

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2293338	<b>(X3) Date Survey Completed</b>  06/19/2024
<b>Name of Provider or Supplier</b>  Andrew M Quinn Iii, Md, PLLC	<b>Street Address, City, State</b>  4a Bayou Brandt Dr, Beaumont, 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 onsite initial survey conducted on 06/19/2024 found the laboratory out of compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition not met was: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel;
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> 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 review of quality control logs, patient logs, and confirmed in interview, the laboratory failed to document acceptable Hematoxylin and Eosin (H&amp;E) staining characteristics for 9 of 26 patients with slide evaluations, from Mohs procedures, performed in March 2024. The findings included: 1. Review of the laboratory document titled "Quality Control Staining" included the following instruction at the bottom of the page: "Quality Assurance A precut slide from a previously processed case submitted to the Mohs lab which consists of NORMAL tissue will be stained for H&amp;E, documented on the control sheet as QA. This slide will be kept in the file with the cases for the day." 2. Review of the laboratory quality control staining log and patient Mohs log, did not include H&amp;E QC documentation for March 6, 2024, to include the following nine patients who had slides stained from tissue obtained from Mohs surgical cases: Case Number AQ24-059 AQ24-060 AQ24-061 AQ24-062 AQ24-063 AQ24-064 AQ24-065 AQ24-066 AQ24-067 3. In an interview on 6/19</p>

/2024 at 15:20 hours, in the laboratory, the laboratory director and testing personnel one confirmed that the QC slide had not been documented to ensure the predictable staining characteristics of the H&E stain for the above day.

**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 the review of Centers for Medicare & Medicaid Services (CMS) form 209 Laboratory Personnel Report, laboratory documents, and confirmed in interview, the laboratory failed to ensure high complexity testing was performed by testing personnel who met the qualification requirements, for 17 of 17 days where high complexity testing was performed, for records reviewed from December 2023 to June 6, 2024. 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 the Centers for Medicare & Medicaid Services (CMS) form 209 Laboratory Personnel Report, laboratory documents, and confirmed in interview the laboratory failed to ensure two of two testing personnel met the qualification requirements to perform high complexity testing, tissue grossing, for 17 of 17 days for records reviewed from December 2023 to June 6, 2024. The findings included: 1. Review of the CMS form 209, Laboratory Personnel Report, included the following two laboratory testing personnel (TP) performing the high complexity testing tissue grossing: TP1 TP2 2. Review of the laboratory documentation titled "Employee Evaluation" included the following assessment points: "Scoring of Tissue: Satisfactory: Y N 1) Has proper scoring technique to allow epidermal edges to lay flat against surface. Mapping Orientation: Satisfactory: Y N 1) Is able to read and understand map orientation and dye the tissue to properly correlate with the map." TP1 evaluated by the laboratory director: 3/6/2024 TP2 evaluated by the laboratory director: 3/6/2024 Surveyor requested the qualifying education documents for TP1 and TP2 and none was provided. 3. Review of the patient Mohs log, since testing began on 12/12/2023, included 17 days and 138 patients where grossing was performed on tissue provided from Mohs surgical procedures. 4. In an interview on 6/19/2024 at 15:45 the laboratory director and TP1 confirmed the two listed testing personnel were performing the grossing of tissue provided from Mohs surgical procedures, and that TP1 and TP2 did not meet the qualification under 493.1489.