Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	20D0088568	10/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Rheumatology Associates	51 Sewall St, Portland, ME	

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
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: Based on record review, observation of the contents of the laboratory refrigerator, and interview with the General Supervisor #1 (GS1) the laboratory failed to follow the manufacturer's instruction concerning the expiration of control materials in the specialty of Hematology. Findings include: 1. Surveyor observation on 10/4/2022 at 10:30 AM of the contents of the laboratory refrigerator revealed: a. Horiba Minotrol 16 Tri-Level Control set 5300000277, 5300000278, 5300000283. b. The above controls where hand labeled for 21 days from opening until expiration. 2. Record review on 10/4/2022 Horiba Hematology Tri-Level Controls package insert revealed the following: a. "Opened tubes are stable for 16 days provided they are handled properly...'. 3. Record review of the laboratory Horiba Micros 60 laboratory manual on 10/4/2022 revealed the following quality control statements: a. "Is the QC material within its expiration date? ... Have any reagent materials deteriorated or expired?" 3. Staff interview with (GS1) on 10/4/2022 at 10:30 AM confirmed the above findings. 6. The laboratory performs 52830 tests annually in the specialty of Hematology.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through

	sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review, observation, and interview, the Technical Supervisor (TS) failed to maintain the Quality Control program throughout the entire testing process prior to the reporting of test results. Refer to D5417.