Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2255427	03/12/2024
Name of Provider or Supplier	**Street Address, City, State**	
Tukhs Cardiovascular Medicine - Switzer	7420 Switzer Rd, Shawnee, 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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 the review of the CMS116 test lists, Individualized Quality Control Plan (IQCP) for the Abbott i-STAT chemistry analyzer S/N 424269, i-STAT quality control (QC) records from 10/7/22 to 3/12/24, lack of documentation for the failure to perform QC as required, the "POC IQCP Annual Assessment" for 2022, and interview with technical consultant (TC) #1, the laboratory failed to re-evaluate the IQCP after the QC interval was not met and implement correct actions (CA) as needed for nine of nine analytes reported. Findings: 1. Review of the CMS 116 application revealed the Abbott i-STAT chemistry analyzer is used to perform the following analytes: sodium (Na), potassium (K), chloride (Cl), total CO2 (tCO2) ionized calcium (iCa), glucose (Glu), blood urea nitrogen (BUN), creatinine (Creat), and B-type natriuretic peptide (BNP). 2. Review of the IQCP for the Abbott i-STAT chemistry analyzers S/N 424269 revealed QC was to be performed monthly, with each new lot, and with each new shipment. Monthly QC interval is considered to be not more than 31 days. 3. Review of the i-STAT QC from 10/7/22 to 3/12/24 revealed QC interval was not met when QC was performed on 11/22/22 when the previous QC was performed on 10/7 /22. The interval between these two test dates was 46 days. a. No documentation of the failed QC interval or CA were noted on the "QML" report. The document was reviewed by TC #1 12/21/22 for the 11/22/22 QC test date and noted as "QC ok, reviewed." 3. Review of the "POC IQCP Annual Assessment" for 2022 revealed: a. The document is dated 3/5/24. b. On page 1, Under Quality Control-Issues Identified-the entry is "None", Corrective Action Taken-the entry is "Not Applicable." c. On page 2, question: "Have test process failures been identified?" The entered response is

	"No." d. The document is signed by the laboratory director and dated 3/7/24. 4. Request was made for CA documents to address QC interval failures. No documentation was provided at the time of survey. 5. From 11/7/22 to 11/22/22, the following number of patient results were reported without acceptable QC performed: Na-32, K- 32 K-32, Cl-32, tCO2-32, iCa-32 Glu-32, BUN-32, Creat-32, and BNP-12. 6. Interview with TC#1 on 3/12/24 at 11:30 a.m. confirmed, the laboratory failed to re-evaluate the IQCP after the QC interval was not met and implement correct actions (CA) as needed for nine of nine analytes reported.