Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0983990	07/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Orthopaedic Hospital Of Wisconsin, Llc	475 W River Woods Pkwy, Glendale, WI	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control records and the IQCP (Individualized Quality Control Plan) and interview with the Technical Consultant, the laboratory did not test control material on one of two iSTAT analyzers each month. Findings include: 1. Review of iSTAT quality control records for June through August 2023 showed the laboratory did not test external control materials monthly for each of the three test cartridges (CG8+, CHEM8+ and Troponin) on each of the two iSTAT analyzers except for the CHEM8+ in August. Reports showed the laboratory performed only the following iSTAT external quality control testing. Cartridge / Control Level / Analyzer Serial Number June 2023 CG8+ / 1, 2 & 3 / 334760 Troponin / 1 & 2 / 334760 CHEM8+ / 1 & 3 / 334760 July 2023 CG8+ / 1 & 3 / 303510 CG8+ / 2 / 334760 Troponin / 1 / 303510 Troponin / 2 / 334760 CHEM8+ / 1 & 3 / 334760 CHEM8+ / 2 / 303510 August 2023 CG8+ / 1, 2 & 3 / 334760 Troponin / 1 & 2 / 303510 CHEM8+ /1 & 3 /334760 CHEM8+ / 1 & 3 / 303510 2. Review of the 'Individualized Quality Control Plan', DX362, showed the plan required performance of external controls monthly for iSTAT testing. The plan did not exempt testing personnel from performing external control testing on both analyzers. 3. Interview with the Technical Consultant on July 22, 2024, at 1:30 PM confirmed the

	laboratory did not perform external quality control on each of the two analyzers monthly.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Consultant, the laboratory did not perform an evaluation twice annually to define the relationship between testing on the two iSTAT analyzers in the last two of two years, 2022 and 2023. Findings include: 1. Review of laboratory records of comparison testing on the two iSTAT analyzers showed testing personnel performed a comparison in May 2022. The records did not show another comparison until July 2023. No other comparison records were available in 2022 or 2023. 2. Interview with the Technical Consultant on July 22, 2024, at 1:15 PM confirmed the laboratory did not have documentation to show the laboratory completed comparison testing twice annually on the two iSTAT analyzers in 2022 and 2023.