Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0990236	02/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Rheumatism Center, Pa	1107 East Sara Swamy Drive, Sherman, TX	

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
D0000	Entrance and exit conferences were held with laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: Based on direct observations, review of manufacturer's instructions, laboratory environmental records for 2019, and confirmed in staff interview, the laboratory failed to ensure room temperature ranges were within the storage specifications for Becton

	Dickinson Blood Collection tubes for 12 of 12 months. Findings included: 1. During a tour of the laboratory area on 02/17/2020 at 1200 hours, the following Becton Dickinson (BD) blood collection tubes were observed stored in cabinets. a. 2 packages of 100 tubes; BD K2 EDTA Blood collection tubes; Lot number 9260575; Expiration date 2021-01-31 b. 3 packages of 100 tubes; BD SST Blood collection tubes; Lot number 9311148; Expiration date 2020-10-31 2. The manufacturer's storage requirements on the blood collection tube package labels stated a storage temperature requirement of 4C to 25C (39F - 77F). 3. Review of the laboratory records titled "Daily Log" for 2019 revealed the laboratory's acceptable room temperature range was 64F - 90F (18C - 32C). This range did NOT ensure the temperature was within storage specifications for BD Blood collection tubes. 4. During an interview on 02/17 /2020 at 1200 hours in the laboratory, testing person #1 stated that she did not know blood collection tubes had storage requirements. This confirmed the above findings. Word Key: EDTA=Ethylenediaminetetraacetic acid SST=Serum Separation Tube C=Celsius F=Fahrenheit