

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2170188	<b>(X3) Date Survey Completed</b>  02/12/2025
<b>Name of Provider or Supplier</b>  Texas Skin Center Kingwood	<b>Street Address, City, State</b>  350 Kingwood Medical Dr Ste 220, Kingwood, 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>D0000</b>	An announced survey of the laboratory was conducted on 02/12/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's submitted "Listing of Tests Performed in the Facility", laboratory's policies/procedures and staff interview, the laboratory failed to</p>

establish written protocols/procedures for one of two tests performed by the facility, Toluidine Blue Stain. Findings included: 1. Review of laboratory's submitted "Listing of Tests Performed in the Facility" revealed the laboratory performed Toluidine Blue Stain on Mohs surgery samples. 2. Review of laboratory's policies/procedures revealed there were no written protocols in place for performance of Toluidine Blue Stain. 3. In an interview on 02/12/2025 at 1030 hours in the laboratory, Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on surveyor's observations, review of laboratory's policies/procedures and staff interview, the laboratory failed to label as required three of three containers of a dark blue solution observed stored in the cabinet. Findings included: 1. Surveyor's observations on 02/12/2025 at 1010 hours in the laboratory revealed three screwcap containers stored in the cabinet. One of the containers had handwritten "Toluidine Blue" on the cap, but there was no lot number or expiration date annotated. The other two screwcap containers with dark blue liquid were not labeled at all. 2. Review of laboratory policies/procedures revealed there were no protocols in place for labeling reagents' secondary containers. 3. In an interview on 02/12/2025 at 1010 hours in the laboratory, Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:  
Based on review of laboratory's quality control (QC) records, submitted test volumes and staff interview, the laboratory failed to document QC on the day test was performed for two of two stains used by the laboratory, Hematoxylin and Eosin (H&E) stain, and Toluidine Blue stain used to stain Mohs surgery tissue samples in 2023 and 2024. Findings included: 1. Review of laboratory's QC records titled "QA (quality assurance) SLIDE & MICROSCOPE ENVIRONMENT LOG" revealed: "For each day the laboratory is conducting testing, the histotechnologist on duty will provide a QA slide prior to the initiation of testing. The Lab Director or Mohs Surgeon will validate the QA slide and initial below". 2. Review of the QA Slide and Microscope Environment Logs revealed the QC/QA of the stained slides was last documented on 06/27/2023. There were no other stain QC/QA documents available for review prior to survey exit. 3. Review of laboratory's submitted test volumes

revealed the laboratory performed approximately 500 tests annually. 4. In an interview on 02/12/2025 at 1035 hours in the laboratory, Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, personnel records and staff interview, the Laboratory Director failed to ensure testing personnel's training was documented prior to starting testing patient samples for two of two new testing personnel (TP) employed in November 2024, TP number two and three. Findings included: 1. Review of laboratory's policy "Laboratory Manual Addendum-QA" (effective 07/14/2021) revealed: "All laboratory personnel conducting tests in this Lab will be required to demonstrate competence to perform their duties and functions by: - Completing an internal training program ..." And, "The Laboratory Director / Technical Supervisor will approve the testing personnel to conduct unsupervised testing." 2. Review of laboratory's personnel records for TP number two and TP number three revealed there was no documentation of completion of internal training, or Laboratory Director's approval to conduct unsupervised testing for either of these two TPs. 3. In an interview on 02/12/2025 at 1020 hours in the laboratory, Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals 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 laboratory's policies/procedures, personnel records and staff interview, the laboratory's Technical Supervisor failed to document required competency assessment for one of three testing personnel (TP) employed by the facility in 2023 and 2024, TP number one. Findings included: 1. Review of laboratory's policy "Laboratory Manual Addendum-QA" (effective 07/14/2021) revealed: "Twice per year, the Laboratory Director / Technical Supervisor will conduct a competency evaluation of each testing person ..." 2. Review of laboratory's personnel records revealed TP number one had his competency assessments documented on 09/06/2022 and 07/11/2024. There was no competency assessment documented for TP number one for 2023. 3. In an interview on 02/12/2025 at 1015 hours in the laboratory, TP number one (as indicated on submitted Form CMS 209) confirmed the findings.