Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D2011390	**(X3) Date Survey Completed** 07/14/2021
Name of Provider or Supplier Healthy Care Clinical Laboratory Inc	**Street Address, City, State** 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**
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 Surveyor review of laboratory's policy & procedure, and proficiency testing (PT) records, and interview with the laboratory technical supervisor on July 14, 2021 at 11:30 am, the laboratory failed to successfully participate in the proficiency testing program for the analyte, TRIGL. The findings include: 1. The laboratory participated in the American Association of Bioanalysts (AAB) PT testing program for the analyte TRIGL at the 1st and 2nd events in 2021. However, it received an unsatisfactory score of 40 and 0 at the 1st and 2nd events, correspondingly, resulted in an unsuccessful PT participation. Therefore, the accuracy of the patients' TRIGL test results rendered by the laboratory during that time period can not be assured. 2. The laboratory technical

	supervisor on July 14, 2021 at 11:30 am, affirmed that the laboratory did not receive a satisfactory score for the analyte TRIGL at the 1st and 2nd events of PT in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/11 /2021, stated that the laboratory performs approximately 1,200 TRIGL tests, annually.
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 Surveyor review of laboratory's policy & procedure, and proficiency testing (PT) records, and interview with the laboratory technical supervisor on July 14, 2021 at 11:30 am, the laboratory failed to achieve satisfactory performance for the analyte TRIGL in two consecutive testing events. The findings include: 1. The laboratory participated in the American Association of Bioanalysts (AAB) PT testing program for the analyte TRIGL at the 1st and 2nd events in 2021. However, it received an unsatisfactory score of 40 and 0 at the 1st and 2nd events, correspondingly, resulted in an unsuccessful PT performance. Therefore, the accuracy of the patients' TRIGL test results rendered by the laboratory during that time period can not be assured. 2. The laboratory technical supervisor on July 14, 2021 at 11:30 am, affirmed that the laboratory did not receive a satisfactory score for the analyte TRIGL at the 1st and 2nd events of PT in 2021. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/11/2021, stated that the laboratory performs approximately 1,200 TRIGL tests, annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, automated complete blood count (CBC) test verification records, and interview with the laboratory technical supervisor on July 14, 2021 at 2:30 pm, the laboratory failed to verify its test accuracy for basophils, monocytes and mean corpuscular hemoglobin concentration (MCHC). The findings include: 1. The laboratory replaced its old, automated Cell-Dyn CBC instrument with automated Sysmex CBC instrument. It did a test verification on the new, Sysmex instrument by running some samples on both old and new instruments and comparing the results by linear regression using an r value. The results of r values were as follows: Monocytes r=0.42, Basophils r=0.17 and MCHC r=0.52. These low r values showed very poor correlation between 2 instruments. However, the laboratory had accepted this verification data and started patient testing.

	Therefore, the accuracy of the rendered patient test results with the new instrument can not be assured. 2. The laboratory technical supervisor on July 14, 2021 at 2:30 pm, affirmed that the laboratory's test verification was not adequate. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/11/2021, stated that the laboratory performs approximately 16,140 CBC tests, annually.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality control (QC) records, and interview with the laboratory technical supervisor on July 14, 2021 at 12:15 pm, the laboratory failed to update its COVID-19 PCR test limitations to its clients. The findings include: 1. The laboratory performs COVID-19 PCR test by using Azure Seq one-step RT-qPCR kit. The kit manufacturer confirmed that their method does not detect the delta variant of the SARS-COV-2 virus. While there was a surge of the delta variant infection in the community. Therefore, the "not detected" results provided by the laboratory to the patients including specimen # 00179643 might had been positive for the delta variant, and the patients might had misdiagnosed. 2. The laboratory technical supervisor on July 14, 2021 at 12:15 pm, affirmed that the laboratory did not inform the client of the test limitations or put any disclaimer on the test report. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/11/2021, stated that the laboratory performs approximately 51,000 SARS-COV-2 tests, annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC), verification of test accuracy records, and interview with the laboratory technical supervisor during an onsite survey of the laboratory on July 14, 2021, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing high complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to assure compliance with the applicable regulations. (See

	D6079) 2. The laboratory director failed to ensure that the verification procedures used are adequate to determine the accuracy. (See D6086) 3. The laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. (See D6098) 4. The laboratory director failed to ensure that PT samples were tested as required under Subpart H of this Part. (See D6089)
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's policy & procedure, random patient sample, quality control (QC) and verification of test accuracy records, and interview with the laboratory technical supervisor and personnel on July 14, 2021 at 2:30 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations. The findings include: See D2016, D2096, D5421 and D5809.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, and test accuracy verification records, and interview with the laboratory technical supervisor on July 14, 2021 at 2:30 pm, the laboratory failed to verify the test accuracy adequately. The findings include: See D5421
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, and proficiency testing (PT) records, and interview with the laboratory technical supervisor on July 14, 2021 at 11:30 am, it was determined that the laboratory director, high complexity testing,

	failed to ensure that PT samples were tested as required under subpart H. of this part. The findings include: For the analyte, TRIGL, the laboratory repeatedly failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive testing events, resulting in unsuccessful PT performance. (See D2016 and D2096).
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality control records, and interview with the laboratory technical supervisor on July 14, 2021 at 12:15 pm, the laboratory failed to update its COVID-19 PCR test limitations to its clients. The findings include: See D5809.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, and automated complete blood count (CBC) test verification records, and interview with the laboratory technical supervisor on July 14, 2021 at 2:30 pm, the laboratory technical supervisor failed to verify test accuracy for basophils, monocytes and mean corpuscular hemoglobin concentration (MCHC). The findings include: See D5421.