

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0889073	(X3) Date Survey Completed 04/04/2023
Name of Provider or Supplier Boston Mountain Rural Health Center,Inc-Huntsville	Street Address, City, State 934 North Gaskill Street, Huntsville, 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
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: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature in one of two rooms in which supplies with storage temperature requirements were stored on each day of operation. Findings follow: A) During a tour of the laboratory on 4/4/23 at 9:30 a.m.two rooms (main lab and phlebotomy blood drawing area) containing items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the phlebotomy blood drawing area. C) During a tour of the laboratory on 4/4/23 at 12:20 p.m. 38 Vacuette Red Top clot blood collection tubes lot # B220634Y, 24 Vacuette Serum Separator blood collection tubes lot # A2212385B and 23 Vacuette EDTA blood collection tubes lot # B220936A all with a storage temperature requirement of 4 degrees C. to 25 degrees C were observed in the phlebotomy drawing area. D) Upon request, the laboratory could not present the temperature records for the phlebotomy drawing area in which the supplies identified above were stored,. E) In an interview on 4/4/23 at 12:30 p.m. the laboratory staff member (# 2 on the CMS 209) stated that the daily temperature of the phlebotomy drawing area in which the supplies identified above were stored had not been monitored and recorded..</p>