

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0651212	<b>(X3) Date Survey Completed</b>  04/24/2019
<b>Name of Provider or Supplier</b>  Central Regional Pathology Laboratories	<b>Street Address, City, State</b>  2945 Hazelwood Street Suite 310, Maplewood, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5431</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, record review and interview with laboratory personnel, the laboratory failed to establish and follow a procedure for function checks of general laboratory equipment. Findings are as follows: 1. A tour of the laboratory on 4/24/19, at 8:35 a.m., revealed the presence of a Kenmore Refrigerator / Freezer (Serial Number = EK4824644), with a Taylor Analog Alcohol Thermometer, Model 5925 (no serial number) in the refrigerated compartment. 2. The Quality Control - Maintenance: Refrigerator procedure, located in the Histology Procedures manual, did not include instructions for assuring the accuracy of this thermometer on a periodic basis. 3. Function check records from 2017 and 2018 for the thermometer noted above could not be located in the laboratory's files. 4. The laboratory was unable to provide the missing procedure or records upon request. 5. In an interview on 4/24/19, at 11:20 a.m., the Histotechnologist confirmed the above findings. .</p>