

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1053936	(X3) Date Survey Completed 11/15/2021
Name of Provider or Supplier Skin Surgery Center Of Houston,The	Street Address, City, State 915 Gessner, #640, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was performed on 11/15/21. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D6168 - 42 C.F. R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D5473	<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> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory's policies, the laboratory's Efficiency Logs from February 2020 to October 2021, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for seven of 52 days reviewed from February 2020 to October 2021. Findings: 1. Review of the laboratory's policy titled "Histopathology Tech Daily Protocol" revealed the following: "First case of the day (control) should be evaluated by Dr. Wright for stain efficiency and quality assurance." 2. Review of the laboratory's Efficiency Logs from February 2020 to October 2021 revealed no documentation of the intended reactivity for the H&E stain on the following 7 days: 2 /3/20 6/10/20 8/25/20 8/26/20 5/11/21 6/1/21 7/8/21 3. A random review of patient test records revealed the following patients were tested on days when the intended reactivity of the H&E slide was not documented: Date: 2.3/20 Patient: 120-123 Date: 6</p>

/10/20 Patient: 20-538, 20-239, 20-240, 20-241, 20-242, 20-243 Date: 8/25/20 Patient: 20-835, 20-836, 20-837, 20-838, 20-839, 20-840, 20-841, 20-842, 20-843, 20-844 Date: 8/26/20 Patient: 20-845, 20-846, 20-847, 20-848 Date: 5/11/21 Patient: 21-501, 21-502, 21-503, 21-504, 21-505, 21-506, 21-507, 21-508, 21-509, 21-510 Date: 6/1/21 Patient: 21-573, 21-574, 21-575, 21-576, 21-577 Date: 7/8/21 Patient: 21-732 4. An interview with testing person #2 (as indicated on the CMS 209 form) on 11/15/21 at 12:00 p.m. in the laboratory, after review of the records, confirmed the above findings.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 2 testing personnel to perform high complexity testing- grossing (refer to D6171).

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory

Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify one of two testing personnel to perform high complexity testing- grossing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/11/21) revealed the laboratory identified 2 testing personnel performing high complexity testing- grossing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education to qualify testing person #2 to perform high complexity testing- grossing. 3. An interview with testing person #2 on 11/15/21 at 11:28 a.m. in the laboratory, after review of the records, confirmed the above findings.