

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2230514	(X3) Date Survey Completed 01/29/2024
Name of Provider or Supplier Bayou City Dermatology	Street Address, City, State 3747 Westheimer Road Suite A, 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	An announced survey of the laboratory was conducted on 01/29/2024. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D6168 - 42 C. F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, temperature and humidity logs and staff interview, the laboratory failed to define and monitor storage conditions for proper preservation of processed histopathology slides and blocks for 18 of 18 months reviewed from July 2022 to December 2023. Findings included: 1. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place defining storage conditions to ensure proper preservation of processed slides and or blocks. 2. Review of laboratory's temperature and humidity logs revealed the laboratory did not have documentation of temperature/humidity monitoring for the histopathology slides/blocks' storage area for the 18 months reviewed, July 2022 to December 2023. 3. In an interview on 01/29/2024 at 1045 hours in the laboratory, the facility's Office Manager (as identified on submitted facility's Entrance Conference document) confirmed the findings.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other</p>

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

This STANDARD is not met as evidenced by:

Based on surveyor's observations and staff interview, the laboratory failed to label 14 of 14 secondary reagent containers used for Hematoxylin and Eosin (H&E) staining and/or processing of Mohs surgery tissue. Findings included: 1. Surveyor's observations on 01/29/2024 at 0910 hours in the laboratory revealed: a. An automated stainer with 12 unlabeled containers for H&E stain reagents. A legend listing the reagents for the H&E stain was posted above the stainer, but individual receptacles were not labeled to indicate what solutions each contained. b. One unlabeled container with orange liquid sitting on the countertop under the hood. c. One unlabeled squirt bottle with orange liquid sitting inside the flammable cabinet. 2. In an interview on 01/29/2024 at 0910 hours in the laboratory, the facility's Office Manager (as identified on submitted facility's Entrance Conference document) confirmed the findings.

D6101

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Based on review of laboratory's submitted Form CMS-209, policies/procedures and updates, personnel records, patient test logs and staff interview, the Laboratory Director failed to ensure 1 of 10 testing personnel met the minimum education requirements for high complexity testing in histology. Refer to D6171.

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 review of laboratory's submitted Form CMS-209, policies/procedures and updates, personnel records, patient test logs and staff interview, the laboratory failed to ensure 1 of 10 testing personnel met the minimum education requirements to perform high complexity testing in histology. 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 review of laboratory's submitted Form CMS-209, policies/procedures and

updates, personnel records, patient test logs and staff interview, the laboratory failed to ensure 1 of 10 testing personnel listed met the minimum education requirements to perform high complexity testing in histology. Findings Included: 1. Review of laboratory's submitted Form CMS-209, found the laboratory documented 10 individuals as testing personnel performing high complexity testing in histology. 2. Review of laboratory's policy "Bayou City Dermatology Quality Assurance Manual" (placed into use August 2021) revealed: "A copy of employee's credentials (i.e., diploma or transcripts) indicating degrees obtained, certificate, license or other documentation relevant to the position must be maintained at the Bureau level." 3. Review of laboratory's "Mohs Laboratory Policies and Procedure Updates Meeting Overview" (dated 12/18/2021) revealed: "Upon employment of any new lab personal (sic) the Laboratory Director will assess the educational background and qualification for each position to be filled." 4. Review of laboratory personnel records revealed the following personnel did not have documentation of the minimum required academic record/degree in a biological, chemical, physical, or clinical laboratory science sufficient to perform high complexity testing in histology: Testing Person number 4 (TP4), hired 01/09/2023 Testing Person number 7 (TP7), hired 02/17/2022 and terminated 09/01/2023 Testing Person number 8 (TP8), hired 11/11/2020 and terminated 09/02/2022 5. Review of laboratory's patient test logs from 2022 and 2023 revealed: a. The laboratory performed approximately 7,400 histology examinations in 2022. b. The laboratory performed approximately 9,070 histology examinations in 2023. 6. In an interview on 01/29/2024 at 1015 hours in the laboratory, the facility's Office Manager (as identified on submitted facility's Entrance Conference document) confirmed the findings.