Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0667580	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Baptist Health Medical Center-Stuttgart	1703 North Buerkle, 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
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 observation, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature in one of five separate rooms in which supplies with storage temperature requirements were stored . Findings follow: A. In an initial tour of the laboratory on 2/20/19 at approximately 10:00 AM, five separate rooms were observed in which reagents and/or supplies with storage temperature requirements were stored namely; the main laboratory, microbiology laboratory, blood bank, supply storage room, and glass wash room. B. In a tour of the Laboratory on 2/22/19 at approximately 10:30 AM, eight boxes of BD Veritor Flu A&B test kits lot # 8149422 expiration date 2021/03/15 and storage temperature requirement of 0 degrees C. to 30 degrees C., and four boxes of BD Veritor RSV test kits lot # 8204377 expiration date 2021-5-09 and storage temperature requirement of 0 degrees C. to 30 degrees C. were observed in the glass wash room separated from the laboratory by a closable door. C. Upon request, the laboratory was unable to provide documentation of temperature records for the glass wash room identified above. D. In an interview on 2/22/19 at approximately 10:10 AM, the technical supervisor identified as number eight on the CMS 209 form confirmed that the temperature had not been monitored in the glass wash room identified above.

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 quality control policy and procedure for "Coagulation QC for Sysmex CA-500", policy and procedure # CHE.1500.ST-1 "Daily QC Review - Abbott Architect", Levey-Jennings Reports, QC summary reports, "Out of Range QC Protocol" reports, correction action logs, "Revenue and Usage" reports and interview it was determined that the laboratory failed to document evaluation of patient results back to the last acceptable quality control result when quality control values fell outside of acceptable limits on one of one time when quality control for prothrombin times failed to meet criteria for acceptability, one of one time when quality control for amylase failed to meet criteria for acceptability and one of one time when quality control for thyroid stimulating hormone failed to meet criteria for acceptability . Findings follow: 1. The laboratory failed to evaluate patient results back to the last successful quality control when quality control for prothrombin time failed to meet the criteria for acceptability on 7/29/18. 1A. The quality control policy and procedure for prothrombin times states that quality control is unacceptable if either or both of the normal and./or abnormal controls fall outside of plus or minus 2 standard deviation range and if the control(s) are not acceptable after one rerun of the samples corrective action must be taken and documented. 1B. Review of quality control records revealed that the abnormal quality control (lot# 548483) fell outside of acceptable range on three succesive attempts on 7/29/18 with the following results: DATE TIME RESULTS ACCEPTABLE RANGE (41.1-46.3 sec) 07/29/18 1621 39.9 sec 07/29/18 1633 40.3 sec 07/29/18 1654 39.9 sec 07/29/18 1718 43.6 sec (acceptable result) 1C. Review of the corrective action log revealed corrective action included "reran", "new QC", and "new reagent". 1D. Review of the quality control summary report revealed that the last successful quality control was performed on 7/29/18 at 0809 which would require that all prothrombin time results reported between 7/29/18 at 0809 and 7/29/18 at 1718 be evaluated. 1E. Review of the "revenue and usage report" for 07/29/18 revealed that one patient, identified as patient #1 on a separate patient identification list, had a prothrombin time performed and reported on 7/29/18 at 1358. 1F. Upon request, the laboratory was unable to provide documentation that the prothrombin time result performed on the patient, identified as number 1, on the separate patient identification list, on 7/29/18 at 1358 had been evaluated. 1F. In an interview on 2/20 /19 at approximately 1530, the technical supervisor, identified as number eight on the CMS 209 form, confirmed that corrective action indicated a failure in the test system and the prothrombin time result reported since the last successful quality control had not been evaluated. 2. The laboratory failed to evaluate patient results back to the last acceptable quality control result on one of one time when quality control for amylase failed to meet criteria for acceptability . Findings follow: 2A. Review of the "Daily QC Review - Abbottt Architect" policy and procedure revealed that quality control is unacceptable if either or both of the normal and./or abnormal controls fall outside of plus or minus 2 standard deviation range and if the control(s) are not acceptable after

	one repeat and a second repeat with fresh QC material corrective action must be taken and documented and "a spot check of the patient results since the last quality control results within acceptable limits must be completed". 2B. Review of quality control records for amylase revealed that the level 2 quality control (lot# 31870) fell outside of acceptable range on two succesive attempts on 9/17/18 with the following results: DATE TIME RESULTS ACCEPTABLE RANGE (425-473) 09/17/18 0058 477 09/17 /18 0119 478 09/17/18 0156 470 (acceptable) 2C. Review of the "out of range QC protocol" report revealed the comments "rerun, recalibrated". 2D. Review of the quality control "levey-jennings report" revealed that the last successful quality control results for amylase prior to 09/17/18 at 0156 was performed on 09/16/18 at 0052. 2D. Review of revenue and usage report revealed that amylase tests were run and reported on patients , identified as patients numbers two through four on the separate patient identification list, on 09/16/18 at 1558, 0121 and 1126 respectively. 2E. Upon request the laboratory could not produce documentation of evaluation of patient results for patients identified above. 2F. In an interview on 2/21/19 at approximately 0900 the technical supervisor , identified as number eight on the CMS 209 form, confirmed that patient results for those patients identified above had not been evaluated and that they should have been evaluated since they were performed at a time between the last successful quality control results and a quality control failure. 3. The laboratory failed to evaluate patient results back to the last acceptable quality control result on one of one time when quality control for thyroid stimulating hormone failed to meet criteria for acceptability . Findings follow: 3A. Review of quality control records for thyroid stimulating hormone (TSH) revealed that the level 2 quality control (lot# 40920) fell outside of acceptable range on two succesive attempts on 9/6/18 with the following results: DATE TIME RESULTS ACCEPTABLE RANGE (4.1-4.9) 09/6/18 0134 3.9 09/6/18 0229 4.0 09/6/18 0541 4.8(acceptable) 3B. Review of the "out of range QC protocol" report revealed the comments "rerun, out (low reagent) new reagent, calibrated, QC OK". 3C. Review of the quality control "levey-jennings report" revealed that the last successful quality control results for amylase prior to 09/6/18 at 0541 was run on 09/5/18 at 0130. 3D. Review of revenue and usage report revealed that TSH tests were run and reported on patients , identified as patients numbers five through eight on the separate patient identification list on 09/5/18 at 0826, 1120, 1121, and 1257 respectively. 3E. Upon request the laboratory could not produce documentation of evaluation of patient results for patients identified above. 3F. . In an interview on 2/21/19 at approximately 0900 the technical supervisor , identified as number eight on the CMS 209 form, confirmed that patient results were not evaluated for those patients identified above and that they should have been evaluated since they were performed at a time between the last successful quality control results and a quality control failure.