Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468564	10/20/2022
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure, observation and interview it was determined that the laboratory failed to label one of three specimen collection containers with patient name or unique patient identifier. Findings follow: A) During a tour of the laboratory on 10/20/22 at 4:00 p.m. three urine specimen containers were observed in the laboratory testing area; one labeled with the patient's first and last name only. B) Review of the laboratory policy and procedure revealed that "a properly labeled specimen must have 2 forms of identification, the patient name and birthdate, the patient ID or the accession number". . C) In an interview on 10/20/22 at 4:30 p.m. , the laboratory staff members (#10 and #2 on the CMS 209 form) confirmed that the specimens identified above had been analyzed and lacked proper patient identification on the containers as required by policy and procedure.
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, 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 10/20/22 at 01:15 p.m. two rooms containing items with a temperature storage requirement (the main laboratory and storage room) separated 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 was presented. C) During a tour of the laboratory on 10/20/22 at 03:40 p.m., six boxes of Sofia2 Flu/SARS (lot# 708095 expiration date 2023-08-02 storage temperature requirement of 15 degrees C. to 30 degrees C.) and 200 BD Serum Separator blood collection tubes (lot# 2017186 expiration date 2023-01-31 with a storage temperature requirement of 4 degrees C. to 25 degrees C.) were observed in the separate storage room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored,. E) In an interview on 10/20/22 at 3:50 p.m. the laboratory staff members (#10 and #2 on the CMS 209 form) confirmed that the daily temperature of the room in which the supplies identified above were stored had not been monitored and recorded..
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Through a review of the laboratory policy for corrective action, Hematology quality control (QC) records for July 2022, quality control corrective action record, lack of documentation and interviews with staff, it was determined the laboratory failed to document all corrective action when Hematology control data failed to meet the laboratory's criteria for acceptability on two of two occasions. Survey findings follow: A) Review of the laboratory policy for corrective action revealed that the "Out-of-Range Control Form" is "to be completed whenever one control measurement exceeds the control limit of the mean plus or minus 2SD". B) Review of QC records for Hematology high quality control lot# 37221713 revealed that QC was analyzed three times for platelet count on 7/19/22 at 0657, 0659, 0701 with the result being below 2SD from the mean before being acceptable at 0703 . Repeating quality control multiple times is not corrective action. C) Review of QC recods for Hematology high quality control lot# 37221713 revealed that QC was analyzed three times for platelet count on 7/21/22 at 0719, 0720, 0724 with the result being below 2SD from the mean before being acceptable at 0725 . Repeating quality control multiple times is not

	corrective action. D) Upon request the laboratory was unable to provide the "Out-of-Range Control Form" documenting what corrective action was implemented to bring the high level control into acceptable range on both occasions identified above, E) In an interview on 10/20/22 at 03:50 p.m. with laboratory personnel #10 (as listed on CMS form 209) confirmed the lack of documented corrective action for Hematology high control.