

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2171828	(X3) Date Survey Completed 09/24/2020
Name of Provider or Supplier Weland Clinical Laboratories, Pc	Street Address, City, State 2515 Cyclone Drive Ste B, Waterloo, IA	
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	<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 review of laboratory temperature records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 9: 10 am on 09/24/2020, the laboratory failed to document the cryostat temperature for one out of three days of patient testing (05/26/2020) in 2020. The findings include: 1. On 05/26/2020, the laboratory performed a frozen section on patient identifier B using a cryostat for cutting tissue. 2. The laboratory did not document the temperature of the cryostat used for cutting tissue on 05/26/2020.</p>