Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1077487	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sierra Hematology & Oncology Medical Center	8100 Bruceville Rd, Sacramento, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of laboratory written test procedures reflecting the current laboratory practice, review of five (5) randomly chosen patients results, and interview with the laboratory's staff (LS), it was determined that the laboratory failed to have current written procedures for all tests performed in the laboratory reflecting the current practice. The findings included: 1. On the day of the survey on January 25, 2023, at approximately 11:45 a.m. the laboratory failed to provide current written procedures for all test procedures performed in the laboratory. 2. For five (5) out of five (5) random patient test results reviewed covering period from 9/27/2021 to 1/2 /2023 the patients had various Hematology test ordered, analyzed, and reported for which the laboratory had no current written tests procedures available reflecting the current practice. 3. The LS confirmed on January 25, 2025, at approximately 12:30 p. m. that the laboratory did not have current written procedures available for all test performed in the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the lack of a laboratory procedure manual, random patient samples, quality control (QC) and proficiency testing (PT) records for the years of 2021 and 2022, and interview with the laboratory staff (LS) on January 25, 2023, the laboratory failed to have a step-by-step performance of the procedure and quality control procedure for the Cell- Dyne Abbott Emerald instrument. The findings include: 1. The laboratory uses the Cell- Dyne Abbott Emerald instrument Hematology analyzer for analyzing patient samples, however; the laboratory failed to have a step-by-step performance of the procedure and quality control procedures. 2. The LS affirmed the lack of a laboratory procedure manual stating a step-by-step performance of the procedure and quality control procedures for the Cell- Dyne Abbott Emerald instrument. 3. The laboratory's testing declaration form, signed by the laboratory 's director on 1/19/2023, stated that the laboratory performs15,6000 Hematology tests annually.
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 observation on the lack of calibrated thermometers in the refrigerator to verify digital temperature readings and interview with the laboratory staff (LS) it was determined that the laboratory failed to monitor the digital temperature readings of equipment essential for proper storage of reagents and specimens that adversely affect patient test results. The findings included: 1. On the day of the survey, January 25, 2023, at approximately 11:45 a.m. based on observation and interview with the LS the laboratory failed to have calibrated thermometers on the refrigerator that verify accurate digital thermometers readings which affect reagents and patients' samples testing. 2. The LS confirmed on 1/25/23, at approximately 12:00 p.m. that the

	laboratory has no calibrated thermometers in the refrigerator to verify digital temperature readings. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 15,600 samples annually.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on direct observation and interview with the laboratory staff; it was determined that the laboratory director failed to ensure that an approved written procedure manual is available at all times to all personnel responsible for any aspect of the testing process. See D5401 and D5403.