Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305141	10/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mizell Memorial Hospital	702 N Main Street, Opp, AL	

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: Based on observations, a record review of the 2016-2018 temperature charts, a review of storage requirements for the Biorad QC (Quality Controls) (used for Chemistry, Endocrinology and Toxicology assays) and the Beckman Coulter (BC) Access 2 immunoassay calibrators, and an interview with the Laboratory Manager (also the Technical Consultant), the laboratory failed to define appropriate acceptable ranges (as defined by the manufacturer), and ensure QC and calibrators were stored at temperatures specified by the manufacturer for two of two freezers reviewed. The findings include: 1. A review of the August 2016 thru 4 October 2018 temperature records for Freezer #2 revealed the laboratory specified an acceptable range of less than -12 degrees C (Celsius) on the charts. Temperatures were documented in the specified range, and generally in the range of -14 to -18 degrees C. The surveyor noted Freezer #2 had temperatures documented at -20 degrees C or colder three times (less than one percent of the time) for the period reviewed. 2. A review of temperature records for the Storage Room Freezer for the period 1/18/17 thru 10/4/2018 revealed the laboratory specified an acceptable range of less than -12 degrees C (Celsius) on the charts. Temperatures were documented in the specified range, and generally in the range of -15 to -19 degrees C. The Storage Freezer had temperatures documented at -20 degrees C or colder 27 times (approximately 4 percent of the time) for the period

	reviewed. 3. During an interview with the Laboratory Manager on 10/4/2018 at 9:30 AM, freezer temperatures were reviewed, and then the surveyor inventoried the contents of the freezers. Contents of the Storage Room Freezer included approximately twelve boxes (six vials each) of Biorad QC, and two boxes Biorad Pediatric QC. An icon on the Biorad QC packages specified storage requirements of -20 to -70 degrees C. 4. A review of the contents of Freezer #2 revealed individual bottles Biorad QC (the current lot numbers in use), and fourteen boxes of BC Access 2 immunoassay calibrators, with specified storage requirements of -20 degrees C. 5. As the interview continued, the Laboratory Manager confirmed the freezers were not consistently maintaining temperatures in the range required for the long-term storage of the Biorad QC and calibrators. The surveyor also discussed the concern of the "acceptable ranges" on the freezer logs not reflecting the manufacturer's storage requirements for the items the freezer contained, and the CLIA requirement of following Biorad's QC and Beckman Coulter's calibrator storage instructions. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor