Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441665	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Samaritan Hospital	1205 N Missouri Street, Macon, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency and laboratory correlation records for 2017, 2018 and interview with the general supervisor, the laboratory failed to establish a means to verify the accuracy of wet mount testing twice a year. Findings: 1. Review of proficiency records for 2017 and 2018 revealed the laboratory failed to enroll to prove accuracy on the nonregulated analyte, wet mounts. 2. Review of correlation records for 2017 and 2018 revealed a lack of documentation to prove accuracy 2 times a year for wet mounts. 3. Interview with the general supervisor on August 28, 2018 at 12:30 PM confirmed the laboratory failed to verify the accuracy of the nonregulated wet mount testing twice annually for 2017 and to date 2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the hematology procedure manual and interview with the general supervisor, the procedure manual failed to include control procedures and test calculations for the semen analysis procedure. Findings: 1. The semen analysis procedure did not include control procedures for quantitative sperm count testing. 2. The semen analysis procedure did not include test calculations for counting sperm by hemocytometer method. 3. Interview with the general supervisor on August 28, 2018 at 12:15 PM confirmed, the procedure manual failed to include control procedures and test calculations applicable to the test procedure.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation of the fresh frozen plasma (FFP) freezer, review of the blood bank procedure manual, lack of audible alarm system documentation and interview with the general supervisor, the laboratory failed to ensure FFP was stored under appropriate temperature conditions that included an audible alarm system and monitored over a twenty-four hour period for 2017 and to date August 28, 2018. Findings: 1. Observation of the FFP freezer revealed no audible alarm system to monitor FFP storage over a twenty-four hour period. 2. The blood bank procedure, Routine Storage of Blood and Components states," Refrigerators, freezers and platelet incubators shall have a system to monitor the temperature continuously including an alarm that is at a location that is staffed 24/7 and record the temperature at least every four hours." 3. No documentation was available to show the laboratory monitored the temperature of the FFP freezer with an audible alarm system over a twenty-four hour period for 2017 and to date August 28, 2018. 4. Interview with the general supervisor on August 28, 2018 at 12:15 PM confirmed, the laboratory failed to have an audible alarm system to monitor FFP storage over a twenty-four hour period and follow written procedure.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually

	evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of delegation and personnel documentation and interview with the general supervisor, the general supervisor failed to perform 1 of 6 competency evaluations for 2017 and 2018. Findings: 1. Review of the general supervisor delegation document signed by the laboratory director, showed the general supervisor was delegated the responsibility of evaluating the performance of all testing personnel. 2. Review of 2017, 2018 personnel competencies revealed the general supervisor failed to perform 1 of 6 competencies for testing personnel performing wet mounts. 3. Interview with the general supervisor on August 28, 2018 at 12:30PM confirmed the general supervisor failed to perform 1 of 6 annual competencies for 2017 and 2018.