

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0952961	<b>(X3) Date Survey Completed</b> 08/01/2024
<b>Name of Provider or Supplier</b> Arthritis & Osteoporosis Center Inc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2087</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #1, the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in 5 of 6 Chemistry testing events in 2022, 2023 and 2024. Findings include: 1. On the day of survey, 08/01/2024 at 9:00 am, review of the laboratory's API PT records revealed the laboratory scored below 80 percent for each analyte in the following chemistry testing events: - 2022 Chemistry-core 3rd event: Sodium 0% - 2023 Chemistry-core 1st event: Bilirubin, total 60% - 2023 Chemistry-core 2nd event: Sodium 60% - 2024 Chemistry-core 1st event: Parathyroid hormone 50% - 2024 Chemistry-core 2nd event: Bilirubin, direct 40% 2. TP #1 confirmed the findings above on 08/01/2024 at 11:47 am.</p>
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documents and interview with Testing Personnel (CMS 209 TP# 1) the laboratory failed to perform and document maintenance on laboratory equipment</p>

and test systems in 2023. Findings include: 1. On day of the survey, 08/01/2024 at 9:31 AM, review of laboratory equipment and test system maintenance records revealed: - BS-200 Mindray (S/N WN-47105465F) maintenance was performed on 11/08/2022 and due on 11/08/2023 - 3 of 3 Drucker Centrifuges 642E (S/N 210113GD033, 200313FH096 and 180613DH558) performed on 10/13/2022 and due on 10/13/2023 - 1 of 1 Summit /Accucold Refrigerator (S/N ARS23ML-20040023) performed on 10/13/2022 and due on 10/13/2023 - 1 of 1 Whirlpool Refrigerator /Freezer (S/N EP3521460) performed on 10/13/2022 and due on 10/13/2023 - 1 of 1 Frigidaire Freezer (S/N WB93536151) performed on 10/13/2022 and due on 10/13/2023 - 1 of 1 Summit/Acuucold Freezer (S/N 2020-07-100) performed on 10/13/2022 and due on 10/13/2023 - 1 of 1 Boekel Incubator (S/N 042202843) performed on 10/13/2022 and due on 10/13/2023 - 1 of 1 Digi-Sense RT thermometer (S/N 19236536) performed on 10/13/2022 and due on 10/13/2023 2. Observation during the laboratory tour on 08/01/2024 at 11:45 AM, revealed that the laboratory failed to calibrate or replace the following: - 1 of 1 AccuTherm refrigerator/freezer thermometer that expired 04/29/2023 - 1 of 1 Fisher Brand Traceable thermometer for Incubator temperature expired 04/14/2023 3. The laboratory failed to provide documentation of maintenance performed in 2023. 4. TP#1 confirmed the above findings on 08/01/2024 at 12:00 PM.