Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2048767	01/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hope Health Center	24100 Calabasas Rd, Calabasas, 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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, five (5) random patients sampling, and interview with the technical consultant (TC); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hematology on the third event of 2022 (Q3-2022). The findings included: 1. The API proficiency program gave an overall unsatisfactory score of 0% for Hematology for Q3-2022. 2. The TC confirmed on January 9, 2024, at approximately 11:30 a.m. that the laboratory received the above proficiency score of 0% for Hematology as described in 1. 3. Based on the laboratory's annual testing declaration submitted on the day of the survey January 9, 2024; the laboratory analyzed and reported approximately 1,3000 Hematology samples (quarterly) during the time the laboratory had unsatisfactory proficiency testing results.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of competency assessment documentation and interview with the

	technical consultant (TC) on the day of the survey, January 9, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the TC and TP competency for the years 2022 and 2023. Findings include: 1. The laboratory fail to provide documentation of competency assessment for the TC and TP performing sample processing, testing, and reporting at the laboratory for the years 2022 and 2023. 2. This deficient practice stated in 1 was affirmed by interview with the TC on 1 /9/2024, at approximately 2:15 p.m. 3. The laboratory reported to process and report 4,000 hematology tests annually.
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 procedure, review of five (5) randomly chosen patients results, and interview with the laboratory's technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to have current written procedures for hematology tests performed in the laboratory. The findings included: 1. On the day of the survey on January 9, 2024, at approximately 1:30 p.m. the laboratory failed to provide the current written procedure approved and dated by the laboratory director for hematology tests performed in the laboratory. 2. For five (5) out of five (5) randomly chosen patient's hematology test results reviewed covering period from 5/17/2022 to 1/3/2024 no current written tests procedure was available to reflect a procedure followed by the TP for the hematology tests performed and reported. 3. The TC and TP confirmed on January 9, 2024, at approximately 1:00 p.m. that the laboratory did not have current written procedures available for hematology tests performed in the laboratory.
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 observation during the laboratory tour of quality control (QC) reagents used for hematology and interview with the laboratory's TC and TP; it was determined that the laboratory failed to label QC reagents to indicate date of use and expiration date when such reagents are used in the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on January 9, 2024, at 1:30 pm.; no opening, preparation, or expiration date labels were used or documented for the QC reagents used on the daily basis. 2. The laboratory's TC affirmed in an interview conducted 1/09/2024, at approximately 2:15 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 4,000 hematology test 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 the laboratory's policies and procedures, lack of documentation, and interview with the laboratory's technical consultant (TC), it was determined that the laboratory failed to perform and document preventive maintenance and calibration of the thermometer as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory equipment. The findings included: 1. The laboratory's policies and procedures and temperature logs indicated that annual maintenance and calibration according to manufacturer's requirements be performed on the thermometers used in the laboratory. 2. The TC confirmed on January 9, 2024, at approximately 1:00 p.m. that the laboratory failed to follow policies and procedures for maintenance and calibration of the thermometer used in the laboratory S/N 12220568 Expired 4/23/2014, indicated by the lack of preventive maintenance documentation. 3. According to the annual test volume declared by the laboratory LD, the laboratory performs approximately 4,000 hematology tests annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory quality control (QC) records, randomly chosen patients' hematology tests results, lack of QC failure documentation policy and procedure, and interview with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to establish quality control failure procedures that monitor the accuracy and precision of the complete analytic process including the number, the type, and the correction and documentation of those QC failures when performing hematology examinations. 1. On the day of the survey January 9, 2024, at approximately 2:00 p.m., the surveyor observed that QC failures were not documented on two (2) out of five (5) patients' records reviewed. In addition,

	patients' samples were run, and results were reported despite of QC failures. 2. The TC and TP confirmed on January 9, 2024, that the laboratory lacked an established policy and procedure for QC failures and documentation of such failures were not performed. 3. 3. According to the annual test volume declared and signed by the laboratory LD on January 8, 2024, the laboratory performs approximately 4,000 hematology tests annually.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures (P&P) and records, and interview with the laboratory's technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to follow written P&P to maintain an ongoing quality assessment, and to ensure accuracy, reliability, and timely of the patient test results reports. The findings included: 1. The laboratory failed to follow its written quality assessment P&P. 2. On the day of the survey (1/9/2024) the TC and TP failed to have any documentation of an ongoing mechanism to monitor, assess, and ensure accuracy, reliability and timely of the patient test result reports for the years 2022 and 2023. 3. The TC and TP confirmed by interview on 1/9/2024, at approximately 2:00 p.m. pm that the laboratory failed to follow its policies and procedures to maintain an ongoing quality assessment program. 4. Based on laboratory records the laboratory performed and reported approximately 4,000 diagnostic hematology 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 laboratory 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: See D2121, D5209, D5401, D5415, D5429, D5441 and D5791.

D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: The technical consultant is cited herein based on review of random patient test results reported when quality control failure had occurred. The technical consultant failed to ensure that patient test results are not reported until all corrective actions have taken place and the test system is functioning properly. The findings included See D5441.