Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0652158	10/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ste Genevieve County Memorial Hospital	800 Ste Genevieve Drive, Sainte Genevieve, 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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of procedure manual, maintenance documentation, observation of pipettes and interview with the general supervisor, the laboratory failed to define and perform a function check to verify the accuracy of 5 of 5 pipettes. Findings: 1. Review of the "Calibration of Pipettes" procedure showed to calibrate all pipettes at least annually. 2. No documentation was found to show the laboratory performed a function check protocol to verify the accuracy of the volumes of 2 of 2 Biohit pipettes for immunohematology testing and 3 of 3 MLA pipettes for routine chemistry testing. 3. Observation of the 100 microliter, 200 microliter, 1000 microliter MLA pipettes and 2 repeater Biohit pipettes located in the laboratory available for use showed no function check since 2014. 4. Interview with the general supervisor on October 23, 2018 at 1: 00 PM confirmed, the laboratory failed to define a protocol and perform a function check to verify the accuracy of the volumes of 5 of 5 pipettes.
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 2017, 2018 instrument comparison documentation and interview with the general supervisor, the laboratory failed to perform instrument comparisons for two of two iSTAT analyzer for blood gas testing two times a year. Findings: 1. Review of the laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for 2 of 2 iSTAT analyzers performing pH, pCO2, and pO2 analytes testing for 2017 and to date 2018. 2. Interview with the general supervisor on October 23, 2018 at 1:00 PM confirmed, the laboratory failed to perform instrument comparisons for two iSTAT analyzers twice a year for 2017 and to date 2018.