Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315659	10/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Memorial Hospital	631 R B Wilson Dr, Huntingdon, TN	

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 record review and interview the laboratory failed to ensure testing personnel number one have documented training prior to performing transfusion medicine testing, (Refer to D5209); failed to follow the procedure manual (Refer to D5401), and failed to ensure the laboratory's quality assessment process effective to correct problems with recording transfusion medicine testing (Refer to D5791), resulting in a condition level deficiency.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory Transfusion Service Testing Record, testing personnel number one employee records and interview with the general supervisor, the laboratory failed to ensure testing personnel number one have documented training prior to performing transfusion medicine testing, in 2019. The findings include: 1. Review of the laboratory's Transfusion Service Testing Record revealed patient testing for ABO and Rh for patient number four performed by testing

	personnel number one on 02.04.2019. 2. Review of testing personnel number one employee records revealed a hire date of 01.16.19 with no documented training for performing transfusion medicine testing to include ABO/Rh type, antibody screen and crossmatch testing. 3. Interview with the general supervisor on October 7, 2019 at 3: 30 p.m. confirmed testing personnel number one performed transfusion medicine testing in 2019 with no documented training.
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 the Component Ordering Process procedure, patient number one history card and interview with testing personnel number one, testing personnel number one failed to follow the procedure for releasing blood units for transfusion, in 2019. The findings include: 1. Review of the Component Ordering Process procedure revealed, "After order is placed, a product order sheet will print in the lab. This order will contain the first and last name of the patient, date of birth, medical record number, ordering physician, type and number of units, and indications for the transfusion. At this point, check to see if patient has a history card in the blood bank. ... Crosscheck history card against component order with first and last names, date of birth, and medical record number." 2. Review of patient number one blood bank history card revealed no documentation of transfusion on 09-27-19 by testing personnel number one. 3. Interview on October 7, 2019 at 2:45 p.m. with testing personnel number one, via telephone, confirmed the blood bank history card was not reviewed to crosscheck the component order, the blood transfusion log containing each patient results was reviewed. The result on the line above patient number one was looked at (O positive), the O positive unit W040819104617 was removed from the refrigerator, the immediate spin crossmatch was compatible. The paperwork was completed with the patient type as O positive, the history card was not reviewed and the unit was released to the nurse staff for transfusion. The laboratory received a call from the surgery department shortly after transfusion began, inquiring of the patient blood type. This time testing personnel reviewed the blood transfusion log along with the patient history card and determined the patient was O Negative, resulting in administration of the wrong blood type to patient number one.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of hospital patient records, the laboratory's document titled "Transfusion Service Testing Record," the Blood Bank Reagent Usage Sheets and

	interview with the laboratory supervisor, the laboratory's quality assessment process was ineffective when it failed to correct problems with recording transfusion medicine testing in 2019. The findings include: 1. Review of hospital records for patient number two revealed an order for "Type and screen preadmit." 2. Review of the laboratory procedure for ABO reverse group revealed the laboratory uses A1 cells to confirm ABO blood group. 3. Review of the "Transfusion Service Testing Record" revealed the following: Patient number two tested for blood type and antibody screen by testing personnel number one on 04.18.2019. No results were recorded for antibody screen on the Transfusion Service Testing Record. Review of the Transfusion Service Testing Record was performed by the general supervisor on 04.23.2019 with no corrective action documented. Review of the Transfusion Service Testing Record revealed testing recorded for the use of A2 cells from 09.24.2019 to 09.27.2019. Review of the Transfusion Service Testing Record was performed by the general supervisor on 10.02.2019 with no corrective documented. 4. Review of patient number two final test results revealed the patient antibody screen was reported as "Negative." 5. Review of the Blood Bank Reagent Usage Sheets revealed the general supervisor signed review of the sheets but no corrective action performed for the following expired reagents in use: Ortho Anti-Human globulin Anti-IGG, -C3D lot number 702022 expiration date 7-12-18 was in use until 2-27-19; Ortho Confidence System lot CNF163 expiration date 09-24-19 in use until 09-27-19; Ortho Coombs control cells lot K594 expiration date 8-20-19 in use until 09-03-19; and, Ortho MTS IGG Card lot number 092418001-08 expiration date 07-18-19 in use until 09-30-19 6. Interview on October 7, 2019 at 3:30 p.m. with the general supervisor confirmed review of the transfusion medicine procedure log and Blood Bank Reagent Usage Sheets with no corrective action performed or documented for the incorrect documentation on the transfusion service testing record log or the expired reagents in use.