Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2337159	04/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Orthopedic & Shoulder Center	2200 Fort Jesse Rd - Ste 250, Normal, IL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the federal Certification and Survey Provider Enhanced Reporting (Casper) Report 0096D, laboratory policies and procedures, lack of laboratory proficiency testing (PT) records, and interview with testing personnel (TP) #1; the laboratory failed to enroll in proficiency testing challenges from the start of testing, 02 /25/26, to the date of survey, 04/21/26, for six of six regulated hematology analytes including white blood cell differential, white blood cell count, erythrocyte count, hematocrit, hemoglobin, and platelet count testing performed on the Sysmex XN-330 Hematology analyzer. Findings include: 1. Review of the laboratory's procedure manual titled, "Standard Operating Procedure Sysmex XN -330 Hematology Analyzer Operation, Quality Control & Maintenance ", which indicated, under "16.Proficiency Testing", "Laboratory must participate in a CMS-approved proficiency testing (PT) program for all regulated analytes performed in the laboratory, per 42 CFR 493.801." 2. Review of eight of eight patient test results confirmed the laboratory reported results for white blood cell differential, white blood cell count, erythrocyte count, hematocrit, hemoglobin, and platelet count. Patient number: Date of service: a) P-01 02/25/26 b) P-02 03/02/26 c) P-03 03/02/26 d) P-04 03/02/26 e) P-05 03/16/26 f) P-06 03/16/26 g) P-07 04/01/26 h) P-08 04/16/26 3. The laboratory lacked PT records and

	failed to have documentation for enrollment in proficiency testing for the following six regulated hematology analytes: a) White Blood Cell differential b) White Blood Cell count c) Erythrocyte count d) Hematocrit e) Hemoglobin f) Platelet count 4. Review of the federal Casper report 0096D revealed no scores were reported to the Center for Medicare and Medicaid Services from the start of testing, 02/25/26, to the date of survey, 04/21/26, for the specialty of hematology. 5. On survey date 04/21/26 at 10:41 am, TP#1 confirmed the laboratory failed to enroll in PT for the six regulated analytes identified above for testing in the specialty of hematology.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: D5205 Based on review of the laboratory's policy and procedure manual and interview with testing personnel (TP) #2; the laboratory failed to have a system in place to ensure it documents all complaints and problems reported to the laboratory. Findings Include: 1. Review of laboratory policy and procedure manual failed to identify a policy on the handling of complaint investigations. 2. On survey date 04/21 /26 at 11:04 PM, TP# 2 confirmed the laboratory did not have a policy in place to ensure complaints are documented and investigated.