

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0937388	<b>(X3) Date Survey Completed</b>  08/09/2022
<b>Name of Provider or Supplier</b>  Baptist Health Family Clinic - South	<b>Street Address, City, State</b>  8600 South 36th Terrace Ste A, Fort Smith, 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, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature of 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 8/9/22 at 11:30 AM two rooms containing items with a temperature storage requirement , the main laboratory and a separate phlebotomy area separated from the main laboratory by a closable door, were observed. B) During a review of the laboratory's temperature records it was noted that temperature records for only the main laboratory were presented. C) During a tour of the laboratory on 8/9/22 at 03:55 pm, 80 BD EDTA blood collection tubes lot number 2048406 expiration date 2023-06-30' 90, BD Serum Separator blood collection tubes lot number 2046862 expiration date 2023-2-28 and 5 BD Heparin blood collection tubes lot number 1165649 expiration date 2022-10-31, all with a storage temperature range of 4 degrees C to 25 degrees C., were observed in the phlebotomy room. D) Upon request, the laboratory could not present the temperature records for the phlebotomy room in which the supplies identified above were stored,. E) In an interview on 8/9/22 at 04:20 pm the</p>

laboratory staff member, identified as number six on the CMS 209 form, stated that the daily temperature of the phlebotomy room in which the supplies, identified above, were stored had not been monitored and recorded..