Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0317612	11/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Simpson General Hospital	1842 Simpson Hwy 149, Mendenhall, MS	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: 1. Based on observation of Bio-Rad Liquichek Specialty Immunoassay controls in use by the laboratory on 11-19-18 at 10:45 a.m., review of quality control (QC) records for the Ortho Clinical Vitros 5600 Integrated System from 7-1-18 through 11-19-18, and patient Vitamin D reports, Bio-Rad Liquichek Specialty Immunoassay controls, Level 1 (Lot #57491) and Level 2 (Lot #57492), were used for quality control testing for 27 days after they had exceeded their expiration date of 8-31-18, with a total of 31 patient Vitamin D results reported on these days. Findings include: Observation of Bio-Rad Liquichek Specialty Immunoassay controls, Lot #57491 and Lot #57492, in use by the laboratory on 11-19-18 at 10:45 a.m., revealed these lots had an expiration date of 8-31-18. Review of QC records for the Ortho Clinical Vitros 5600 Integrated System from 7-1-18 through 11-19-18 and patient Vitamin D reports revealed Lot #57491 and Lot #57492 were used for quality control testing for 27 days from 9-1-18 through 11-16-18, after they had exceeded their expiration date, when a total of 31 patient Vitamin D results were reported. 2. Based on review of quality control (QC) records for the Beckman Coulter AcT Diff 2 hematology analyzer from 8-1-18 through 10-31-18, manufacturer's package inserts, and lab test order logs, Coulter 4C-ES Cell hematology controls (Lots #069700, #079700, and #089700) were used for quality control testing for 14 days after they had exceeded their expiration date of 8-13-18, with a total of 206 patient CBC results reported during this time frame. Findings include: Review of the manufacturer's package inserts for Coulter 4C-ES Cell hematology controls (Lots #069700, #079700, and #089700) revealed these lots had an expiration date of 8-13-18. Review of QC records for the Beckman Coulter

	AcT Diff 2 hematology analyzer from 8-1-18 through 10-31-18 and lab test order logs revealed Coulter 4C-ES Cell hematology controls, Lots #069700, #079700, and #089700, were used for quality control testing from 8-14-18 through 8-27-18 after they had exceeded their expiration date, when a total of 206 patient CBC results were reported.
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 calibration and calibration verification records for the Ortho Clinical Vitros 5600 Integrated system since the last survey on 12-20-16 and interview with the technical consultant on 11-20-18 at 2:30 p.m., the laboratory failed to document, as performed, calibration verification for sodium, potassium, and chloride tests at least once every six months since 12-20-16. Findings include: Review of calibration records for the Ortho Clinical Vitros 5600 Integrated system revealed the sodium, potassium, and chloride tests performed on the integrated system have fewer than three calibrators. Review of calibration verification records revealed no documentation of calibration verification performed for the sodium, potassium, and chloride tests on the Vitros 5600 Integrated system since the last survey on 12-20-16. In an interview on 11-20-18 at 2:30 p.m., the technical consultant confirmed calibration verification has not been performed for sodium, potassium, and chloride since 12-20-16.