

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0947847	<b>(X3) Date Survey Completed</b> 06/04/2018
<b>Name of Provider or Supplier</b> Skin And Beauty Center - Clendale South	<b>Street Address, City, State</b> 1577 E Chevy Chase Dr Ste 320, Glendale, 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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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 review of the Potassium Hydroxide (KOH) patient's log book, direct observation of the KOH Healthlink solution with lot # 1632011, expiration date 11/15 /2017, and interview with the office staff, it was determined that the laboratory failed to check the KOH reagent that exceeded their expiration date and still on the bench for use. The findings included: a. During the inspection (6/4/2018) the inspector noted that the KOH reagent vial has an expiration date of 11/15/2017. No other KOH reagent vial shown. b. For ten (10) out of ten (10) random patient sampling test results covering period from 11/16/2017 to 5/24/2018, the laboratory is using an expired KOH reagent. c. The office staff affirmed (6/4/2018, 12N) that the laboratory is using an expired KOH reagent solution.</p>
<b>D6024</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,</p>

This STANDARD is not met as evidenced by:  
Based on review of the Potassium Hydroxide (KOH) patient's log book, direct observation of the KOH Health link solution with lot # 1632011, expiration date 11/15 /2017, and interview with the office staff, it was determined that the laboratory director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified. See D 5417.