Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445758	07/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Freeman Neosho Hospital	113 W Hickory St, Neosho, MO	

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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of 2022, 2023, and to date July 9, 2024 calibration records for the Ortho Diagnostics Vitros 5600 chemistry analyzer and interview with the technical supervisor (TS) #2, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of Vitros 5600 calibration records for 2022, 2023, and to

	date July 9, 2024 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: Procalcitonin and triiodothyronine uptake 2. Interview with the TS #2 on July 9, 2024 at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range.
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 review of individualized quality control plan (IQCP) for the Cepheid Genexpert analyzer, 2023 to date July 9, 2024 SARS COVID-19 quality control (QC), and interview with the technical supervisor (TS) #2, the laboratory failed to ensure that the IQCP for the Cepheid Genexpert SARS COVID-19 was followed for 5 of 18 months. Findings: 1. Review of Cepheid Genexpert analyzer IQCP for SARS COVID-19 stated "Quality control plan monthly each cartridge type will be QC'd prior to reporting patient results with a detected and not detected value for each target /cartridge". 2. Review of Cepheid Genexpert analyzer QC for SARS COVID-19 showed no QC was performed in July 2023, August 2023, September 2023, October 2023 and December 2023. 3. Interview with the TS #2 on July 9, 2024 at 12:30 PM confirmed the laboratory failed to ensure Cepheid Genexpert IQCP was followed.