Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468564	11/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mana Family Medicine South	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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Through observation, lack of documentation and interview it was determined that the laboratory failed to document room temperature in one of three rooms surveyed in which supplies with storage temperature requirements were located. Findings follow: A) During a tour of the laboratory on 11/18/20 at approximately 11:00 AM, the surveyor observed three boxes of Quidel Sofia SARS Ag tests, lot # 706237 expiration date 2021-09-02 with a storage temperature requirement of 15 degrees C. to 30 degrees C. in a separate Covid-19 testing room separated from the laboratory by a closable door. B) Upon request the laboratory was unable to provide documentation of temperature records for the room identified above. C) In an interview on 11/18/20 at approximately 11:00 AM, the laboratory staff member identified as number eight on the CMS 209 form confirmed that the laboratory failed to measure and document temperature in the room identified above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observation, and confirmed by interview with laboratory staff it was determined that 36 of 36 EDTA blood collection vials that had exceeded their date of expiration was present and available for usein the outpatient phlebotomy area. Findings follow: A) During a tour of the laboratory on 11/18/20 at approximately 11: 00 AM 36 of 36 Vacuette EDTA blood collection vials, lot # B190785 expiration date 11-10-2020 were observed in the phlebotomy supply storage bin in the outpatient phlebotomy area . B) In an interview on 11/18/20 at approximately 11:00 AM, the laboratory staff member, identified as number eight on the CMS 209 form, confirmed that the items identified above had expired and were available for use.