

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2314915	<b>(X3) Date Survey Completed</b>  06/25/2025
<b>Name of Provider or Supplier</b>  Chang Skin Surgery Center	<b>Street Address, City, State</b>  2117 General Booth Blvd, Virginia Beach, VA	
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>	<p>An announced initial CLIA survey was conducted at Chang Skin Surgery Center on June 25, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Chang Skin Surgery Center was not in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control (QC) records, patient logs, lab tour and interviews, the laboratory failed to follow their established policy to document daily Hematoxylin and Eosin (H&amp;E) stain maintenance for four (4) days with sixteen (16) Mohs patients tested during the 99 days reviewed. Review timeframe December 9, 2024 until the date of the survey on June 25, 2025. The findings include: 1. Review of the laboratory's QC records from December 9, 2024 through June 25, 2025 revealed a lack of H&amp;E stain line maintenance documented for the following 4 days: 12/23/2024, 3/31/2025, 4/07/2025, and 4/11/2025. 2. Review of the laboratory's Mohs patient logs revealed the following number of Mohs patient tested on the dates listed above: 12/23/2024 (2 patients) 3/31/2025 6 patients), 4/07/2025 (4 patients), and 4/11/2025 (4 patients), a total of 16 patients. 3. During a lab tour at 3:45 pm, the inspector observed a stain line maintenance chart in use for the</p>

month of June. The histology techs confirmed that they are responsible for documenting stain line maintenance. 4. In an exit interview with the Officer Manager and histology techs on June 25, 2025, at 4:15 PM, the findings were confirmed

**D5413**

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

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory policies, laboratory temperature logs, and an interview, the laboratory failed to follow their established policy to monitor and document laboratory temperatures and humidity for four (4) days out of the 99 patient testing days reviewed. Review timeframe included December 9, 2024 through day of survey, June 25, 2025. The findings include: 1. Review of the laboratory manual revealed a Mohs Laboratory Responsibilities policy that included the MOHS tech monitoring and documenting the laboratory temperature and relative humidity daily. 2. Review of the laboratory's temperature and humidity logs for December 9, 2024 through June 25, 2025 revealed a lack of documented laboratory temperature and relative humidity for the following days of Mohs patient testing: 2/14/25, 3/31/25, 4/07/25, 4/11/25. a total of 4 days of 99 days. 3. In an exit interview with the Officer Manager and Mohs Techs on June 25, 2025 at 4:15 PM, the findings were confirmed.