Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0952961	10/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Osteoporosis Center Inc	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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory Quality Assurance procedure, lack of quality assessment (QA) records, and interview with the Laboratory Supervisor (LS), the laboratory failed to document all general laboratory systems quality assessment activities from 2020 to the day of survey. Findings Include: 1. On the day of survey, 10/18/2022 at 13:07 PM, a review of the laboratory quality assurance procedure revealed that a QA checklist is supposed to be reviewed and signed off by the Laboratory Director Quarterly. 2. LS The laboratory failed to document all general laboratory systems quality assessment activities and there was no QA checklist from 2020 to the day of survey. 3. LS confirmed the finding above on 10/18/2022 at 14:15 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by:

	Based on observation of Chemistry analyzers during the laboratory tour, lack of documents, and interview with the Laboratory Supervisor (LS) the laboratory failed to perform Annual maintenance on 1 of 1 BS-200 Mindray analyzer from 3/24/2021 to 10/18/2022. Findings include: 1. Review of the BS-200 Mindray chemistry analyzer maintenance record revealed that the last maintenance was performed on 3/24/2021 and was due on 3/24/2022. 2. On the day of survey, 10/18/2022 at 13:30 PM, a laboratory tour revealed that the laboratory failed to perform yearly maintenance on 1 of 1 BS-200 Mindray Chemistry analyzer from as at when due. 3. The LS confirmed the above findings on 10/18/2022 at 14:15 PM.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) and College of Americapn Pathologist (CAP) proficiency test (PT) records and interview with the Laboratory Supervisor (LS) the LD failed to ensure that 10 of 12 proficiency testing attestations were signed by the LD in 2021 and 2022 for Chemistry Core and Immunology PT. Findings include: 1. On the day of the survey 10/18/2022 at 12:30 PM, a review of the PT records revealed that the Laboratory Director failed to sign the following events in 2021 and 2022 proficiency attestations. - API Chem Core 1st, 2nd and 3rd Event 2021. - CAP Immunology 3rd event 2021. - API Chem Core 1st and 2nd Event 2022. - API Immunology 1st Event 2022. - CAP Immunology 1st, 2nd and 3rd Event on 2022. 2. Interview with LS confirmed these findings above on 10/18 /2022 at 14:15 PM.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the review of the American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing (PT) records and interview with the Laboratory Supervisor (LS), the Laboratory Director (LD) failed to identify and ensure that corrective actions were followed for 4 of 12 Chemistry Core and Immunology events with PT performance in 2021 and 2022. Findings include: 1. On the day of survey, 10/18/2022 at 12:30 PM, review of API and CAP PT records revealed, the laboratory did not document corrective actions for the following API and

	CAP Chemistry Core and Immunology PT scores that were less than 100% in 2021 and 2022: - API 1st Event Chemistry Core 2021 -Total Protein 0%, Triglyceride 40%, CO2 20%, Total Calcium 40%. -API 2nd Event Chemistry Core 2021- Total Cholesterol 20%, Glucose 0%. - CAP 3rd Event Immunology 2021- Anti Gliadin IgA Qualitative Unacceptable. - API 1st Event Immunology 2022-Anti RnP/sm 80%. -API 2nd Event Chemistry Core Bilirubin- Not Graded. 2. The LS confirmed the above findings on 10/18/2022 at 13:15PM. * Repeated deficiency.