Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2138528	01/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Washington Health System Lab - Ml	80 Landings Drive 2nd Floor, Washington, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a lack of documentation and interview with the laboratory director (LD), the laboratory failed to monitor and document the room humidity to ensure operating conditions were met for the histopathology testing from 02/17/2022 to the day of the survey. Findings Include: 1. On the day of the survey, 01/09/2024 at 11:21 am, a review of the Leica CM 1860 UV cryostat manufacturer's instructions revealed that all specifications related to temperature are valid only for an ambient temperature up to 22 C and for an air humidity lower than 60%. 2. The laboratory failed to provide documentation of humidity for the Leica CM 1860 UV cryostat for histopathology testing from 02/17/2022 to the day of the survey. 3. The LD confirmed the findings above on 01/09/2024 at 11:30 am.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated

	to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a lack of documentation and interview with the laboratory director (LD), the Technical Supervisor (TS) (CMS 209 Personnel #1) failed to evaluate the annual competency assessment for 2 of 3 Testing Personnel (TP) who performed Microscopic Examinations, Grossing, Inking, and Mapping in histopathology laboratory in 2022 and 2023. Findings include: 1. On the day of survey, 01/09/2024 at 10:30 am, the laboratory could not provide competency assessment records for 2 of 3 TP (CMS 209 TP #2 and #3) for their testing responsibilities in histopathology laboratory in 2022 and 2023. 2. The laboratory's total estimated annual volume for histopathology testing was 40 (CMS 116). 3. The LD confirmed the findings above on 01/09/2024 at 11:30 am.