Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 17D0962629	**(X3) Date Survey Completed** 12/13/2019
Name of Provider or Supplier Kansas City Orthopaedic Institute	**Street Address, City, State** 3651 College Blvd, Leawood, KS	
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**
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the I-STAT analyzer for) and interview with the technical supervisor, the laboratory failed to verify reference intervals (normal values). Findings: 1. Review of the verification procedures for the I-STAT analyzer showed no verification of normal values for analytes:PT /INR, blood gas: pH,pCO2,pO2. No documentation of verification on I-STAT of normal reference ranges was available on date of survey: December 13,2019. 2. Interview with the technical consultant on December 13, 2019 at 11:30 a.m. confirmed the laboratory failed to ensure that normal values for the I-STAT analyzer was appropriate for the laboratory's patient population.