Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2011390	10/03/2018
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation and review of the temperature charts and interview with the testing personnel, it was determined that the laboratory failed to monitor acceptable temperature for those conditions that is essential for proper storage of reagents and specimens, accurate and reliable test system operation, and failed to familiarize the features and the functions of a digital thermometer. The findings included: a. The laboratory established its freezer acceptable temperature range between -25 o C and -15 o C. b. Observed a digital thermometer for Freezer #1, and verified with the temperature records for May 1, 2018 thru Oct. 3, 2018. c. There were -14 o C recorded and noted on the following dates: on 5/3/18, 5/25/18, 5/26/18, 5/30/18, 7/7 /18 between May 1 and Oct. 2, 2018,. d. The laboratory used a digital thermometer which features two Mode:: "Min" & "Max" plus "Lo" and "Hi", in addition to the current temperature and alarm on/off. e. "Min" and "Max" represent the lowest temperature and highest temperature were reached, respectively, in the past, but don't know exact when. f. "Lo" and "Hi" represent the laboratory's setting for the acceptable temperature range of the storage conditions. g. At the time of the survey (10/3/2018 @ 12:15 PM), a "Max" of -5 o C was noted in the digital thermometer for the Freezer #1 which was out for the acceptable temperature of -25 o C to -15 o C sometime in the past. h. When checked the Mode of "Lo" and "Hi" setting, the "Lo" was 10 o C while

	"Hi" was at 30 o C, which were inconsistent with the laboratory establishment for freezer acceptable temperature range of -25 o C to -15 o C.. i. The laboratory failed to familiarize how the digital thermometer works, and document the remedial actions when the temperature were not acceptable. j. The laboratory turned off the alarm, so that the alarm does not go off.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's records, and interview with the testing personnel, it was determined that the laboratory failed to document all corrective actions taken, including actions taken when equipment that perform outside of established operating parameters or performance specifications. The findings included: See D-5413
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 patient test result reports, and interview with the testing personnel, it was determined that the laboratory failed to indicate the test result and, if applicable, the units of measurement or interpretation, or both, The findings included: a. The laboratory performed serum PSA for its patient samples. b. The patient test reports failed to indicate the specific reagents or methodology, the laboratory used to report the results..
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 observation, review of the laboratory records, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. The findings included: See D-5413 and D-5805
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 observation, review of the laboratory records, and interview with the testing personnel, 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-5781