

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305199	(X3) Date Survey Completed 08/09/2018
Name of Provider or Supplier Washington County Hospital	Street Address, City, State 14600 St Stephens Avenue, Chatom, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observations, a review of the 2016-2018 environmental logs, a review of storage requirements for the Chemistry QC (quality controls) and an interview with the Laboratory Manager (also the General Supervisor), the laboratory failed to: (1) define appropriate acceptable temperature ranges for the freezer (as defined by the manufacturer of the items therein), (2) ensure QC was stored at temperatures as specified by the manufacturer, and (3) ensure room temperature and humidity was monitored and documented in the room where Arterial Blood Gas (ABG) testing was performed in 2016 thru July 2018. The findings include: 1. A review of the September 2016 thru August 2018 temperature records for the "Big White" Refrigerator/Freezer revealed the laboratory specified an acceptable range of -10 to -20 degrees C (Celsius) on the logs. Temperatures were documented in the specified range, with temperatures generally in the range of -12 to -18 degrees C. The freezer had temperatures documented at -20 degrees C (or colder) 97 times, or approximately thirteen percent of the two year review period. 2. A review of the Blood Bank area temperature logs (where ABG's are performed on the OPTI CCA-TS analyzer) revealed no documentation of room temperature and humidity monitoring until 7/26/2018. 3. A review of the OPTI CCA-TS Operator's Manual on page 2-1 revealed, "...2.2. Choosing a Location ... Room temperature within 10-32 degrees C (Celsius) (50-90</p>

degrees Fahrenheit) [and] Maximum relative humidity of 95% ...". 4. During an interview with the Laboratory Manager on 8/9/2018 at 1:20 PM, freezer temperatures were reviewed on the charts, and on the inside thermometer (observed to be -17 degrees C). The surveyor and the Manager then reviewed the contents of the freezer which contained approximately twenty-five boxes (six vials each) of Biorad Chemistry and Endocrinology QC. An icon on the QC package inserts specified storage requirements of -20 to -70 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. 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 storage and handling instructions. When asked about documentation of room temperature and humidity in the room where ABG testing was performed, the Manager confirmed the laboratory had not monitored these parameters until July 2018. Thus, the above noted findings were substantiated. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor