

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0195312	(X3) Date Survey Completed 05/01/2025
Name of Provider or Supplier Arthur K Balin Md Phd Pc Lab	Street Address, City, State 110 Chesley Drive, Media, 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 the Lab Manager (LM), the laboratory failed to verify twice annually the accuracy of macroscopic histopathology examinations performed for 2 of 2 years from 07/19/2023 to 05/01/2025. Findings include: 1. On the day of survey, 05/01/2025, 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 2023 and 2024. 2. The laboratory could not provide a procedure for the verification of accuracy for macroscopic histopathology examinations (grossing and inking). 3. LM confirmed the findings above on 05/01/2025 at 11:30 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 room temperature and humidity logs, lack of documentation and interview with the Lab Manager (LM), the laboratory failed to monitor and document room temperature and relative humidity to ensure proper test system operating conditions were met for instrumentation used to perform histopathology testing for 226 of 652 days from 07/19/2023 to 05/01/2025. Findings include: 1. On the day of survey, 05/01/2025, review of the laboratory's temperature logs revealed the laboratory failed to monitor and document room temperature (laboratory's acceptable range: 65 to 79 degrees Fahrenheit) to ensure proper test system operating conditions were met for the following from 07/19/2023 to 05/01/2025: For 226 of 652 days: - 1 of 1 Tissue-Tek VIP 2000 Processor - 1 of 1 Leica CM 3000 cryostat - 1 of 1 Leica CM 3050S cryostat - 2 of 2 Biogenex i6000 IHC stainers For 652 of 652 days: - 1 of 1 Olympus AH3 Vanox microscope - 1 of 1 Olympus BH2 multihead microscope 2. The hours of laboratory testing are Monday-Friday 08:00 am to 05:00 pm (CMS 116). The laboratory could not provide documentation of temperature taken on days the laboratory was closed. 3. The laboratory failed to document and define criteria for relative humidity (manufacturer's acceptable limit: less than 60%) for 652 of 652 days from 07/19/2023 to 05/01/2025. 4. The LM confirmed the above findings on 05/01/2025 at 11:30 am.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, lack of maintenance records and interview with the Lab Manager (LM), the laboratory failed to assess the maintenance and function checks as defined by the manufacturer for 1 of 1 Labconco Fume Hood used for Histopathology testing from 07/19/2023 to the day of survey. Findings include: 1. On the day of survey 05/1/2025 at 10:26 am during the laboratory tour, the surveyor observed 1 of 1 Labconco Fume Hood (serial number LA#301116) with no service maintenance date indicated. 2. The laboratory could not provide maintenance/function check records for the 1 of 1 Labconco Fume Hood. 3. LM confirmed the findings above on 05/01/2025 at 11:30 am.