

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0162274	<b>(X3) Date Survey Completed</b>  11/18/2020
<b>Name of Provider or Supplier</b>  Center For Rheumatology Llp,The	<b>Street Address, City, State</b>  4 Tower Place, 8th Floor, Albany, NY	
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>D5413</b>	<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 surveyor's review of laboratory's temperature records and an interview with the testing person, the laboratory failed to include expected refrigerator and freezer temperature ranges on the daily log sheet used to monitor the temperatures for both refrigerator/freezers, located in the infusion area. FINDINGS: 1. The testing person confirmed on November 18, 2020 at approximately 3:00 PM, that the laboratory failed to include the expected refrigerator and freezer temperature ranges on the daily log sheet used to monitor the temperatures. a) Refrigerator/freezer #1 is used to store control, calibration material and proficiency testing specimens. b) Refrigerator/freezer #2 is used to store pharmaceuticals material for patient infusion. 2. The nursing staff did record the temperatures daily from 1/10/2019 through survey date. However, surveyor could not verify if these recorded temperatures were within the expected ranges.</p>