

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0952961	(X3) Date Survey Completed 06/24/2020
Name of Provider or Supplier Arthritis & Osteoporosis Center Inc	Street Address, City, State 2760 Century Boulevard, Wyomissing, 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	<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 observation, review of temperature logs and interview with the testing personnel, on the date of the survey (06/24/2020), the laboratory failed to meet laboratory defined criteria for proper storage of chemistry reagents from (06/01/2019) through (06/24/2020). Findings include: 1. The laboratory defined refrigerator temperature range was (2 to 8 C). 2. The laboratory defined freezer temperature range was (-12 to -20C). 3. At (10:00 06/24/2020), the surveyor observed chemistry reagents for the Mindray BS200 and the Theratest EL analyzers were stored in the GE#2 refrigerator/freezer. 4. Review of the temperature logs revealed the GE#2 refrigerator temperature was out of range (57 of 389 days). 5. Review of the temperature logs revealed the GE#2 freezer temperature was out of range (181 of 389 days). 6. The laboratory testing personnel confirmed the above findings.at (10:30 06 /24/2020).</p>