Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0466816	08/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Stuttgart Medical Clinic	1609 Medical Drive, Stuttgart, 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	Baptist Health Stuttgart Medical Clinic Laboratory is in compliance with the applicable Standards and conditions of 42 CFR Part 493, Laboratory Requirements. The following standard level deficiencies were cited on current survey: D5411: CFR 493.1252(a) - The laboratory failed to employ an accurate mean normal patient value used in the determination of INR, D5413: CFR 493.1252(b) - The laboratory failed to amend the expiration date of Innovin reagent when reconstituted snf placed into use. D5781: CFR 493.1282(b) - The laboratory failed to document corrective action when humidity levels fell below acceptable range. D5783: CFR 492.1282(b)(2) - In the event that quality control samples failed to be within acceptable limits, the laboratory failed to evaluate patient results reported back until the last acceptable quality control run
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Through review of the laboratory's records for establishing the Normal Patient Mean Prothrombin Time (MNPT), the user's manual for the CA 500 coagulation analyzer, observation of the MNPT set in the CA 500 instrument for calculating the International Normalized Ratio (INR) and interview it was determined that the laboratory had entered the incorrect MNPT value in the CA 500 coagulation analyzer for the Innovin reagent Lot # 539397 used fron 6/2/1017 until date of survey . Findings follow: A. Review of the user's manual for the CA 500 coagulation analyzer revealed that the MNPT must be determined specifically for each lot of Innovin and entered into the instrument settings. The MNPT value is used in the calculation of the

	patient INR result. B. Review of records used to establish the MNPT for Siemens Dade Innvovin lot # 539397 dated 6/2/2017 revealed that the geometric mean of the 25 samples used to establish the MNPT was reported as 10.55, which was rounded to the nearest one tenth of a second to 10.6 in a hand written note. C. In a tour of the laboratory on 8/9/18 at approximately 1400, the MNPT set in the CA 500 coagulation analyzer was observed to be 10.4 instead of 10.6 as reported on the records for establishment of the MNPT which would have caused an error in the calculation of the INR. D. In an interview on 8/9/18 at approximately 1400, the testing personnel identified as number 2 on the CMS 209 form confirmed that the correct MNPT determined for Innovin lot # 539397 was 10.6 seconds and the MNPT set in the CA 500 coagulation instrument was 10.4.
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: Through review of package insert for Dade Innovin prothrombin time reagent, observation and interview it was determined that the laboratory failed to label one of one vial of Dade Innovin with an amended date of expiration after the vial was reconsituted. Findings follow: A. Review of the manufacturer's package insert for Dade Innovin prothrombin time reagent revealed that the date of expiration is ten days after reconsituting and stored in a closed vial at 2-8 degrees Centigrade. B. During a tour of the laboratory on 8/10/18 at approximately 09:15 AM one of one vial of Dade Innovin lot # 530397 with an expiration date of 2019-10-13 was observed opened and reconstituted in a laboratory refrigerator without a date of reconsitution or an amended expiration date. C. In an interview on 8/10/18 at approximately 09:30 AM the testing personnel identified as number 2 on the CMS 209 form confirmed that the innovin was opened and in use and was not labeled with the date placed into use and/or the amended expiration date.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Through review of the laboratory's records of temperature and humidity levels, lack of documentation, manufacturer's instrument user's manual, and interview it was determined that the laboratory failed to take effective corrective action when humidity ranges were outside of acceptable ranges for the Status Clinitek instrument on 7 of 23 days of operation in January 2018. Findings follow: A. The performance specifications for the Status Clinitek urinalysis intrument revealed an operating humidity level requirement of 18% to 80%. B. Review of the laboratory's temperature and humidity records revealed an acceptable humidity requirement of 18% to 80% C. Review of laboratory humidity levels for January 2018 reveal the following results: DATE HUMIDITY * 01/03/18 15% * 01/04/18 14% *01/05/18 15% * 01/16/18 16% *01/17/18 16% *01/18/18 14% *01/19/18 17% D. Upon request, the laboratory was unable to produce corrective action taken when humidity levels were below acceptable levels. E. In an interview on 08/10/18 at approximately 01:30 PM the testing personnel identified as number 2 on the CMS 209 form verified that no corrective action had been taken to address humidity levels below requirements.
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: Through review of the laboratory's policy and procedure for quality control, quality control records for July 2017 and November 2017, patient result reports, and interview it was determined that the laboratory failed to evaluate patient results back until the last successful quality control results in the event of quality control failure on one of 20 days of patient testing for Prothrombin Times (PT) in July 2017 and one of 19 days of patient testing for Creatine Kinase (CK) in November 2017. Findings follow: 1. The laboratory failed to evaluate patient results back until the last successful quality control run on one of 20 days of patient testing for PT in July 2017. A. Review of the laboratory policy and procedure for coagulation quality control revealed that "the controls must be within established acceptable range before patient testing can be performed and results reported". B. Review of the instrument print tapes for PT testing for July 25, 2017 revealed that QC4 lot # 548485 with an acceptable range of 47.7 sec. to 50.9 sec. was resulted: * 47.6 with a notation "out" at 09:00 AM, * 47.5 with a notation "rinse probe" at 09:07 AM, * 47.6 with a notation "made new controls" at 09:33 AM, * 47.9 with a notation "ok" at 09:49 AM. C. Review of instrument print tapes for PT testing revealed that the last successful quality control results were performed at 09:39 AM on 7/24/27 and that four patient PT tests, identified as numbers 1 through 4 on a separate patient identification list, were performed between 09:39 AM on 7/24/17 and 09:00 AM on 7/25/17 and there was no instance of successful quality control between those dates and times. D. Upon request, the laboratory was unable to provide documentation that the results of PT tests run and reported on 7/24/17 had been evaluated. E. In an interview on 8/9/18 at approximately 02:45 PM, the testing personnel identified as number 2 on the CMS

	209 report confirmed that quality control had failed on 7/25/17 and patient results reported since the last successful quality control (7/24/17) had not been evaluated. 2. The laboratory failed to evaluate patient results back until the last acceptable quality control run on one of 19 days of patient testing for Creatine Kinase in November 2017. A. Review of the laboratory policy and procedure for quality control revealed that "the controls must be within established acceptable range before patient testing can be performed and results reported". B. Review of quality control summary reports for Level 1 chemistry control lot # 31821 with an acceptable range of (144 to 156) revealed that an acceptable quality control value of 144 was recorded at 08:11 AM on 11/15/17. C. Review of quality control summary reports for Level 1 chemistry control lot # 31821 with an acceptable range of (144 to 156) revealed that quality control was unacceptable on two runs on the morning of 11/16/18 with results of 141 and 142 with a notation "no patients tested". D. Review of quality control summary reports for Level 1 chemistry control lot # 31821 with an acceptable range of (144 to 156) revealed that quality control was unacceptable on two runs on the morning of 11/17 /18 with results of 140 and 139 with a notation "no patients tested". E. Review of patient test reports revealed that one CK test result was reported on a patient, identified as number 5 on a separate patient identification list, on 11/15/17 at 10:45 AM. F. Upon request, the laboratory was unable to produce documentation that the CK result for the patient, identified as number 5 on the separate patient identification list, had been evaluated. G. In an interview on 8/9/18 at approximately 02:45 PM, the testing personnel identified as number 2 on the CMS 209 report confirmed that quality control for CK had failed on 11/16/17 and 11/17/17 and that patient results reported since the last successful quality control (11/15/17) had not been evaluated.