/25025, stated that the laboratory performs 18,000 histopathology tests annually.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's policy/procedure, randomly selected patient test records, preventive maintenance documentation, direct observation during the laboratory tour, and interviews with the laboratory's manager and the laboratory director of operation on June 26, 2025, the laboratory director is herein cited due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. The findings include: 1. Using expired reagents. See D5417. 2. Fail to establish a turn-around-trine TAT policy. See D5815.