Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0952961	02/18/2026
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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathology (CAP) proficiency testing (PT) records and interview with testing personnel (TP) #1, the laboratory failed to verify the accuracy of the PT results obtained for 2 of 2 CAP Immunology testing events in 2025 that were not graded by the PT program (CAP). Findings include: 1. On the day of the survey, 2/18/2026 at 10:30 am, review of the laboratory's CAP PT records revealed the laboratory failed to verify the accuracy of the following analytes that were not graded by the PT agency (CAP) for 2 of 2 CAP Immunology PT testing events performed in 2025: CES-A 2025: Clinical Immunology 1st event: - Anti-gliadin IgA quantitative, Anti-gliadin IgG quantitative, Anti-tTG IgA quantitative (CES-01, 02, 03: insufficient peer group) - Anti-tTG IgG quantitative (CES-01, 02, 03: educational challenge) CES-B 2025: Clinical Immunology 2nd event: - Anti-gliadin IgA quantitative, Anti-gliadin IgG quantitative, Anti-tTG IgA quantitative (CES-04, 05, 06: insufficient peer group) - Anti-tTG IgG quantitative (CES-04, 05, 06: educational challenge) 2. The CAP's, actions laboratories should take when a PT result is not graded document stated, "Document that the laboratory performed a self-evaluation using the data presented in the participation summary. Evaluation criteria is not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 3. Review of the laboratory's test logs revealed the laboratory performed 388 immunology tests for Glia IgA, Glia IgG, TTG IgA and TTG IgG in 2025. 4. TP #1 (CMS-209 personnel #2, dated 02/16/2026) confirmed the findings above on 2/18/2026 at 12:15 pm.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs, lack of documentation and interview with testing personnel (TP) #1, the laboratory failed to monitor and document humidity as required under standard 493.1252 to ensure reliable test system operation and test result reporting for the Biotek Elx 800/Teris used to perform immunology testing for 18 of 18 months from 08/01/2024 to 2/18/2026. Findings include: 1. On the date of the survey, 2/18/2026 at 11:30 am, the laboratory could not provide documentation for monitoring room humidity (manufacturer acceptable range 10-85% RH) to ensure operating conditions were met for the following instrumentation used to perform immunology testing for 18 of 18 months from 08/01 /2024 to 2/18/2026: - Biotek Elx 800/Teris 2. The lab performed 6,460 immunology tests in 2025. (CMS-116 estimated annual volume, dated 2/16/2026). 3. TP #1 (CMS-209 personnel #2, dated 02/16/2026) confirmed the findings above on 2/18/2026 at 12: 00 pm.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with Testing Personnel (TP) #1, the laboratory failed to establish and follow written policies for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the postanalytic system specified in 493.1291 for 18 of 18 months from 08/01/2024 to the day of survey. Findings include: 1. On the day of survey, 02/18/2026 at 12:21 pm, the laboratory could not provide a procedure for the ongoing mechanism to monitor, assess and correct problems found in the postanalytic system specified in 493.1291 for 18 of 18 months from 08/01/2024 to the day of survey. 2. The laboratory failed to provide records for the following periodic checks performed to verify the accuracy of the Laboratory's Information System (Orchard Harvest LIS) from 08/01/2024 to 02/18 /2026: - Calculated Data - Patient results transmitted between the BioTek ELx800 microplate reader (s/n 2626) and LIS - Patient specific data 3. The laboratory performed 6,640 Immunology tests in 2025 (CMS 116, estimated annual volume, dated 02/16/2026). 4. TP #1 (CMS 209 personnel #2, dated 02/16/2026) confirmed the findings above on 02/18/2026 at 12:40 pm.