Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0581257	10/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Orange County Global Medical Center Inc	1001 N Tustin Ave, Santa Ana, 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
D0000	A complaint investigation was conducted on 10/29/2025, wherein the laboratory was found not in compliance with the CLIA regulations with the following CONDITION: 42 CFR 493.1250 Condition: Analytic systems 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 direct observations, review of laboratory policies and procedures, patient test records, and interviews with laboratory staff, it was determined the laboratory failed to monitor and evaluate the overall quality of the analytical systems and correctly identify problems as it occurred. The findings include: 1. The laboratory used control materials beyond its expiration date for high sensitivity Troponin-I assay (See D5417). 2. The laboratory tested and reported high sensitivity Troponin-I patient test results using expired quality control (QC) materials and failed to establish and verify performance specifications prior to reporting patient test results (See D5423). 3. The laboratory failed to establish and follow written policies and procedures to monitor and assess, and when indicated, correct problems identified in the analytic systems (See D5791).
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	(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 surveyors' review of ten randomly selected patient records, quality control (QC) documentation, and interviews with laboratory staff, it was determined the laboratory failed to ensure that testing personnel did not use expired control materials. The findings include: 1. The surveyors reviewed the quality control documentation for high sensitivity Troponin-I (hsTnI) analyte, lot number 3170322T, which expired on March 31, 2025. The laboratory reported patient test results from May 1, 2025, to October 10, 2025, utilizing this expired control material. 2. The control manufacturer's package insert indicated that quality control materials must not be used beyond the expiration date. 3. All ten randomly chosen patient reports reviewed showed QC records with an instrument flag indicating the use of expired control materials. Accession# Test Date 22512029 05/01/2025 225170052 06/19/2025 225209015 07/28 /2025 225211011 07/30/2025 225225045 08/13/2025 225241044 08/29/2025 225247045 09/04/2025 225263049 09/20/2025 225274011 10/01/2025 225283002 10 /10/2025 4. The quality and reliability of patient results reported could not be assured. 5. The laboratory staff confirmed on October 29, 2025, at approximately 12:26 p.m. that the laboratory used expired control material for hsTnI when it tested patient samples and reported test results from May 1, 2025, to October 10, 2025. 6. According to the testing declaration form (Lab-144) submitted at the time of survey, the laboratory reported approximately 11,568 patient test results for hsTnI annually including the period when the expired QC material was used.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient test records, quality control records, and interviews with laboratory staff, it was determined the laboratory used expired control materials in reporting high sensitivity Troponin-I (hsTnI) patient test results but failed to establish performance specifications before reporting patient test results. The findings include: 1. The assay manufacturer's manual stated that there should be at least one level of QC material targeted near the myocardial infarction (MI) cutoff. 2. The control manufacturer's package insert also indicated that quality control materials must not be used beyond the expiration date. 3. To monitor assay performance at the MI cutoff, the laboratory used high sensitivity Troponin-I (hsTnI)

	control, lot number 3170322T, which expired on March 31, 2025. 4. Further record review revealed the laboratory began using hsTnI QC material on May 1, 2025. The staff presented a signed quality variance/patient safety report (QVR) form dated 3/31 /2025, indicating the permission usage of the expired control material. 5. However, the laboratory failed to provide documentation showing it established and verified performance specification for accuracy, precision, analytical sensitivity, analytical specificity, reportable range of test results, reference intervals, and other performance characteristics required for test performance using expired QC materials, before reporting patient test results. 6. Review of patient test records showed the laboratory used expired high sensitivity Troponin-I (hsTnI) control lot number 3170322T but failed to establish performance specifications for using expired QC material. 7. The patient census provided to surveyors during the inspection on October 29, 2025, showed the following record summary from May 1, 2025, to October 10, 2025: a. May = 67 total patients, 844 total hsTnI tests performed. b. June = 67 total patients, 868 total hsTnI tests performed. c. July = 97 total patients, 364 total hsTnI tests performed. d. August = 83 total patients, 826 total hsTnI tests performed. e. September = 94 total patients, 853 total hsTnI tests performed. f. October =17 total patients, 280 total hsTnI tests performed. 8. The staff confirmed by interview on October 29, 2025, at approximately 10:45 a.m. that no performance specifications was established to support the use of QC materials beyond its expiration date. Thus, the quality and reliability of test results reported cannot be assured. 9. According to the testing declaration form (Lab-144) submitted at the time of survey, the laboratory performed approximately 11,568 patient test samples for hsTnI annually including the period when no performance specifications were established.
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. This STANDARD is not met as evidenced by: Based on the lack of policies and procedures, review of patient reports, quality assurance documentation, and interviews with staff, the laboratory is herein cited for failure to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specific to the use of control materials beyond its expiration date prior to patient testing. The findings include: 1. It was practice of the laboratory to perform high sensitivity Troponin-I (hsTnI) using Beckman Coulter Access2 instrument. 2. The laboratory failed to establish a policy and procedure specific to the usage of control materials beyond its expiration date. Instead, the laboratory had a signed quality variance/patient safety report (QVR) form dated 3/31/2025, indicating the permission usage of the expired control material. 3. The staff confirmed by an interview on October 29, 2025, at approximately 9:55 a.m. that the laboratory lacked a policy and procedure to support the use of expired quality control materials. 4. According to the testing declaration form (Lab-144) submitted at the time of survey, the laboratory performed approximately 11,568 patient test samples for hsTnI annually including the period when no policy and procedure was established.
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: D6000 Based on review of laboratory policies and procedures, patient test records, and interviews with laboratory staff, it was determined the laboratory director failed to provide overall management and direction of the laboratory. The findings include: 1. The laboratory director failed to ensure personnel were competent to perform test procedures, and record and report test results promptly, accurate, and proficiently (See D6004). 2. The laboratory director failed to ensure performance specifications were established and verified prior to reporting test results for high sensitivity Troponin-I when it used expired quality control materials (See D6013). 3. The laboratory director failed to ensure expired control materials were not used in reporting high sensitivity Troponin-I patient test results (See D6020). 4. The laboratory director failed to ensure personnel competency assessment records was performed only by a qualified technical consultant (See D6046). .
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 staff interviews, review of patient test records and competency assessment records, it was determined that the laboratory director failed to ensure personnel were competent to perform test procedures, and record and report test results promptly, accurate, and proficiently. The findings include: 1. One out of six assessment records reviewed was performed by an unqualified technical consultant under 493.1411 CLIA requirement (See D6046).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on staff interviews, review of laboratory policies and procedures, patient test records, and the absence of documentation showing performance specifications were established and verified for high sensitivity Troponin-I prior to reporting patient test

	results. The findings include: 1. The laboratory utilized Beckman Coulter Access2 instrument to test and report high sensitivity Troponin-I (hsTnI) patient test results. 2. The laboratory used expired control materials in reporting high sensitivity Troponin-I (hsTnI) patient test results but failed to establish performance specifications before reporting patient test results (See D5423).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on the surveyors' review of the laboratory's policies and procedures, quality control documentation, and interviews with the staff; it was determined that the laboratory director failed to ensure that quality control and quality assessment programs were established and maintained to assure the quality of laboratory services. The findings include: 1. The laboratory used expired quality control materials in reporting patient test results (See D5417). 2. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (See D5791).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of competency assessment records, patient test records, and interviews with laboratory staff, it was determined that the laboratory director failed to ensure that only qualified technical consultants (TCs) perform personnel competency assessments. The findings include: 1. The laboratory's current practice was for technical consultants to conduct competency assessments to all personnel involved in patient testing. 2. For one out of six assessment records reviewed, the competency assessment was performed by an unqualified TC under 493.1411, affecting Patient #225263049 tested on 9/20/2025. 3. A laboratory staff confirmed by interview on October 29, 2025 at approximately 2:05 p.m. that the competency assessment for one out of six records reviewed was performed by an unqualified TC. No corrective action was presented by the laboratory at the time of survey. 4. According to the testing declaration form (Lab-144) submitted on the day of the survey, the laboratory performed 11,568 patient test samples for hsTnI annually.