Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0962629	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Kansas City Orthopaedic Institute	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
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 review of test lists, presence of three Abbott iSTAT analyzers, lack of comparison records and interview, the laboratory failed to evaluate and define the relationship between test results using three of three instruments for 13 of 13 analytes. Findings: 1. Review of analytes pH, pO2, pCO2, prothrombin time (PT), Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Glucose, Creatinine, Blood Urea Nitrogen (BUN), Hematocrit (Hct), and total Carbon Dioxide (tCO2) showed they were performed on the Abbott iSTAT analyzer. 2. Three iSTAT analyzers were used for testing: serial number (S/N) 32594, S/N 352004, and S/N 331089. 3. No iSTAT testing comparison records from 12/13/19 to 2/16/22 were made available at the time of survey. 4. Interview with technical consultant (TC) #1 on 2/16/22 at 2:30 p.m. confirmed, the laboratory failed to evaluate and define the relationship between three of three Abbott iSTAT test results for pH, pO2, pCO2, prothrombin time (PT), Sodium (Na), Potassium (K), Chloride (Cl), ionized Calcium (iCa), Glucose, Creatinine, Blood Urea Nitrogen (BUN), Hematocrit (Hct),and total Carbon Dioxide (tCO2).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in

	an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) from the provider American Proficiency Institute (API) performed 12/14/19 to 2/16/22, delegation of duties document, and interview with TC #1 revealed that the laboratory director (LD) or designee failed to attest on 11 of 13 events that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. Review of the attestation pages for PT from API revealed no signature of the LD or qualified designee was present on: a. API 2020 Chemistry Core 1st, 2nd, and 3rd events. b. API 2020 Hematology/Coagulation 1st, 2nd, and 3rd events. c. API 2021 Chemistry Core 1st and 2nd events. d. API 2021 Hematology/Coagulation 1st, 2nd, and 3rd events. 2. Delegation of duties documents revealed enrollment and participation in proficiency testing has been delegated to the TC position. 3. Interview with TC#1 on 2/16/22 at 1:15 p.m. confirmed, the laboratory director (LD) or designee failed to attest on 11 of 13 events that proficiency testing samples were handled in the same manner as patient samples.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based upon review of IQCP procedure, QC documents, test volumes and interview with TC#1, the TC failed to ensure acceptable levels of analytic performance were maintained on three of three Abbott iSTAT analyzer for thirteen of thirteen analytes. Findings: 1. Review of the iSTAT IQCP procedure revealed 2 levels of QC is required every 30 days, new lot or new shipment. 2. Review of iSTAT QC records for 1/1/21 through 2/15/22 for prothrombin time revealed: a. two of three analyzers had no QC performed 1/2021. b. three of three analyzers had no or only 1 level of QC performed per lot in 2/2021. c. three of three analyzers had no or only 1 level of QC performed per lot in 3/2021. d. one of three analyzers had no QC performed in 4/2021. e. two of three analyzers had no QC performed 5/2021. f. one of three analyzers had no QC performed in 6/2021. g. one of three analyzers had no QC performed in 7/2021. h. two of three analyzers had no QC performed 8/2021. i. two of three analyzers had no or only 1 level of QC performed per lot in 9/2021. j. one of three analyzers had no QC performed in 10/2021. k. two of three analyzers had no or only 1 level of QC performed per lot in 11/2021. l. one of three analyzers had no QC performed in 12 /2021. m. one of three analyzers had no QC performed in 1/2022. k. two of three analyzers had no QC performed 2/2022. 3. Review of iSTAT QC records for 1/1/21 through 2/15/22 for EG6+ cartridges for pH, PCO2, pO2, Na, K, and Hct revealed: a. two of three analyzers had no or only 1 level of QC performed per lot in 1/2021. b. two of three analyzers had no QC performed 2/2021. c. two of three analyzers had no or only 1 level of QC performed per lot in 3/2021. d. two of three analyzers had no or only 1 level of QC performed per lot in 4/2021. e. two of three analyzers had no QC performed 5/2021. f. two of three analyzers had no or only 1 level of QC performed

	per lot in 6/2021. g. two of three analyzers had no or only 1 level of QC performed per lot in 7/2021. h. two of three analyzers had no or only 1 level of QC performed per lot in 8/2021. i. two of three analyzers had no or only 1 level of QC performed per lot in 9 /2021. j. two of three analyzers had no or only 1 level of QC performed per lot in 10 /2021. k. two of three analyzers had no or only 1 level of QC performed per lot in 11 /2021. l. one of three analyzers had no QC performed in 12/2021. m. one of three analyzers had no QC performed in 1/2022. k. two of three analyzers had no QC performed 2/2022. 4. Review of iSTAT QC records for 1/1/21 through 2/15/22 for Chem8+ cartridges for Na, K, Cl, iCA, TCO2, Glu, BUN, Creat and Hct revealed: a. two of three analyzers had no QC performed in 1/2021. b. two of three analyzers had no QC performed 2/2021. c. one of three analyzers had no QC performed in 3/2021. d. one of three analyzers had no QC performed in 4/2021. e. two of three analyzers had no QC performed 5/2021. f. three of three analyzers had only 1 level of QC performed per lot in 6/2021. g. three of three analyzers had no or only 1 level of QC performed per lot in 7/2021. h. three of three analyzers had no or only 1 level of QC performed per lot in 8/2021. i. two of three analyzers had no or only 1 level of QC performed per lot in 9/2021. j. two of three analyzers had no or only 1 level of QC performed per lot in 10/2021. k. three of three analyzers had no or only 1 level of QC performed per lot in 11/2021. l. one of three analyzers had no QC performed in 12/2021. m. one of three analyzers had no QC performed in 1/2022. k. two of three analyzers had no QC performed 2/2022. 5. All reviewed QC documents were signed by the technical consultant. No documentation of corrective action was present to address missing QC values. 6. Testing was performed on an estimated volume of 27184 patient test results. 7. Interview with TC#1 on 2/16/22 at 1:00 p.m. confirmed, the TC failed to ensure acceptable levels of analytic performance were maintained on three of three Abbott iSTAT analyzer for thirteen of thirteen analytes.