Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0667580	11/19/2021
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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . 1. Through a review of policy and procedure manual, quality control (QC) records for 2021, patient medical records, lack of documentation as well as interviews with staff, it was determined the laboratory reported patients when results of Chemistry Quality Control (QC) failed to meet the laboratory's criteria for acceptability. Survey findings follow: A. A review of the policy and procedure manual revealed the protocol for Chemistry QC: "Two levels of quality control will be run each day of patient testing. Patients will not be report until QC is acceptable." B. A review of Chemistry QC results for June and September of 2021 (two of nine months), revealed on 6/4/2021 Chemistry Control Level 2 was out of range for Alanine Aminotransferase (ALT). C. A review of Chemistry QC results for June and September of 2021 (two of nine months), revealed on 6/4/2021 and 6/7/2021 Chemistry Control Level I and Level 2 was outside of the laboratory's acceptable range for Creatine Kinase. D. A review of medical records revealed on 6/04/2021 the laboratory reported thirteen patients for ALT with only one Level of QC in range of laboratory's criteria for acceptability. E. A review of medical records revealed on 6/4 /2021 the laboratory reported seven patients for CK and on 6/7/2021, the laboratory reported four patients for CK without documentation of acceptable QC. D. In an interview on 11/18/2021 at 10:00, technical consultant confirmed that patients were reported when the quality control results were outside of the laboratory's acceptable range. 2. The laboratory failed to evaluate patient results back to the last acceptable quality control result when quality control for ALT and CK failed to meet the laboratory's criteria for acceptability. Survey Findings follow: A. Review of the

	"Daily QC Review - Abbott 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". B. A review of the quality control "levey-jennings report" revealed that the last successful QC results for CK was performed on 6/3/2021 at 07:36. C. A review of patient's medical records revealed a total of eleven patients were reported for CK on 6/4/21 and 6/7/21. D. The surveyor requested documentation of patient evaluation for the days when QC was not in laboratory's acceptable range. None was provided. F. In an interview on 11 /18/2021 at 10:30 the technical consultant confirmed that patient results were not evaluated between the last successful quality control results and a quality control failure.