

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0468729	<b>(X3) Date Survey Completed</b>  01/15/2020
<b>Name of Provider or Supplier</b>  Gentry Medical Center	<b>Street Address, City, State</b>  643 East Third Street, Gentry, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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: Through observation, lack of documentation and interview it was determined the laboratory failed to monitor room temperature in two of three rooms in which supplies with storage temperature requirement were stored. Findings follow: A) During a tour of the laboratory on 1/15/20 at approximately 11:45 AM, 400 Vacuette SST blood collection tubes lot# B191133B expiration date 2021-05-05; 400 Vacuette EDTA blood collection tubes lot# B19063 VP expiration date 2020-10-12 all with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed stored in a storage room separate from the laboratory and 18 Vacuette SST blood collection tubes lot# B190838S expiration date 2021-02-06; 34 Vacuette EDTA blood collection tubes lot# B19053M expiration date 2020-09-12 and 80 BD SST blood collection tubes lot# 9213122 expiration date 2020-07-31 all with storage temperature requirement of 4 degrees C. to 25 degrees C. were observed in a phlebotomy room separate from the laboratory. . B) Upon request, the laboratory was unable to provide records of room temperature in the separate storage room or the phlebotomy room identified above. C) In an interview on 1/15/20 at approximately 11:45 AM, the laboratory staff member, identified as number two on the CMS 209 form, stated that the laboratory did not monitor the room temperatures in the storage and phlebotomy rooms identified above.</p>

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Through review of package insert for Boule Hematology quality controls, observation, and interview it was determined that the laboratory did not label the control vials with the date and time opened and placed into use, or an amended expiration date and time as required by the manufacturer. Findings follow: A) The manufacturer's package insert for Boule Hematology controls state "once opened controls are stable in their original vials for 14 days if kept at 2 to 6 degrees C. ". B) During a tour of the laboratory on 1-15/20 at approximately 11:45, three of three vials of Boule Hematology controls lot #'s 21911-21, 21911-22, 21922-23 were observed in the refrigerator which were not labeled with the date and time that the controls were opened and placed in use or an amended expiration date. C) In an interview on 1/15 /20 at approximately 11:45 AM, the laboratory staff member, identified as number 2 on the CMS 209 form, confirmed that the vials of hematology controls identified above had not been labeled with the date opened and were currently in use.