

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0466177	<b>(X3) Date Survey Completed</b>  06/12/2018
<b>Name of Provider or Supplier</b>  Baptist Health Family Clinic Bryant	<b>Street Address, City, State</b>  4411 Hwy 5 North, Bryant, 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 room temperature in one of two rooms in which laboratory supplies with a storage temperature requirements were stored. Findings follow: A: During a tour of the laboratory on 6/12/18 at approximately 1300, two ea. Alere Influenza A&amp;B Control Swab kits lot number 094931 with a storage temperature requirement of 2 degrees C. to 30 degrees C. , two ea. Alere Influenza A&amp;B Control Swab kits lot number 985537 with a storage temperature requirement of 2 degrees C. to 30 degrees C., and two ea. Hemosure IFOB Test kits lot number A6150077 with a storage temperature requirement of 2 degrees C. to 30 degrees C. were observed in a storage room separate from the laboratory. B. Upon request, the laboratory was unable to produce a record of temperature measurement in the storage room identified above. C. In an interview on 6/12/18 at approximately 1330, the Laboratory Director identified as number 7 on the CMS 209 form, confirmed that laboratory supplies with a storage temperature requirement were stored in the storage room and that room temperature had not been monitored in that room.</p>