Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468338	05/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Baxter Health Fulton County Hospital	679 N Main St, Salem, AR	

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
D0000	This is the CLIA recertification survey of the laboratory conducted on 5/3/2023. The laboratory was not in compliance with the following conditions: 493.1217 - Immunohematology 493.1250 - Analytic Systems 493.1441 - Laboratory Director
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of proficiency test documentation and interviews with laboratory staff, the laboratory director failed to sign proficiency testing attestation statements for six of twenty proficiency events reviewed from 2022 and 2023. Survey findings include: A. A review of proficiency testing documentation from 2022 and 2023 it was determined the laboratory director failed to sign the attestation statement on the Second Hematology Testing Event of 2022, the Second and Third Microbiology Testing Events of 2022, The First Immunology and Immunohematology Testing Event of 2022, The First Hematology Testing Event of 2023, and the First Immunology and Immunohematology Testing Event of 2023. B. In an interview, at 2:

	26 p.m. on 5/2/2023, laboratory employee #2 (as listed on the form CMS-209) confirmed the attestation statements listed above had not been signed by the laboratory director.
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 a review of laboratory policies and procedures for blood bank, a review of the Bloodbank ID_MTS Daily QC Record, a review of the blood bank log, and interviews with laboratory staff, it was determined the laboratory failed to meet requirements for the specialty of Immunohematology as evidenced by: 5401 - the laboratory failed to follow written procedures for Antibody Detection Method - Two Cell Screen 5551 - the laboratory failed to perform and document quality control for immunohematology testing on five days of patient testing
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of laboratory policies and procedures for blood bank, a review of the Bloodbank ID_MTS Daily QC Record, a review of the blood bank log, a review of quality control documentation, and interviews with laboratory staff, the laboratory failed to meet analytic systems requirements as evidenced by: 5401 - the laboratory failed to follow written procedures for Antibody Detection Method - Two Cell Screen 5441 - the laboratory failed to monitor over time the accuracy and precision of test performance. 5551 - the laboratory failed to perform and document quality control for immunohematology testing on five days of patient testing 5783 - the laboratory failed to document corrective actions to ensure control results meet the established criteria for acceptability when there were quality control failures
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 a review of laboratory policies and procedures for blood bank, a review of the blood bank log, and interviews with laboratory staff, the laboratory failed to follow written procedures for Antibody Detection Method - Two Cell Screen. Survey findings include: A. The laboratory procedure for antibody screen is the Antibody Detection Method - Two Cell Screen which uses two different vials of Antibody Screen Cells. The procedure uses 50 uL of each 0.8% antibody screen cell suspension (labeled I and II) combined with 25 uL of patient serum to give separate antibody screening results for Screen Cell I and Screen Cell II. B. A review of the blood bank log book for 2022 and 2023 revealed that seventy-one antibody screens were documented during that period. Four of seventy-one antibody screens failed to have documentation that Screen Cell I and Screen Cell II were used. On 4/22/2022 a type and antibody screen were ordered on patient #10006231 but no results are documented in the blood bank log for Screen Cell I or Screen Cell II. On 6/17/2022 a type and antibody screen were ordered on patient #10008095 but no results of the screen are documented on the log for Screen Cell I or Screen Cell II. On 11/11/2022 a crossmatch for two units of blood was ordered on patient #100136. The documentation of the antibody screen performed as part of the crossmatch on patient #100136 only included results for Screen Cell I. On 11/18/2022 a type and antibody screen was ordered on patient #10013823 but the blood bank log only has documentation of the results of Screen Cell I. C. In an interview, at 1:53 p.m. on 5/3 /2023, laboratory employee #2 (as listed on the form CMS-209) confirmed the patients listed above did not have properly documented antibody screens recorded in the blood bank log book and further confirmed that there is no other documentation that would prove that the antibody screen was performed correctly using Screen Cells I and Screen Cells II.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory policies and procedures, a review of quality control documentation, and interviews with laboratory staff, the laboratory failed to monitor over time the accuracy and precision of test performance. Survey findings include: A. A review of the Quality Control policy (# 2.4.1.3) revealed there were no policies for corrective actions for shifts in data. The Quality Control policy does state, "Other factors can cause drift away from the mean. This is referred to as a Trend...The sooner a trend can be recognized, the sooner it can be resolved....Attempts should be made to determine the cause of a trend and institute corrective action if it is indicated." B. Levy-Jennings quality control graphs, dated September 2022, for sixteen chemistry tests (thirty-two control levels) were reviewed. Four of thirty-two

	control levels included data points that had drifted away from the mean. Controls with demonstrated shifts and trends were as follows: VP1 - Performance VER 1 (lot #D8955), which was used as a control for HDL, (high density lipoprotein) was above the mean the entire month of September (42 consecutive points); VP1 - Performance VER 1 (lot #D8955), which was used as a control for Total Bilirubin, was below the mean the entire month of September (39 consecutive points); CX1 - CARDIOIMMUNE 1 (lot # CXL23061), which was used as a control for CKMB (Creatine Phosphokinase MB fraction) was below the mean the entire month of September (33 consecutive points); and CX3 - CARDIOIMMUNE 3 (lot # CXL23063), which was used as a control for CKMB (Creatine Phosphokinase MB fraction) was below the mean the entire month of September (32 consecutive points). There was no documentation that the shifts or trends had been identified by the laboratory or that corrective actions had been taken to resolve the shifts or trends. C. In an interview, at 1:51 p.m. on 5/3/2023, laboratory employee #2 (as listed on the form CMS-209) confirmed that quality control results were shifted and not corrected.
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: Through a review of the Bloodbank ID_MTS Daily QC Record and blood bank logs for 2022 and 2023, as well as interviews with laboratory staff it was determined the laboratory failed to perform and document quality control for immunohematology testing on five days of patient testing. Survey findings follow: A. Through a review of the Bloodbank ID_MTS Daily QC Record for 2022 and 2023 it was determined the laboratory failed to document immunohematology (blood bank) quality control on 9 /23/2022 and 9/28/2022 (two of thirty days in September 2022), 12/8/2022 and 12/15 /2022 (two of thirty-one days in December 2022), and 3/30/2023 (one of thirty-one days in March 2023). B. Through a review of the blood bank logs for 2022 and 2023 it was revealed that one patient (#10011577) had a crossmatch documented on 9/23 /2022, one patient (#10011723) had a type and Rh documented on 9/28/2022, one patient (#10014698) had a crossmatch documented on 12/8/2022, one patient (#10014959) had a type and screen and a crossmatch for three units of packed red blood cells documented on 12/15/2022, and one patient (#10018161) had a crossmatch for two units of packed red blood cells documented on 3/30/2023. C. At 2: 55 p.m. on 5/3/2023, laboratory employee #2, from the Form CMS-209, confirmed the lack of documented quality control on the five days of blood bank patient testing in 2022 and 2023.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on a review of laboratory policies and procedures, a review of hematology and chemistry quality control documentation, and interviews with laboratory staff, the laboratory failed to document corrective actions to ensure control results meet the established criteria for acceptability when there were quality control failures. Survey findings include: A. The Quality Control (QC) policy # 2.4.1.3 states, "1,3sd: One data point is greater than 3 sd. The QC is considered out of range and patient values cannot be reported. This rule will flag red in the LIS. 2,2sd: Two consecutive values for one level of QC are greater than 2sd or both levels of QC are greater than 2sd. These will flag as yellow in the LIS, but no patient data should be reported until the issue is resolved. ALL CORRECTIVE ACTION AND TROUBLESHOOTING MUST BE DOCUMENTED IN THE LIS WITH THE OUT OF RANGE QC DATA." The policy also states, "Once QC falls within acceptable limits, patient results may be reported." B. A review of September 2022 QC documentation for Prothrombin Time (PT) revealed that on 9/1/2022, at 23:14, the result for the normal control (AC3-Norm) was documented as 15.4 (acceptable range 14.1 +/- 1.2) and flagged as a 2,2sd failure. The next documented result for this control was on 9/2 /2022 at 06:18 and resulted as 15.4 and flagged as a 2,2sd failure. No acceptable quality control result is documented for 9/1/2022 or 9/2/2022. On 9/1/2022 one patient PT was reported (order #4034974) and on 9/2/2022 one patient PT was reported (order # 4035142). On 9/14/2022, at 00:53 the AC3-Norm control result was reported as 15.5 and flagged with 2,2sd failure then at 10:37 on the same date reported as 15.6 and flagged with 2,2sd failure. An acceptable result for AC3-Norm control was not documented until 21:30 on 9/14/2022. Two patient PT results were reported prior to acceptable controls. Order #4036692 was reported at 11:03 and order #4036765 was reported at 17:25. C. A review of September 2022 QC documentation for D-Dimer revealed that on 9/8/2022, at 23:04, the result for the normal control (AC3-Norm) was documented as 1.69 (acceptable range 2.14 +/- 0.22) and flagged as a 1,3sd failure. The next documented result for this control was on 9/8/2022 at 23:29 and resulted as 1.72 and flagged as a 1,3sd failure. Unacceptable results were also documented at 09:01 and 14:17 on 9/9/2022. No acceptable quality control result is documented for 9/8/2022 or 9/9/2022 until 15:21 on 9/9/2022.. The following patients had D-Dimer reported before acceptable control results were documented: On 9/8 /2022 D-Dimer order # 4035904 was reported at 15:50 and order #4035963 was reported at 23:29. On 9/9/2022 D-Dimer on order #4036021 was reported at 09:22. D. A review of December 2022 QC documentation for Glucose revealed that on 12/1 /2022, at 03:48, the result for the control (OP2 - Ortho PV2) was documented as 278.1 (acceptable range 300 +/- 13) and flagged as a 1,3sd failure and repeated at 05:51 on 12/1/22 with the result being 281.3 and flagged as a 1,3sd failure. The next documented result for this control was on 12/1/2022 at 14:17 and resulted as 285.7 and flagged as a 1,3sd failure. Unacceptable results were also documented at 02:24 on 12/2/2022. No acceptable quality control result is documented for 12/1/2022 or 12/2 /2022 until 10:27 on 12/2/2022. The following patients had Glucose reported before

	acceptable control results were documented: On 12/1/2022 a glucose for Patient # 10014378 was reported at 13:05, a glucose result for Patient # 10014428 was reported at 13:46 and Patient #10014458 was reported at 13:59. On 12/2/2022 Glucose on Patient #10014473 was reported at 06:11 and Patient #10014476 was reported at 08: 34. On 12/30/2022 the Glucose result for control (OP2 - Ortho PV2) was documented as 283.4 and flagged as a 2,2sd failure. No acceptable quality control is documented for 12/30/2022 and the following patient results were reported: Patient # 10015352 was reported at 10:27 on 12/30/22; Patient # 10015358 was reported at 11:32 on 12/30 /2022; Patient # 10015364 was reported at 16:30 on 12/30/2022; and Patient # 10015366 was reported at 19:58 on 12/30/2022. E. A review of December 2022 QC documentation for Lipase revealed that on 12/1/2022, at 03:48, the result for the control (OP2 - Ortho PV2) was documented as 578.0 (acceptable range 631.0 +/- 31) and flagged as a 1,3sd failure and repeated at 05:51 on 12/1/22 with the result being 579.5 and flagged as a 1,3sd failure and at 14:17 and resulted as 582.1 and flagged as a 1,3sd failure. There were no acceptable results documented for Lipase on the OP2 - Ortho PV2 control on 12/1/2022. A Lipase result was reported on patient #10014454 at 13:14 on 12/1/2022. F. A review of December 2022 QC documentation for SGOT /AST (Aspartate amino Transferase) revealed that on 12/1/2022, at 03:48, the result for the control (OP2 - Ortho PV2) was documented as 154.3 (acceptable range 180 +/- 13) and flagged as a 1,3sd failure and repeated at 14:17 and resulted as 156.3 and flagged as a 1,3sd failure. An unacceptable result of 157.2 was also documented at 02: 24 on 12/2/2022. No acceptable quality control result is documented for 12/1/2022 or 12/2/2022 until 10:27 on 12/2/2022. Twenty patients has SGOT/AST results reported on 12/1/2022 and nine had SGOT/AST results reported on 12/2/2022 before acceptable QC was documented. G. In an interview, at 1:53 p.m. on 5/3/2022, employee #2 (as listed on the form CMS-209) confirmed patients were reported on days when quality control was unacceptable and corrective actions were not documented to bring the quality control results within the acceptable range.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures for blood bank, a review of the blood bank log, and interviews with laboratory staff, the laboratory failed to perform antibody screens as required for reliable results. Survey findings include: As cited at D5401 the laboratory failed to follow written procedures for Antibody Detection Method - Two Cell Screen.

D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency test documentation and interviews with laboratory staff, the laboratory director failed to ensure proficiency test samples are tested as required in six of twenty proficiency test events in 2022 and 2023. Survey findings include: As cited at D2015, the laboratory director failed to sign proficiency testing attestation statements for six of twenty proficiency events reviewed from 2022 and 2023
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 a review of the laboratory policies and procedures, a review of the Bloodbank ID_MTS Daily QC Record, a review of quality control documentation, and interviews with laboratory staff, A. As cited at D5441 the laboratory failed to monitor over time the accuracy and precision of test performance B. As cited at D5551 the laboratory failed to perform and document quality control for immunohematology testing on five days of patient testing C. As cited at D5783, the laboratory failed to document corrective actions to ensure control results meet the established criteria for acceptability when there were quality control failures.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, laboratory personnel files, lack of documentation, and interviews with laboratory staff, the technical supervisor failed to assess the competency of six out of six clinical laboratory testing personnel annually after the first year. A. The CMS-209 form for the clinical laboratory, dated 5/1/2023, includes nine testing personnel (numbered #2 through #10). B. Through a review of personnel files it was determined that six employees had documentation that they had been employed for more than one year. C. Six of six laboratory testing personnel, who were employed over one year, failed to have competency documented in the last year (12 months) D. In an interview, at 1:55 p.m. on 5/2/2023, laboratory employee #2 (as

	listed on the form CMS-209) confirmed that competency assessments have not been documented in the last year.