

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468564	(X3) Date Survey Completed 04/05/2018
Name of Provider or Supplier Mana Family Medicine South	Street Address, City, State 2523 East Huntsville Road, Fayetteville, 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 and document room temperature in one of two rooms in which laboratory supplies with storage temperature requirements were stored. Findings follow: A. During a tour of the laboratory on 4/5/18 at approximately 1100 AM, 70 ea. 5.0 ml BD SST vacutainers lot# 7321646 expiration date 2019-11-30, 56 ea. 4.0 ml BD EDTA blood collection tubes lot # 7339691 and expiration date of 2019-04-30, 15 ea. 8.5 ml BD SST blood collection tubes lot # 7160782 with an expiration date of 2018-5-31 all with a storage temperature of 4degrees C. to 25 degrees C. were observed in a separate phlebotomy room isolated from the laboratory by a closable door. B. Upon request, the laboratory was unable to provide documentation of temperature measurements of the phlebotomy room. C. In an interview on 4/5/18 at approximately 11:30 AM, the testing personnel identified as number 1 on the CMS 209 form confirmed that supplies with storage temperature requirements were in the separate phlebotomy room and room temperature was not monitored and documented.</p>