Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1021114	02/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Geisinger Clinic Dba Geisinger Medical Group	200 Scenery Drive, State College, 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 supervisor (LS), the laboratory failed to monitor and document the room humidity to ensure operating conditions were met for the operation of the Leica CM 1860 UV cryostat used for histopathology testing from 04/19/2022 to the day of the survey. Findings Include: 1. On the day of the survey, 02/15/2024 at 01:00 pm, 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 for the monitoring of humidity to ensure operating conditions were met for the Leica CM 1860 UV cryostat used for histopathology testing from 04/19/2022 to the day of the survey. 3. The LS confirmed the findings above on 02/15/2024 at 01:33 pm.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For 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 establish a

	maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, record review, and interview with the laboratory supervisor (LS), the laboratory failed to establish and maintain a maintenance protocol that ensures equipment performance for 1 of 1 thermometer used for Room Temperature (RT) monitoring for histopathology testing from 4/19 /2022 to the day of the survey. Findings include: 1. At the time of survey, 02/15/2024 at 12:00 pm, the laboratory failed to establish and maintain a maintenance protocol for 1 of 1 thermometer (SPER Scientific) used for RT monitoring for the use of Leica cryostat from 04/19/2022 to the day of survey. 2. Acording to Leica CM 1860 UV cryostat manufacturer's instructions all specifications related to temperature are valid only for an ambient temperature up to 22 C and for an air humidity lower than 60%. 3. The LS confirmed the findings above on 02/14/2024 at 01:33 pm.