Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465641	07/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Magnolia Regional Health System Inc	101 Hospital Drive, Magnolia, 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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the manufacturer's instructions for Bio-Rad Multiqual chemistry controls, chemistry policies and procedures, Monthly Levey-Jennings Charts for chemistry tests, and Bio-Rad Unity Laboratory Comparison Reports, and through interviews with laboratory staff, it was determined the laboratory failed to follow manufacturer's instructions which required establishing quality control ranges for chemistry tests. Survey findings include: A. The laboratory policy titled "Chemistry DXC 700 AU Analyzer and QC" states, "All QC data is checked daily by the testing personnel and QC out of range >2 SD (standard deviation) is logged in the Daily QC log and corrective action documented for review by the administrative laboratory director or designee." B. The laboratory uses Bio-Rad Multiqual quality control (QC) material for assessing quality of routine chemistry tests performed on the Beckman Coulter DxC 700 chemistry analyzer. C. Examples of May 2021 chemistry QC ranges in use by the laboratory (as documented on the Monthly Levey-Jennings Charts),

	which do not reflect the calculated 2 SD from the Unity Laboratory Comparison Report are as follows: Lactic Acid Level 1 (lot #45871) SD in use 0.15 (calculated SD 0.03); Lactic Acid Level 2 (lot #45872) SD in use 0.44 (calculated SD 0.068); Lactic Acid Level 3 (lot #45873) SD in use 0.8 (calculated SD 0.104); GGT Level 1 (lot #45871) SD in use 3.65 (calculated SD 0.463); GGT Level 2 (lot #45871) SD in use 10.45 (calculated SD 0.810); GGT Level 3 (lot #45873) SD in use 16.35 (calculated SD 1.49); CK Level 1 (lot #45871) SD in use 10.05 (calculated SD 2.86); CK Level 2 (lot #45872) SD in use 33.0 (calculated SD 4.95); CK Level 3 (lot #45873) SD in use 76.5 (calculated SD 9.51); Alkaline Phosphatase Level 1 (lot #45871) SD in use 5.85 (calculated SD 1.24); Alkaline Phosphatase Level 2 (lot #45872) SD in use 24.5 (calculated SD 3.74); and Alkaline Phosphatase Level 3 (lot #45873) SD in use 50 (calculated SD 8.06). D. In an interview, at 9:58 a.m. on 7/14/2021, laboratory employee #2 (as listed on the form CMS-209) stated that the laboratory does not calculate a 2 SD range but instead the laboratory uses the range listed in the package insert. E. The manufacturer's instructions for use of Bio-Rad Multiqual states, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides."