Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2044073	03/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Sc Medical Inc	19042 Soledad Canyon Rd, Santa Clarita, CA	

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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on the request for patient/test records, review of five (5) randomly chosen patients' test requisitions and test results, and interviews with the technical consultant (TC) and testing personnel (TP); the laboratory failed to record the time patient samples were received and tested. Findings include: 1. The laboratory was unable to provide the complete test results according to the test ordered and documentation of the reason why the testing was performed three days later for one (1) out of five (5) randomly chosen patient samples. 2. The TC confirmed on March 6, 2024 at approximately 12:00 p.m. that the laboratory did not document the reason the requisition did not match the time the specimens were received and tested.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory tour and interview with the technical consultant (TC) the laboratory failed to label quality control reagents used for hematology. The findings included: 1. Based on the surveyor's observation during

	the laboratory's tour on March 6, 2024 at approximately 12:15 p.m.; no opening, preparation, or expiration date labels were used or documented for the quality control reagents used for hematology sample processed daily. 2. The TC affirmed in an interview conducted 3/6/2024, at approximately 12:30 p.m. that the reagents mentioned in statement 1 were not labeled with the opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 2,700 hematology samples.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, lack of documentation, the surveyor's observation, and interview with the laboratory's technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that preventive maintenance and calibration be performed on all equipment and instruments used in the laboratory. 2. The TC and TP confirmed on March 6, 2024, at approximately 12:30 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and calibration of small equipment such as timers. 3. According to the test volume declared by the laboratory on 2/20/2024 the laboratory performs approximately 2,700 hematology diagnostic tests annually.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation, review of the laboratory records, and interview with the technical consultant and testing personnel it was determined that the laboratory director failed to be responsible for the overall operation, including, but are not limited to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings included: D5313, D5415, and D5429.