Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0975508	05/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ccsmg/City Of Hope Medical Group	209 Fair Oaks Ave, South Pasadena, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. See D5469, D5481 and D5791.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on Surveyor review of quality control and patient test records, policies and procedures, lack of quality control (QC) material verification data, and interview with the laboratory Technical Consultant, the laboratory failed to verify the criteria for acceptability of hematology CBC QC materials of all 3 lots, reviewed from 2017 and 2018. The findings include: a. The laboratory used the following QC materials for quality control process: lots# 72130804, 83520806 and 90430806. However, the laboratory did not have any records showing that it had verified the manufacturer provided acceptability criteria. b. The laboratory Technical Consultant, on 5/17/2019 at 11:10 am, confirmed that no verification of the acceptability criteria was done for the QC materials. c. The laboratory's testing declaration form, signed by the laboratory Director on 5/7/2019, stated that the laboratory performs 1,560 tests annually.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of patient testing records, quality control data, and interview with the laboratory Technical Consultant, the laboratory reported patient test results even though the results of quality control materials failed to meet the laboratory's acceptability criteria in 1 day out of 45 days, reviewed. The findings include: a. The laboratory's data showed that the results of its quality control material, lot# 72130804 ran on 8/23/2017, failed to meet the laboratory's acceptability criteria. The laboratory's policy and procedure stated that accept the run if controls are within acceptable range of expected results from Quality control log or reject the run if any control is greater than 3 Standard Deviation. The results of WBC, 7.18 was outside of the acceptable range 6.61 - 7.04 or greater than 3 Standard Deviation. On that day, the laboratory reported WBC results for 13 patients while control failed. b. On 5/17/2019 at 11:40 am, Laboratory Technical Consultant affirmed that quality control failed on 8 /23/2017. c. The laboratory's testing declaration form, signed by the laboratory Director on 5/7/2019, stated that the laboratory performs 1,560 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 Surveyor review of patient testing records, quality control data, and interview with the laboratory Technical Consultant, it was determined that the laboratory's ongoing mechanism for monitoring and assessing the problems in quality control was inadequate. The findings include: a. The laboratory's data showed that the

	results of its quality control, ran on 8/23/2017, failed to meet the laboratory's acceptability criteria. However, the laboratory's analytical systems quality assessment process failed to detect the problem. b. On 5/17/2019 at 11:40 am, Laboratory Technical Consultant affirmed that quality control failed on 8/23/2017, and quality assessment through Levy-Jennings could not detect the problem. c. The laboratory's testing declaration form, signed by the laboratory Director on 5/7/2019, stated that the laboratory performs 1,560 tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Moderate complexity testing laboratory director was not met. See D6004, D6042 and D6072.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, and patient and quality control test records for hematology testing, and interview with the Laboratory Technical Consultant, it was determined that the laboratory director failed to meet the responsibilities of a moderate complexity lab director. See D5400, D6042, D6072.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) 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 Surveyor review of laboratory's policy & procedure, and patient and quality control test records for hematology testing, and interview with the Laboratory

	Technical Consultant, it was determined that the laboratory Technical Consultant failed to ensure the acceptable levels of analytic performance are maintained throughout the entire testing process. The findings include: a. The laboratory did not have any record of verifying the acceptable ranges for quality control materials, lots# 72130804, 83520806 and 90430806. Moreover, the results of quality control ran on 8 /23/2017, failed to meet the laboratory's acceptability criteria. However, Technical Consultant was unable to detect the failure through analytic systems quality assessment. b. On 5/17/2019 at 11:48 am, Laboratory Technical Consultant admitted that the laboratory never verified the acceptable quality control ranges and never changed the ranges into the instrument which caused the Technical Consultant's inability to detect the problem in the analytical system. c. The laboratory's testing declaration form, signed by the laboratory Director on 5/7/2019, stated that the laboratory performs 1,560 tests annually.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, quality control test records for hematology testing, and interview with the Laboratory Technical Consultant, it was determined that the laboratory testing personnel did not adhere to the laboratory's quality control policies and document all quality control activities. The findings include: a. The laboratory's quality control data showed that the results of its quality control, ran on 8/23/2017 by testing person #1, failed to meet the laboratory's acceptability criteria. The laboratory's policy and procedure stated that accept the run if controls are within acceptable range of expected results from Quality control log or reject the run if any control is greater than 3 Standard Deviation. The results of WBC, 7.18 was outside of the acceptable range 6.61 - 7.04 or greater than 3 Standard Deviation. However, the testing person did not reject the run, and continued to run patient sample. b. On 5/17/2019 at 11:40 am, Laboratory Technical Consultant affirmed that quality control failed on 8/23/2017, and the testing person did not record it nor reject the run. c. The laboratory's testing declaration form, signed by the laboratory Director on 5/7/2019, stated that the laboratory performs 1,560 tests annually.