

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D0943813	<b>(X3) Date Survey Completed</b>  06/07/2023
<b>Name of Provider or Supplier</b>  John Q Binhlam, Md Pc	<b>Street Address, City, State</b>  1649 Westgate Circle, Suite 100, Brentwood, TN	
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>	The John Q. Binhlam MD PC DBA Advanced Skin and Laser Center laboratory was found not to be in compliance with the following CLIA conditions: 5200: 493.1230 Condition: General Laboratory Systems 6076: 493.1441 Condition: Laboratories performing high complexity testing; Laboratory Director
<b>D3011</b>	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of records, review of 2018 laboratory survey findings, and staff interview, the laboratory failed to ensure personnel were protected from potential harm when it did not monitor for exposure to xylene in 2021, 2022, and 2023, did not have policies and procedures in place to ensure employees were protected from potential harm from chemical exposure and it was determined the laboratory failed to ensure the previous plan of correction was maintained. The findings include: 1. Observation of the laboratory on 06/07/2023 at 12:15 pm revealed xylene in use on the Tissue-Teck SCA (serial 47641296) instrument used to prepare patient slides from tissue removed during MOHS surgical procedures. 2. No records for xylene monitoring were available. 3. Review of the 10/09/2018 survey including the Department of Health and Human Services Centers for Medicare and Medicaid Services Statement of Deficiencies and Plan of Correction (Form CMS-2567) and documents provided with the plan of correction revealed the laboratory would provide passive dosimeter badges to testing personnel to wear during their entire shifts to monitor exposure and reports would be reviewed annually. This policy could not be located on 06/07/2023. The laboratory failed to maintain compliance with the previous plan of correction. 3. Interview on 06/07/2023 at 3:00 pm with testing person</p>

	<p>one and the office manager confirmed the laboratory used xylene weekly in preparation of tissue removed during MOHS procedures. They further confirmed the laboratory did not monitor for xylene exposure in 2021, 2022, and 2023 and the exposure policy from the 10/09/2018 laboratory survey plan of correction was not available.</p>
<p><b>D5200</b></p>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records, lack of records, and laboratory policies /procedures the laboratory failed to establish and follow a testing personnel competency policy (See 5209), failed to perform twice a year verification of accuracy of histopathology procedures(See 5217), and failed to follow the quality assurance policy (See 5291).</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, lack of records, and staff interview the laboratory failed to establish and follow competency assessment policies for assessing testing personnel competency of inking and grossing of patient tissue removed during MOHS surgical procedures in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory personnel records revealed competency assessment documents were not available for testing person (TP) one. 2. Laboratory policy for personnel competency assessment was not available. 3. Interview on 06/07 /2023 at 1:00 pm with TP one confirmed that TP one performed patient testing to include inking and mapping of tissue removed during MOHS surgical procedures beginning in 2020. TP one further confirmed no documented training or competency assessments were performed in 2020, 2021, 2022, or 2023 and that the laboratory did not have a testing personnel policy or procedure for training and competency assessment.</p>
<p><b>D5217</b></p>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:  
 Based on review of Form CMS-116, laboratory procedure manual, lack of records, and staff interview the laboratory failed to follow it's own policy for semi-annual verification of accuracy for histopathology procedures performed on tissue removed during MOHS surgical procedures and did not verify accuracy of potassium hydroxide (KOH) testing in 2021, 2022 and 2023. The findings include: 1. Review of the Form CMS-116 revealed Provider Performed Microscopy (PPM) KOH testing and histopathology testing on tissue removed during MOHS surgical procedures. 2. Review of the laboratory policy titled "Proficiency Testing" revealed semi-annually the laboratory would send out two patient slide/cases to an outside Dermatopathologist. A policy for verification of accuracy of KOH testing was not available. 3. Semi-annual case review documentation was not available for 2021, 2022, or 2023. 4. Interview with TP one and the office manager on 06/07/2023 at 3:00 pm confirmed the laboratory failed to follow it's policy for semi-annual case review by an outside Dermatopathologist for histopathology samples and did not verify the accuracy of PPM KOH testing in 2021, 2022, and 2023.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
 Based on review of laboratory policy, lack of records, and staff interview, the laboratory failed to follow it's own policy for quality assurance in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory policy titled "Quality Assurance Manual" revealed the laboratory director would monitor general quality policies, patient test management, quality control, semi-annual verification of accuracy, personnel, communications, and complaints on a monthly basis. 2. No documented reviews were available for 2021, 2022, and 2023. 3. Interview on 06/07 /2023 at 3:00 pm with TP one and the office manager confirmed the laboratory failed to follow the policy for quality assurance when the laboratory director failed to document quality assurance reviews in 2021, 2022, and 2023.

**D5417**

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
 Based on observation of the laboratory, review of the Department of Health and Human Services Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) application for certification form (CMS-116), patient reports, and staff interview, the laboratory failed to ensure reagents used to process patient tissue removed during MOHS surgical procedures were not expired in

2020, 2021, 2022, and 2023. This standard was cited from survey on 10/09/2018 and determined that compliance was not maintained at the recertification survey on 06/07/2023. The findings include: 1. Observation of the laboratory on 06/07/2023 at 12:15 pm revealed Eosin stain (lot H262-14) in use for staining patient tissue removed during MOHS surgical procedures with an expiration date of 10/05/2020. 2. Review of the CMS-116 annual testing volumes revealed an annual test volume of 240 patient histopathology samples per year, resulting in approximately 600 patient tissue samples processed with the expired Eosin stain. 3. Random review of patient cases revealed the following patient tissue samples had been processed with expired Eosin stain: M23-050 Reported 05/17/2023 M23-021 Reported 02/15/2023 M22-151 Reported 09/28/2022 M22-028 Reported 03/02/2022 M21-071 Reported 07/28/2021 4. Interview with TP one on 06/07/2023 at 12:30 pm confirmed the Eosin stain (lot H262-14) was in use past the manufacturer listed expiration date with patient tissue processing performed in 2020, 2021, 2022, and 2023.

**D5609**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records and staff interview the laboratory failed to document control procedures including lot numbers and open/expiration dates for reagents and stains used to process patient tissue removed during MOHS surgical procedures in 2021, 2022, and 2023. The findings include: 1. Review of laboratory reagent logs and quality control logs revealed the reagent logs were not maintained to include lot numbers, open/expiration dates, or demonstrate that controls were tested with each shipment for reagents and stains used for processing patient tissue removed during MOHS surgical procedures in 2021, 2022, and 2023. 2. Interview on 06/07/2023 at 2:00 pm confirmed the laboratory failed to document lot numbers and open/expiration dates for reagents and stains used for processing patient tissue specimens removed during MOHS surgical procedures in 2021, 2022, and 2023.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of 10/09/2018 laboratory survey plan of correction, laboratory policy, and personnel records the laboratory director failed to maintain compliance with the plan of correction submitted in 2018 (See 6079), failed to ensure the quality assurance program was maintained (See 6094), failed to ensure personnel competency assessment policy was established and maintained (See 6103), and failed to ensure testing personnel responsible for processing patient tissue samples removed during MOHS surgical procedures had documented training (See 6102) in 2021, 2022, and 2023.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of previous laboratory survey (10/09/2018) documents, laboratory policies, reagent logs, and quality control logs, the laboratory director failed to ensure compliance with applicable regulations and maintain compliance with the previous plan of correction in 2021, 2022, and 2023. Refer to D3011 and D5417. The findings include: 1. Review of the 10/09/2018 laboratory survey documents including the CMS Form 2567 and plan of correction revealed the following: Annual monitoring exposure plan for employees for the use of formaldehyde and xylene. MOHS quality control form to monitor reagent and stain expiration dates. 2. Review of laboratory policies, reagent logs, and quality control logs revealed compliance with policies and procedures submitted as part of the plan of correction from the previous survey were not maintained in 2021, 2022, or 2023.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, lack of records, and staff interview, the laboratory director failed to ensure the Quality Assurance program was maintained for 2021, 2022, and 2023. Refer to D5291. The findings include: 1. Review of the laboratory policy titled "Quality Assurance Manual" revealed the laboratory would monitor all processes for pre-analytic, analytic, and post analytic activities on a monthly basis. It also stated the laboratory director is the responsible individual for monitoring the plan. 2. Quality assessment records were not available for 2021, 2022, or 2023. 3. Interview with the TP one and the office manager on 06/07/2023 at 3:00 pm confirmed the laboratory director failed to ensure the quality assurance program was maintained in 2021, 2022, and 2023.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

The laboratory director must 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 the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), staff interview, and lack of records, the laboratory director failed to ensure testing personnel had documented training prior to performing grossing of patient tissue samples removed during MOHS surgical procedures. The findings include: 1. Review of the Form CMS-209 revealed TP one listed on the personnel report. 2. Interview with TP one on 06/07/2023 at 12:15 pm revealed TP one performs grossing (inking and mapping) of tissue removed during MOHS procedures. 3. No records of documented training of TP one were available.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:  
Based on record review, lack of records, and staff interview, the laboratory director failed to ensure a personnel policy for competency assessment was in place for testing personnel that performed inking and mapping of patient tissue samples removed during MOHS surgical procedures in 2020, 2021, 2022, and 2023. (See 5209) The findings include: 1. Review of laboratory personnel records revealed no documentation of competency assessments for testing personnel listed on the Form CMS-209. 2. Review of laboratory policies and procedures revealed the laboratory did not have a personnel competency policy. 3. Interview on 06/07/2023 at 1:00 pm with TP one confirmed that TP one performed inking and mapping of patient tissue removed during MOHS procedures beginning in 2020 and further confirmed the laboratory did not have a personnel policy or procedure for competency assessment.