

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2042676	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Baxter Health Family Clinic At Melbourne	Street Address, City, State 1019 E Main, Melbourne, 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, lack of documentation and interview it was determined that the laboratory failed to monitor the room temperature in one of two rooms in which supplies with a storage temperature requirement were stored. Findings follow: A. In a tour of the laboratory on 4/10/19 at approximately 11:30 AM, two containers of Coulter AcT Diff PAK reagent lot # 11221816 with an expiration date of 2019-09-17 and a storage temperature requirement of 0 degrees C. to 30 degrees C. were observed in a storage room separated from the laboratory by a closed door. B. Upon request, the laboratory was unable to provide room temperature records for the room identified above. C. In an interview on 4/10/19 at approximately 12:30 PM, the technical consultant identified as number 2 on the CMS 209 form and the testing personnel identified as number 3 on the CMS 209 form confirmed that room temperature of the storage room identified above had not been monitored.</p>