Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441665	12/14/2022
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
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of blood bank procedures, blood bank quality control (QC) logs, blood bank patient records/logs, and interviews, the laboratory failed to meet the requirements for the specialty of immunohematology. The laboratory failed to provide a procedure for checking patient history in blood bank and for confirmation retying patient blood types (Refer for D5401); the laboratory failed to document quality control (QC) for nine blood bank testing days from January 1, 2022 to date December 14, 2022 (Refer to D5551); and the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post-analytic systems (Refer to D5891).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of blood bank procedures, and interview with the general supervisor (GS) #1, the laboratory failed to provide a procedure for checking patient history in

	blood bank and for confirmation retying patient blood types. Findings: 1. Review of blood bank procedures showed no procedure for checking patient history prior to performing blood bank procedures and no procedure for performing a confirmation retype of the patient blood type. 2. Interview with the GS #1 on December 14, 2022 at 11:30 AM confirmed the laboratory failed to provide a blood bank procedure for checking patient history and for confirmation retying patient blood types.
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 the review of control procedures and lack of corrective action for unacceptable controls and interview with the general supervisor (GS) #1, the laboratory failed to ensure quality assessment programs were established and failed to provide a procedure for corrective action to take when control results fail to meet the laboratory's criteria for acceptability. Findings 1. Review of laboratory procedures and lack of corrective action for unacceptable controls showed the laboratory failed to ensure quality assessment programs were established and failed to provide a procedure for corrective action to take when control results fail to meet the laboratory's criteria for acceptability. 2. Interview with GS #1 on December 14, 2022 at 11:30 AM confirmed the laboratory failed to ensure quality assessment programs were established and failed to provide a procedure for corrective action to take when control results fail to meet the laboratory's criteria for acceptability.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of performance verification procedures for the Siemens Rapid Point 500 E blood gas analyzer and interview with testing personnel (TP) #8, the laboratory failed to verify reference intervals (normal values) prior to reporting patient results. Findings 1. Review of the laboratory's performance verification procedures for the Siemens Rapid Point 500 E blood gas analyzer showed the laboratory failed to perform the normal range study for the measured analytes: pH, PCO2, and PO2 prior to the beginning of patient testing in August 2022. 2. Interview with TP #8 on December 14, 2022 at 12:00 PM confirmed the laboratory failed to perform verification of normal ranges for the Siemens Rapid Point 500 E blood gas analyzer.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 review of blood bank procedures, blood bank patient logs, blood bank quality control (QC) logs, and interview with the general supervisor (GS) #1, the laboratory failed to document quality control (QC) for nine blood bank testing days from January 1, 2022 to date December 14, 2022. Findings: 1. Review of the laboratory's blood bank procedure "MTS A/B/D Monoclonal Grouping- Instructions for Use" states, "It is recommended that each lot of cards be tested each day of use with antigen positive and antigen negative red blood cells." 2. Review of blood bank patient testing logs showed blood bank testing was performed on January 8, 2022, January 30, 2022, May 8, 2022, May 28, 2022, May 31, 2022, July 31, 2022, September 18, 2022 and November 1, 2022. 3. Review of blood bank QC logs showed no documented QC on January 8, 2022, January 30, 2022, May 8, 2022, May 28, 2022, May 31, 2022, July 31, 2022, September 18, 2022 and November 1, 2022. 4. Review of blood bank patient logs showed seven patients and nine red blood cell units were tested while blood bank QC was not documented. 5. Interview with the GS #1 on December 14, 2022 at 11:30 AM, confirmed the laboratory failed to document quality control for nine blood bank testing days.
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 review of the laboratory's procedures, laboratory's blood bank patient history cards, lack of corrective action and interview with the general supervisor (GS) #1, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post-analytic systems. Findings: 1. No approved quality assessment programs were available for review. 2. Review of the laboratory's blood bank patient history card for patient #1 showed: "May 31, 2022 type and screen GRP O RH Positive ABS Negative" "June 1, 2022 Group "O" RH Negative Retype" 3. No corrective action was documented to show an investigation or resolution of the patient blood type discrepancy. 4. Interview with the GS #1 on December 14, 2022 at 11:00 AM confirmed the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post-analytic systems.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of Vitros 350 chemistry analyzer quality control (QC) and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure the quality assessment program identified failures in quality as they occur. Findings: 1. Review of Vitros 350 QC showed on 11/24/22, 12/11/22, 12/12/22 and 12/14/22 Lipase QC Vitros Performance verifier 11 was out three standard deviations and no documentation of failure was documented. 2. Interview with the GS #1 on December 14, 2022 at 11:00 AM confirmed the LD failed to ensure failures in chemistry QC was documented.