

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1056432	<b>(X3) Date Survey Completed</b>  02/08/2019
<b>Name of Provider or Supplier</b>  Tru-Skin Dermatology	<b>Street Address, City, State</b>  3500 Jefferson Street Suite 200, Austin, TX	
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 surveyor observations and interview with facility personnel, the laboratory failed to ensure 3 of 5 tissue marking dyes were not used beyond their expiration and 1 of 1 hematoxylin tissue stains was not used beyond its expiration. The findings included: 1. At 13:31 hours on 2/8/2019 in the laboratory, the surveyor observed the following three (3) of five (5) tissue stains on the tool cart next to a cryostat: Cancer Diagnostics, Inc. Tissue Marking Dye, Applicator Series Color: Orange Lot: 15240 Expiration: 2017/03 Elapsed time: expired for 1 year, 10 months, 8 days Cancer Diagnostics, Inc. Tissue Marking Dye, Applicator Series Color: Red Lot: 16047 Expiration: 2017/08 Elapsed time: expired for 1 year, 5 months, 8 days Cancer Diagnostics, Inc. Tissue Marking Dye, Applicator Series Color: Green Lot: 16042 Expiration: 2017/08 Elapsed time: expired for 1 year, 5 months, 8 days 2. At 13:37 hours on 2/8/2019 in the laboratory, the surveyor observed the following expired hematoxylin stain in the laboratory's flammable cabinet: Avantik Gill 3 - Hematoxylin Lot: 045097 Expiration date: 09/17 Elapsed time: expired for 1 year, 4 months, 8 days 3. In an interview at 13:37 hours on 2/8/2019 in the laboratory, the medical assistant /histotechnican confirmed the expired tissue marking stains and hematoxylin stain had been used in patient testing. None of the containers contained an open date. Based on the CMS-116 submitted on the day of the survey, the laboratory performed 250 tests in histopathology annually.</p>