

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0340535	(X3) Date Survey Completed 02/09/2022
Name of Provider or Supplier Crystal Arthritis Center, Inc	Street Address, City, State 471 North Cleveland-Massillon Road, Akron, OH	
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
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 record review and an interview with the Technical Supervisor (TS), the laboratory failed to attain a proficiency testing (PT) score of at least 80 percent of acceptable responses for the analyte antinuclear antibody (ANA) for the first testing event of 2021. This deficient practice had the potential to affect 334 out of 334 patient ANA test results from the first PT event in 2021 to the second PT event in 2021. Findings Include: 1. Review of the laboratory's 2020 and 2021 College of American Pathologists (CAP) PT documentation, provided on the date of the inspection, revealed an analyte testing score of 0% for ANA for the first testing event of 2021. 2. The TS confirmed the laboratory did not achieve a PT analyte testing score of at least an 80% for ANA for the first testing event of 2021. The interview occurred on 02/09/2022 at 9:30 A.M.</p>
D2087	<p>ROUTINE CHEMISTRY 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 record review and an interview with the Technical Supervisor (TS), the laboratory failed to achieve a proficiency testing (PT) score of 80% (percent) for the analyte blood urea nitrogen (BUN) in the third PT event in 2020 in the specialty of</p>

Chemistry. This deficient practice had the potential to affect 144 out of 144 patient ANA test results from the third PT event in 2020 to the first PT event in 2021. Findings Include: 1. Review of the laboratory's 2020 College of American Pathologists (CAP) Chemistry PT documentation, provided on the date of the inspection, revealed the following unsatisfactory analyte testing scores: Third PT Event 2020 BUN; 60% 2. The TS confirmed the unsatisfactory BUN PT score in the third testing event of 2020. The interview occurred on 02/09/2022 9:30 A.M.