Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0895021	07/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Claremont Medical Center	995 W Foothill Blvd, Claremont, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory failed to successfully participate in a PT program approved by CMS for Total Cholesterol (Chol) which was certified under CLIA. The findings included: a. The laboratory failed to achieve satisfactory performance for the same analyte, Chol, in two out of two consecutive testing API PT events in the specialty of Routine Chemistry constituting unsuccessful PT performance. (See D-2096).

D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) test results reports, and interview with the testing personnel and the laboratory director, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used Mindray BS200 to perform Routine Chemistry including, but not limited to Glucose (Glu), Chloride (Chl), Sodium (NA), Total Iron (Iron), BUN, Total Protein (TP), Alk Phos, Triglyceride (TG), b. To ensure the accuracy of the Routine Chemistry testing, the laboratory enrolled its PT with API PT program. c. The laboratory failed to attain a score of at least 80 percent of acceptable responses for the following analyte listed in each PT testing event was unsatisfactory analyte performance for the testing event. Test/% = analyte/attained % score PT event Test/% Test/% Test/% Test/% Q1 2019 Na/60 Q1 2021 Glu/40 Iron/60 BUN/40 Alk Phos/0 Q2 2021 Chl/40 Na/40 TP./20 TG/60 d. The laboratory performed routine chemistry including test in approximately 25 patient sample weekly. e. The laboratory testing personnel affirmed (7/16/21 @ 12:15 PM) that the laboratory failed to attain scores of at least 80 percent of acceptable responses for each analyte in Q2 2021 PT events which were unsatisfactory analyte performance.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) test results reports, and interview with the testing personnel and the laboratory director, it was determined that the laboratory failed to achieve satisfactory performance for Total Cholesterol (Chol) in two consecutive PT testing events was unsuccessful performance. The findings included: a. The laboratory used Mindray BS200 to perform Routine Chemistry including, but not limited to Chol. b. To ensure the accuracy of the Routine Chemistry testing, the laboratory enrolled a CMS approved PT program with API. c. The laboratory attained scores of 60 % for Chol in both Q3 2020 and Q1 2021 PT events which was unsuccessful performance. d. The laboratory performed Routine Chemistry including Chol test in approximately 25 patient sample weekly. e. The laboratory personnel affirmed (7/16/21 @ 12:15 PM) that the laboratory attained scores of 60 % for Chol in both Q3 2020 and Q1 2021 PT events was unsuccessful performance.
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 review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) test results reports, and interview with the testing personnel and the laboratory director, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for hematology testing in each testing event was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used Horiba ABX Micro60 with 3-part differentials to perform CBC (Complete Blood Cell Count) including, but not limited to Hemoglobin (Hgb), and WBC with cell differentials (Cell). b. To ensure the accuracy of the CBC testing, the laboratory enrolled its PT program with API. c. The laboratory failed to attain a score of at least 80 percent of acceptable responses for the following analyte listed in each testing event was unsatisfactory analyte performance for the testing event. Test/% = analyte/attained % score PT event Test/% Test/% Q3 2020 Hgb/60 Cell/53 53% = Granulocyte 60%, Lymphocytes 60% Monocyte 40%) d. The laboratory had stopped performing CBC since January 2021.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 touring the facility and observation of the storage areas of the laboratory supplies, and interview with the laboratory testing personnel and the laboratory director it was determined that the Urine Drug Screen calibrators found in the refrigerator, they have exceeded their expiration date. The findings included: a. The laboratory performed Urine Drug Screen qualitatively using Thermo Fisher calibrators. b. The UDS calibrators with Lot # 73893546 for level I, II, and III were found in a refrigerator with expiration date on 3/31/2021, . c. The laboratory testing personnel affirmed (7/16/2021 @ 11:45 AM) that the UDS calibrators level I, II and III were expired on 3/31/2021.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's patient test results reports, interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory failed to include the report date and provide proper information in the patient test results reports. The findings included: a. To ensure the accuracy, reliability and timely, the patient test report must indicate and include but not limited to the followings: (1) The test report date. (2) The test performed. (3) The test result and, if applicable, the units of measurement or interpretation, or both. b. Review of the laboratory's patient test result reports found that the laboratory failed to include the report date in the report. c. A test name of TSH3 is improperly used to represent a test name of TSH, Thyroid Stimulating Hormone. d. The unit of measurement for a test of TSH was "uLu/ML", instead of uIU/mL (where "u" is micro, IU is international Unit). e. The laboratory testing personnel affirmed (7/16/2021 @ noon) that the laboratory's patient test result reports missing the report date and having inaccurate test name of TSH with its measurement unit.
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: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D-6016 and D-2016)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) test results reports, and interview with the testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required. The findings included: a. The laboratory used Mindray BS200 to perform Routine Chemistry including, but not limited to Chol. b. To ensure the accuracy of the Routine Chemistry testing, the laboratory enrolled a CMS approved PT program with API. c. The laboratory attained scores of 60 % for Chol in both Q3 2020 and Q1 2021 PT events which was unsuccessful performance see D-2096.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6)

	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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on touring and observation of the facility, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) test results reports, review of the patient test result reports, and interview with the testing personnel and the laboratory director, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory used Mindray BS200 to perform Routine Chemistry and Horiba ABX Micro 60 to perform hematology testing. b. To ensure the accuracy of the Routine Chemistry testing, the laboratory enrolled a CMS approved PT program with API for Routine Chemistry and Hematology testing systems. c. The laboratory failed to attain at least 80 percent of acceptable responses for each analyte in each testing event was unsatisfactory analyte performance for the testing event, see D-2087, and D-2121. d. The laboratory failed to achieve satisfactory performance for the same analyte in two consecutive testing events consecutive testing events was unsuccessful performance, see D-2096 e. The laboratory was found to use expired UDS calibrators, See D-5417 f. The laboratory's patient test result reports did not include the information required by CLIA's rules and regulations, see D-5805