

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2065598	(X3) Date Survey Completed 11/13/2025
Name of Provider or Supplier John K Wildemore Md, Llc	Street Address, City, State 744 West Lancaster Ave Suite 230, Wayne, PA	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel (TP) #2, the laboratory failed to verify twice annually the accuracy of macroscopic histopathology examinations performed for 2 of 2 years in 2024 and 2025. Findings include: 1. On the day of survey, 11/13/2025, the laboratory failed to provide documentation for the verification of accuracy performed at least twice annually for macroscopic histopathology examinations (grossing and inking) performed in 2024 and 2025. 2. The laboratory could not provide a procedure for the performance of the verification of accuracy for macroscopic histopathology examinations (grossing and inking). 3. TP #2 (CMS 209 personnel #2, dated 11/13/2025) confirmed the findings above on 11/13/2025 at 10:50 am.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's temperature records, lack of documentation, and interview with Testing Personnel (TP) #2, the laboratory failed to establish acceptable criteria for relative humidity to ensure operating conditions were met for reliable test system operation and test result reporting of MOHS microscopic slide examinations performed for 2 of 2 years from 11/02/2023 to 11/13/2025. Findings Include: 1. On the day of the survey, 11/13/2025 at 09:43 am, review of the laboratory's temperature logs revealed the laboratory failed to establish acceptable criteria for relative humidity to ensure operating conditions were met for the following instrumentation used when Mohs microscopic slide examinations were performed from 11/02/2023 to 11/13/2025: - Avantik QS11 cryostat (s/n 57840) manufacturer's acceptable range: 0% to 60% - Leica DM 750 microscope (s/n 29VP0086) manufacturer's acceptable range: 20% to 90% 2. The laboratory could not provide documentation of monitoring relative humidity for 2 of 2 years when Mohs microscopic examinations were performed from 11/02/2023 to 11/13/2025. 3. Review of the laboratory's Mohs test logs revealed the laboratory performed 473 histopathology slide examinations from 11/02/2023 to 11/13/2025. 4. TP #2 (CMS 209 personnel #2, dated 11/13/2025) confirmed the findings above on 11/13/2025 at 10:50 am.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, lack of maintenance/function check records and interview with Testing Personnel (TP) #2, the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 Extech thermometer/humidity monitor used in the Histopathology laboratory from 11/02/2023 to the day of survey. Findings Include: 1. On the day of survey, 11/13/2025 at 10:22 am, observation of the laboratory revealed 1 of 1 Extech hygro-thermometer clock (model number 445703), with no expiration date. 2. The laboratory could not provide maintenance/function check records for the 1 of 1 Extech thermometer/humidity monitor used to record room temperature in the Histopathology laboratory from 11/02/2023 to 11/13/2025. 3. TP #2 (CMS 209 personnel #2, dated 11/13/2025) confirmed the findings above on 11/13/2025 at 10:50am.