

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D0530924	<b>(X3) Date Survey Completed</b>  06/09/2023
<b>Name of Provider or Supplier</b>  Southwest Skin Specialists, Llc DbA	<b>Street Address, City, State</b>  14155 N 83rd Ave Ste 110, Peoria, AZ	
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 direct observation of histopathology stain reagents and interview with the facility personnel, the laboratory used the stain reagent, Hematoxylin, past the expiration date. Findings include: 1. The laboratory performs the Hematoxylin and Eosin (H&amp;E) stain on patient slides in conjunction with dermatopathology testing, with an approximate annual test volume of 1,752 tests. 2. During the survey conducted on June 9, 2023, direct inspection of the Hematoxylin reagent in use at the time of the survey, lot# 124499, expiration date 12/31/22, revealed the reagent was used for patient testing past the expiration date. 3. Approximately 876 patients were tested using the expired reagent. 4. The facility personnel interviewed on 6/09/2023 at 10:25am confirmed the expired reagent indicated above was in use on the day of the survey.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's quality assessment (QA) records, direct observation of stain reagents and interview with the facility personnel, the laboratory's QA processes failed to identify and correct errors found in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. The laboratory processes and interprets dermatopathology slides from patient specimens for Mohs testing. The laboratory's approximate annual test volume is 1,752. 2. The laboratory used the stain reagent, Hematoxylin, past the expiration date. See D5417 for specific findings. 3. The laboratory utilizes a "Quality Assessment Review Form and Checklists" which is completed on a quarterly basis by laboratory personnel. 4. Review of the 'Quality Assessment Review Form and Checklists' completed on June 1, 2023 by laboratory personnel failed to identify errors found with expired reagents. 5. The facility personnel interviewed on June 9, 2023 at 10:45am confirmed the laboratory's QA processes failed to identify and correct errors found with using stain reagents past the expiration date.