

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2017227	(X3) Date Survey Completed 06/05/2019
Name of Provider or Supplier Mersi Immunopathology Laboratory	Street Address, City, State 1440 Main St, Waltham, MA	
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
D0000	A CLIA recertification survey was conducted for the MERSI Immunopathology Laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed document conditions for accurate and reliable test system operation and test result reporting as evidenced by the following: A review of temperature records for calendar years 2018 and 2019 revealed that the laboratory was not documenting the temperature of the cryostat when histopathology slide preparation was being performed. The histotechnician confirmed in an interview on 6/5/19 at 9:45 AM that the cryostat temperature were being monitored but not documented when histopathology slide preparation was being performed. .</p>
D6084	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from</p>

physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based on observation and interview, the laboratory director failed to ensure that the environmental conditions provided a safe environment in which employees were protected from biological hazards as evidenced by the following: On the day of the survey at 9:41 AM it was observed that an air conditioning unit in the laboratory was located in close proximity to a hematology analyzer used in research. It was observed venting air into the laboratory area with the potential of dispersing infectious agents into the air. The Histotechnician interviewed on 6/5/19 at 9:45 AM confirmed that the air conditioning unit had been installed recently due to problems with the regulation of the temperature in the laboratory area. She further stated that the temperature of the laboratory had been too warm for the preparation of histology slides.