Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2011390	04/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Healthy Care Clinical Laboratory Inc	4650 Arrow Hwy, Ste B3, Montclair, 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	
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 surveyor review of the AAB proficiency testing evaluation report for 2022, 2023 and 2024 and interview with the laboratory technical supervisor on 04/05/2024 at 12:00PM, the laboratory failed to attain a score of at least 80 percent of acceptable responses for HDL in the second event of 2023. The finding include: 1) The laboratory performed routine chemistry testing using Olympus AU640 Chemistry Analyzer. The laboratory participated in the AAB proficiency testing program in 2022, 2023 and 2024. The laboratory attained a score of 20 percent for HDL in the 2nd event of 2023, which was unsatisfactory for the testing event. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 04/05/2024 at 12:00 PM, the laboratory technical supervisor confirmed the laboratory attained a score of 20 percent for HDL in the 2nd event of 2023 which was unsatisfactory analyte performance for the testing event. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/27/2024 stated that the laboratory performed 26,000 tests in routine chemistry, annually.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a

	proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on surveyor review of the AAB proficiency testing evaluation report and interview with the laboratory technical supervisor on 04/05/2024 at 12:00PM, the laboratory failed to take remedial action for unacceptable analytes. The finding include: 1) The laboratory performed routine chemistry testing using Olympus AU640 Chemistry Analyzer. The laboratory participated in the AAB proficiency testing program in 2022, 2023 and 2024. The laboratory attained a score of 80 percent for Albumin and ALT in the second event of 2022 and a score of 80 percent for glucose in the second event of 2023, both of which were unacceptable for the analytes in the proficiency testing event. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 04/05/2024 at 12:00 PM, the laboratory technical supervisor confirmed that the laboratory did not take remedial action for unacceptable analytes. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/27/2024 stated that the laboratory performed 26,000 tests in routine chemistry, annually.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's testing records and interview with the laboratory technical supervisor on 04/05/2024 at 12:00PM, the laboratory failed to retain documentation for analytic system activities for routine chemistry. The finding include: 1) The laboratory performed routine chemistry testing using Olympus AU640 Chemistry Analyzer. Laboratory did not retain instrument records for chemistry tests prior to June 16, 2923. Therefore, the accuracy of the chemistry test results rendered by the laboratory cannot be assured and might have harmed patients. 2) On 04/05 /2024 at 12:00 PM, the laboratory technical supervisor confirmed that the laboratory did not retain the data for Olympus AU640 Chemistry Analyzer. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/27/2024 stated that the laboratory performed 26,000 tests in routine chemistry, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and

	493.1487 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 report and interview with the laboratory technical supervisor on 04/05/2024 at 12:00PM, the laboratory director failed to ensure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D3031 and D2087.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of the proficiency testing evaluation report and interview with the laboratory technical supervisor on 04/05/2024 at 12:00PM, the laboratory director failed to ensure laboratory's compliance with the applicable regulations and potentially harmed patients. The finding include: See D6029.