Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468338	10/25/2018
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Through review of proficiency testing attestation forms, API proficiency testing instructions and interview with laboratory staff it was determined that the laboratory director did not attest that the proficiency testing was performed in the same manner as patient testing in seven of seventeen events reviewed. Survey findings follow: A. The instructions for API proficiency testing states, "signatures required: testing personnel and the laboratory director must physically sign an attestation statement for all proficiency testing results". B. Review of API proficiency testing documentation revealed that API Chemistry Core first event 2017, API Chemistry Core second event 2017, API Chemistry Core and API Chemistry Miscellaneous third event 2017, API Chemistry Core first event 2018, API Hematology Coagulation second event 2018, and API Immunohematology second event 2018 all lacked the signature of the laboratory director (or designee) attesting that testing was performed in the same manner as patient testing . E. In an interview at 10:45 AM on 10/24/18, the technical consultant identified as number two on the CMS 209 form confirmed that the laboratory director's signature was not present on the API proficiency testing events identified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and

	test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: 1) Through observation, review of the manufacturer's instrument manual, lack of documentation and interview it was determined that the laboratory failed to document humidity levels in one of two rooms in which equipment with an operating humidity requirement was located. Findings follow: A. In a tour of the laboratory on 10/25/18 at approximately 09:00 AM a Gem 3500 Arterial Blood Gas analyzer was observed in the laboratory. B. Review of the manufacturer's manual for the Gem 3500 Arterial Blood Gas analyzer revealed that the analyzer has an operational humidity requirement of 5% to 90%. C. Upon request, the laboratory was unable to provide humidity records for the years of 2017 and 2018. D. In an interview on 10/25/18 at approximately 09:00 AM, the testing personnel identified as number 13 on the CMS 209 form confirmed that the laboratory had not documented the humidity level in the laboratory room in 2017 or 2018. 2) Through observation, review of the manufacturer's package insert, and interview it was determined that 37 of 37 Hemochron Prothrombin Time cuvettes, lot # J201 C, were stored at room temperature without an amended date of expiration or date of when the cartridges were placed at room temperature noted, Findings follow: A. In a tour of the laboratory on 10/25/18 at approximately 10:00 AM, 37 Hemochron Prothrombin Time cuvettes were observed on the counter adjacent to the Hemochron Jr. coagulation instrument and no date of when they were placed at room temperature or amended expiration date was noted on the box in which the cuvettes were stored. B. Review of the manufacturer's package insert for the Hemochron Prothrombin Time cuvettes revealed that "when refrigerated, the foil pouched cuvettes are stable until the marked expiration date". The cuvettes may be stored at room temperature (15 to 30 degrees C.) but "re-dating is necessary if stored at room temperature and should be indicated by completing the storage information section on the side panel of each cuvette box". C. In an interview on 10/25/18 at approximately 10:00 AM, the technical consultant, identified as number 2 on the CMS 209 form, confirmed that the Hemochron Prothrombin Time cuvettes were stored at room temperature and had not been re-dated.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observation and interview with laboratory staff it was determined that one of two containers of Gem plastic capillary tubes had exceeded the expiration date and was available for use. Findings follow: A. During a tour of the laboratory on 10/25/18 at approximately 09:00 AM, one container of Gem capillary tubes, lot number 90772103 with an expiration date of 2013-03 was observed in the supply drawer under the Gem 3500 arterial blood gas analyzer. B. In an interview on 10/25/18 at

	appropximately 09:00 AM, the testing personnel identified as number thirteen on the CMS 209 form confirmed that the capillary tubes identified above had exceeded the expiration date and were available for use.
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: A) Through review of the laboratory's policy and procedure for "Quality Control ", quality control (QC) summary reports, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to document the evaluation of patient results back to the last successful quality control result on one of one occasions when quality control results for prothrombin time (PT) and International Normalized Ratio (INR) test quality control results failed to meet criteria for acceptability in March 2018 and one of one times when partial thromboplastin time (PTT) results failed to meet criteria for acceptability in July 2018. Findings follow: A.1). The laboratory did not evaluate PT or INR results back to the last successful QC result when QC for PT/INR tests failed to meet the criteria for acceptability in March 2018. A.1(a). Review of the laboratory's policy and procedure for "Quality Control" revealed that under the heading of "Procedure" "2.2sd: two consecutive values for one level of QC are greater than 2sd no patient data should be reported until the issue is resolved" and paragraph 3 (e) states "document all troubleshooting and notify supervisor of problem". A.1(b). Review of the quality control summary for PT testing revealed that on 3/29/18, the level 1 quality control material lot # N-C70NC006 with an acceptable INR range of 1.2 to 2 was resulted as 1.1 at 09:51 AM, 2.2 at 09:59 AM before an acceptable value of 1.6 was recorded at 10:42 AM. A.1(c). Review of patient results revealed that thirty-seven patient PT/INR resultswere reported since the last successful QC during the month of March 2018 prior to 3/29/18. The Patient ID's, dates and times are identified on "PT Citrate Patient /QC Analysis Report By Test Date". A.1(d). Upon request, the laboratory was unable to provide documentation of patient PT/INR result evaluation on the patients identified above. A.1(e). In an interview on 10/24/18 at approximately 10:45 AM, the technical consultant identified as number two on the CMS 209 form confirmed that the patient PT/INR results identified above were not evaluated back to the last successful QC after the QC failure to meet criteria for acceptability on 3/29/18. A.2) The laboratory did not evaluate PTT results back to the last successful QC result when QC for PTT tests failed to meet the criteria for acceptability in November 2017.. A.2 (a). Review of the laboratory's policy and procedure for "Quality Control" revealed that under the heading of "Procedure" "2.2sd: two consecutive values for one level of QC are greater than 2sd no patient data should be reported until the issue is resolved" and paragraph 3 (e) states "document all troubleshooting and notify supervisor of problem". A.2(b). Review of the quality control summary for PTT testing revealed that on 11/7/17, the normal quality control material lot # C70NC006 with an acceptable PTT range of 21.9 to 37.1 was resulted as 20.0 at 04:58 AM, 20.0 at 05:01

	AM. "QC Failed Low" at 05:05 AM before an acceptable value of 28.7 was recorded at 05:46 AM. A.2(c). Review of patient results revealed that nine PTT resultswere reported since the last successful QC during the month of November 2017 prior to 11 /7/17. The Patient ID's, dates and times are identified on "PT Citrate Patient/QC Analysis Report By Test Date". A.2(d). Upon request, the laboratory was unable to provide documentation of patient PTT result evaluation on the patients identified above. A.2(e). In an interview on 10/24/18 at approximately 10:45 AM, the technical consultant identified as number two on the CMS 209 form confirmed that the patient PTT results identified above were not evaluated back to the last successful QC after the QC failure to meet criteria for acceptability on 11/7/17. B.Through review of the laboratory's policy and procedure for "Quality Control ", the laboratory's IQCP for PT /INR and PTT, quality control (QC) summary reports, lack of documentation and interview with laboratory staff it was determined that the laboratory failed to document corrective action on one of one occasions when quality control results for prothrombin time (PT) and International Normalized Ratio (INR) test quality control results failed to meet criteria for acceptability in March 2018 and one of two times when partial thromboplastin time (PTT) results failed to meet criteria for acceptability in July 2018. Findings follow: B.1) Corrective action was not documented when QC for PT/INR failed to meet criteria for acceptability. B.1(a). Review of the laboratory's policy and procedure for "Quality Control" revealed that under the heading of "Procedure" "2.2sd: two consecutive values for one level of QC are greater than 2sd no patient data should be reported until the issue is resolved" and paragraph 3 (e) states "document all troubleshooting and notify supervisor of problem". B.1(b). Review of the laboratory's IQCP for PT/INR and PTT the section "Quality Assessment (QA) states "document corrective action based on reason for QC failure". B.1(c). Review of the quality control summary for PT testing revealed that on 3/29/18, the level 1 quality control material lot # N-C70NC006 with an acceptable INR range of 1.2 to 2 was resulted as 1.1 at 09:51 AM, 2.2 at 09:59 AM before an acceptable value of 1.6 was recorded at 10:42 AM : B.1(d). Upon request, the laboratory was unable to provide documentation of the corrective action taken to bring level 1 quality control within acceptable range. B.1(e). In an interview on 10/24/18 at approximately 10:45 AM the technical consultant, identified as number 2 on the CMS 209 form stated that, in the instance cited above, QC results failed to meet criteria for acceptability and no correction action was documented. B.2) Corrective action was not documented when QC for PTT testing failed to meet criteria for acceptability . B.2 (a). Review of the laboratory's policy and procedure for "Quality Control" revealed that under the heading of "Procedure" "2.2sd: two consecutive values for one level of QC are greater than 2sd no patient data should be reported until the issue is resolved" and paragraph 3 (e) states "document all troubleshooting and notify supervisor of problem". B.2(b). Review of the laboratory's IQCP for PT/INR and PTT the section "Quality Assessment (QA) states "document corrective action based on reason for QC failure". B.2(c). Review of the quality control summary for PTT testing revealed that on 7/2/18, the abnormal quality control material lot # F7dAT004 with an acceptable PTT range of 73.1 to 114.3 was resulted as 117.5 at 02:40 AM, 115.8 at 02:44 AM before an acceptable value of 114.1 was recorded at 03.06 AM. B.2(d). Upon request, the laboratory was unable to provide documentation of the corrective action taken to bring level 1 quality control within acceptable range. B.2(e). In an interview on 10/24 /18 at approximately 10:45 AM the technical consultant, identified as number 2 on the CMS 209 form stated that, in the instance cited above, QC results failed to meet criteria for acceptability and no correction action was documented.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)

	(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Through review of the laboratory's Individualized Quality Control Plan (IQCP) for Prothrombin Time (PT/INR) and Partial Thromboplastin Time (PTT) testing on the Hemochron Jr. coagulation analyzer, quality control reports for PT/INR and PTT testing, proficiency testing (PT) reports for PT/INR and PTT testing, lack of documentation and interview it was determined that the laboratory failed to review the effectiveness of the IQCP or corrective actions in the event of QC failures in PT/INR or PTT testing performed on the Hemochron Jr. coagulation analyzer. Findings follow: A. Review of the laboratory's IQCP for PT/INR and PTT testing revealed that the IQCP calls for the laboratory to perform liquid QC testing monthly and upon beginning a new lot number of PT/INR and PTT reagents and the IQCP was based upon performance data of prior liquid QC results and proficiency testing results. B. Review of the laboratory's QC reports for PT/INR and PTT testing for November 2017, March 2018 and July 2018 revealed that QC failed to meet criteria for acceptability for on one of five instances reviewed for PT/INR testing and two of three instances reviewed for PTT testing. C. Review of the proficiency testing (PT) results for 2017 and 2018 revealed that there were challenge failures on three of five events reviewed for PT/INR tests and one of five events reviewed for PTT tests. D. Upon request, the laboratory could not provide documentation of data used to establish the IQCP or quality assurance documentation that the IQCP had been evaluated and revised to prevent recurrence of problems. E. In an interview on 10/24 /18 at approximately 11:45 AM, the technical consultant identified as number two on the CMS 209 form confirmed that data used to establish the IQCP for PT/INR and PTT testing on the Hemochron Jr. coagulation analyzer was not available and there had been no quality assurance performed to evaluate the effectiveness of the IQCP for PT/INR and PTT testing.