Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0895021	11/02/2018
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
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 proficiency testing (PT) result reports, and interview with the technical consultant (TC) and the testing personnel (TP), 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 performed and reported routine chemistry including, but are not limited to the following: Alk Phos, AST, Na, CA, for its patient test result reports.. b. The laboratory enrolled its PT with American Proficiency Institute (API) to evaluate to ensure the ace proficiency testing performance to ensure the curacy of the testing systems. c. The laboratory attained a score of 60 % for analyte of Alk Phos in the 1st 2017 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory attained scores of 60 % for analyte of AST and Na in the 3rd 2017 PT event which were unsatisfactory analyte performance for the testing event. e. The laboratory attained scores of 40 % for analyte of CA in the 3rd 2017 PT event which was unsatisfactory analyte performance for the testing event. f. The laboratory performed the analyte mentioned above in approximately 82 patient samples monthly for each analyte. g. The laboratory affirmed (11/2/18 @ 11:35) that the laboratory failed to attain a score of at least 80 percent of acceptable responses for those analyte mentioned above in each testing event were unsatisfactory analyte performance for the testing event.
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 proficiency testing (PT) result reports, and interview with the technical consultant (TC) and the testing personnel (TP), 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 ABX Micro 60, a hematology analyzer, and performed hematology and reported results including, but is not limited to the following: Hematocrit (Hct), for its patient samples. b. The laboratory enrolled its PT with American Proficiency Institute (API) to evaluate the proficiency testing performance and to ensure the accuracy of the testing systems. c. The laboratory attained a score of 60 % for analyte of Hct in the 2nd 2018 PT event which was unsatisfactory analyte performance for the testing event. d. The laboratory performed the analyte Hct in approximately 340 patient samples monthly g. The laboratory affirmed (11/2/18 @ 11:35) that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Hct the 2nd 2018 PT event was unsatisfactory analyte performance for the testing event.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory documents and records, and interview with the technical consultant (TC), and the testing personnel (TP), it was determined that the laboratory failed to retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. The findings included: a. The laboratory failed to retain the manufacturer's inserts and/or the assay quality control target values inserts for at least two years. b. At the time of the survey (11/2/18 @ 13:15), the laboratory failed to provide manufacturer's insert to verify the current assay quality control target data for the period of time the laboratory. c. Where the laboratory can provide the inserts, the laboratory failed to date and retain the manufacturer's instructions of test system performance specifications for at least two years.
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 of the storage areas, interview with the testing personnel (TP), it was determined that the laboratory failed to label and date when the reagents and the expiration date once the reagents opened . The findings included: a. Observed the refrigerator reagent storage areas and noted that the routine chemistry reagent bottles in use were not labeled and dated for expiration date when opened . b. The reagent bottles in use inside the instrument reagent carousel were not labeled with date. c. The TP affirmed (11/2/18 @ 13:50) that the laboratory failed to label and date the reagent once it opened to indicate the expiration date.
D5419	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the reagent storage areas and the instrument, interview with the testing personnel (TP), it was determined that the laboratory failed to follow the manufacture's instructions that the reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer. The findings included: a. Interview with the TP, the laboratory bought bulk reagents and refill the reagent bottles in the instrument chamber when the reagents in use is low. b. Observed the routine chemistry analyzer, Mindray BS200, the reagent bottle barcode with a lot number of D. Bili (direct Bilirubin) R2 (lot #701602-032) in use was different from the one lot in stock in the refrigerator (lot # 701602-026) when the TP refill the bottle.. c. The TP mixed D. Bili (R2) reagent lot 701602-032 with 701602-026 to its reagent bottle in the instrument chambers, d. The TP affirmed (11/2/18 @ 13:45) that the laboratory mixed different lot of D. Bili (R2) reagent.
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 review of the laboratory quality control documents and interview with the technical consultant (TC), and the testing personnel (TP), it was determined that the laboratory failed to update and follow the written quality control policy to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance and monitor over time the accuracy and precision of test performance that may be influenced by changes in test system. The findings included: a. Based on interview with the TP, when the QC out of the

	acceptable ranges, the TP first would repeat the failed QC sample once more and go further, if failed again. b. No repeated noted for the day a QC indicated that the QC run on 01/15/18 @07:44, a normal QC level result of RBC (lot # MX 409 Expiry of 03 /05/18) was 4.45 L, which was out of the acceptable range between 4.54 and 4.90. c. Review of the laboratory's written "QUALITY CONTROL DECISIONS" procedure, with subtitle of "USING A TWO OR THREE CONTROL SYSTEM", no written procedures or instruction to instruct the TP what to do when the QC out in the first run. d. The verbiage in the "ACCEPT RUN IF:" on the third paragraph of "QUALITY CONTROL DECISIONS" , "the laboratory MUST ONLY RUN 2 LEVELS of controls,..." not consistent with the laboratory daily operations, for hematology the laboratory regularly performs "three levels" control material, namely. Abn low, Norm, and Abn Hi. e. The TC affirmed (11/2/18 @ 12:35) that the QC policies and procedures need to be updated and revised.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory instrument print-out documents and the final patient test result reports, and interview with the technical consultant (TC), the testing personnel (TP), it was determined that the laboratory failed to ensure the patient test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. The findings included: a. The laboratory failed to ensure the patient test results and patient-specific data electronically reported to network or interfaced systems. b. Review of the patient test result reports and its instrument print-out data, the laboratory's patient tests final reports provided inconsistent between sample collection date and reported date. c. A patient ID #7299, the instrument print-out sheet indicated a collected (draw) date of 10/18/2018 , while the final report indicated a report date of 10/17/18. c. The collected date was one day AFTER the patient final test results reported date. d. The laboratory used Medcom, an LIS (laboratory information system) to generate their patient final test results. e. The laboratory was aware of the problems and notified the LIS vendor long ago, but failed to correct it. f. The laboratory affirmed (11/2/18 @ 13: 45) that the laboratory failed to correct the LIS system.
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 observation of the facility and laboratory operations, the laboratory documents, and interview with the technical consultant (TC) and the testing personnel (TP), it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory to assure compliance with the applicable regulations. The findings included: See D-6016, D-6020, and D-6021
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 proficiency testing (PT) result reports, and interview with the technical consultant (TC) and the testing personnel (TP), it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2087 and D-2121
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) documents, and interview with the technical consultant (TC), the testing personnel (TP) and the owner, it was determined that the laboratory director failed to ensure that the quality control program was established, revised and maintained to assure the quality of laboratory services provided. The findings included: See D-3033, D-5415, D-5419, and D-5441
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory documents, and interview with the technical consultant, the testing personnel and the owner, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: See D-5801