

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2146573	<b>(X3) Date Survey Completed</b> 06/10/2021
<b>Name of Provider or Supplier</b> Tru-Skin Dermatology Lab	<b>Street Address, City, State</b> 1202 Fm 685, Unit C-6, Pflugerville, 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 observation, interview and query, the laboratory failed to ensure stains and supplies used to process tissue specimens for dermatopathology specimens had not exceeded their expiration date by 41 days. Findings follow. 1. During a tour of the facility on June 10, 2021 at 1505 hours, surveyor observed the following expired stain and supply located in the cabinet in the storage room: a. Fisher Brand Eosin-Y Solution, Lot 511186, expiration date of 04/2021 (expired by 41 days) b. Stat Lab Dissect Aid, Lot 065107, expiration date of 03/2021. 2. Interview with the testing personnel #1 on June 10, 2021 at 1505 hours confirmed the Eosin used in the Hematoxylin and Eosin stain was expired and in use by the laboratory. The Dissect Aid was used to help the ink attach to the specimen, so it doesn't blot up in the processor, was available to the laboratory, but not currently in use. 3. Query from the computer revealed from 05/01/2021 - 06/10/2021, the laboratory had processed 554 number of cases/patients, and 994 number of blocks/slides.</p>
<b>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's policies and procedures, review of quality control (QC) records, interview, and query, the laboratory failed to document the performance of the Hematoxylin and Eosin quality control, including the intended reactivity to ensure predictable staining characteristics, used to stain specimens for dermatopathology interpretations for 5 of 5 months reviewed. Findings follow. 1. Review of the laboratory's policy and procedure titled, Staining Policy, stated, "a QC control slide will be stained with the first rack of the day to ensure accurate staining." The laboratory did not have a Quality Control policy and procedure. 2. On June 10, 2021 at 1530 hours quality control records were requested from January 2021 to June 2021, but not provided. 3. Interview with testing personnel #1 on June 10, 2021 at 1530 hours in the office confirmed there was no documentation of the Hematoxylin and Eosin quality control. A control slide was prepared each day of staining and checked by the histotechnician, but the slide was sent to the reference laboratory that also interpreted dermatopathology slides. A control slide was not retained for the dermatopathology specimens interpreted at the laboratory, but the laboratory could include one moving forward. When asked what they would do if slides were unacceptable, testing personnel #1 stated they would recut and remake the slides. The laboratory began interpreting slides on-site in January 2021. Specimens were processed and stained Monday through Friday, and the dermatopathology interpretations performed at the laboratory were performed once per week. Interview with the Laboratory Director on June 10, 2021 at 1537 hours via phone confirmed he did not document the quality of the Hematoxylin and Eosin stain. 4. Query from the computer revealed from January 2021 - June 10, 2021 the laboratory had processed 2257 number of cases/patients, and 4197 number of blocks/slides.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's policies and procedures, attempted review of quality control (QC) records, interview, and query, the laboratory director failed to establish a quality control program to ensure the quality of laboratory services provided for dermatopathology interpretations for 5 of 5 months reviewed (see D5473).

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and interview, the technical supervisor failed to perform annual competency evaluations for 2 of 2 testing personnel who performed grossing in 2019 and 2020. Findings follow. 1. Review of the Employee Training Competency Evaluation provided during the survey showed at the bottom of the page lines for: "Initial training: \_\_\_\_\_ Semi-Annual training: \_\_\_\_\_ Annual training: \_\_\_\_\_" 2. Available Annual training forms showed: Testing personnel #1 was trained on 05/01/2018 (signed by the TS on 05/01/2019) and 05/01/2020 (signed by the TS on 05/01/2020) and Testing personnel #2 was trained on 07/10/2018 (signed by the TS on 07/10/2019) and 07/10/2020 (signed by the TS on 07/10/2020). 3. Interview with testing personnel #1 on June 10, 2021 at 1500 in the office revealed the form was used to document initial, semi-annual, and annual training that was performed, the technical supervisor reviews the training document (as indicated by his signature on the form). Competency evaluations were not performed.