Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0930808	08/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Crestview Clinical Laboratory, Llc	5 Holland, Ste 209, Irvine, 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
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 review of test result reports requested and interview with the laboratory director (LD) and laboratory personnel (LP); it was determined that the laboratory failed to retrieve quality control (QC) failed- retesting results and instruments printouts for patients testing. The findings included: 1. The laboratory maintained digital electronic records only. 2. At the time of the survey on August 6, 2024, at approximately 1:30 p.m. the LP failed to retrieve QC failed - retesting and instrument printouts records for three (3) out of fourteen (14) randomly selected patients records requested for review. 3. The LP affirmed that QC failed - retesting and instrument printouts records for September 9, 2022 (two patients testing records) and January 27, 2023 (one patient testing records) were not retrievable at the time of the survey. 4. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 1,200 tests annually for which the laboratory was unable to retrieve QC failed - retesting documentation and instrument printouts records from the Quant Studio analyzer.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures and interview with the laboratory director (LD) it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. The findings included: 1. Based on the lack of a quality assurance plan and interview with the LD on the day of survey on August 6, 2024, at approximately 1:30 p.m., no documentation could be retrieved to show that the laboratory had established and performed quality assessment and assurance. 2. The LD affirmed by interview that the laboratory did not have any documentation of written policies and procedures reflecting the current practice for an ongoing mechanism to monitor and assess records identified in the general laboratory systems. 3. According to the testing declaration signed and dated by the LD submitted on August 6, 2024, the laboratory performed 1,200 tests annually.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyors' review of the laboratory's policies and procedures, test requisitions, and interview with the laboratory director, and laboratory personnel; it was determined that the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as speciefied in 493.1249. for each specialty and subspecialty of testing performed. See D 5311 and D5391.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of randomly selected patients' sampling test orders and interviews with the laboratory director (LD) and laboratory personnel (LP) on August 6, 2024 at approximately 3:00 p.m., it was determined that the laboratory failed to have written or electronic requests for patient testing from an authorized person. The findings included: 1. On the day of the survey August 6, 2024, the laboratory failed to provide a complete list of authorized submitters. 2. In 2021 the laboratory accepted 3,561 tests requests from Community Wellness of America from a non-authorized person (non-MD). 3. From 3,561 accepted test requests from Community Wellness of America from a non-authorized person, the laboratory rejected 232 patients' specimens for reasons other than being submitted from a non-authorized person. 4. The laboratory

	tested and reported 3,321 SARS-CoV-2 test results from Community Wellness of America from a non-authorized test requestor. 5. The LD and LP confirmed that the laboratory had processed and reported test results from a non-authorized submitter.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the surveyors' review of the preanalytical policy and procedures and interview with the laboratory director (LD) and laboratory personnel (LP) on 08/06 /2024 at approximately 2:00 pm, the laboratory failed to follow written policy and procedure for specimen acceptability and rejection criteria. The findings included: 1. The laboratory performed SARS-CoV-2 (Covid19) and the Multiplex (Covid19, Influenza A&B, and RSV) detection tests on patient specimens by Real Time Polymerase Chain Reaction (Rt-PCR) using the QuantStudio analyzer. 2. The LD and LP confirmed that the laboratory failed to follow written policies and procedures for patient Covid19 and Multiplex Rt-PCR tests for acceptance and rejection policy in regard to requisition validity. 3. According to the LD and LP, the laboratory begun testing for Covid19 on September 20, 2021, and Multiplex testing was performed in 2023 until April 30, 2024, without establishing and following policies for specimen acceptability and rejection as stated in 2.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on the surveyors' review of the laboratory's policies & procedures, patients' test records, and interview with the laboratory director (LD) and laboratory personnel (LP); the laboratory failed to establish and follow written policies and procedure to assess quality of its preanalytical systems. The findings include: 1. The laboratory did not have a system in place to identify problems in the preanalytical system such as test request and sample rejection. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification, immediate resolution of the problem, and development of policies that will prevent its reoccurrence. 2. The LD and LP on the day of the survey at approximately 2:30 p.m., affirmed that the laboratory did not establish and follow preanalytic systems quality assessment policies and procedures. 3. The laboratory's testing declaration form, signed by the laboratory director on 8/6 /2024 stated that the laboratory performed approximately 1,200 tests annually.

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 surveyor's review of laboratory's corrective actions records for quality control (QC) failures and retesting, fourteen (14) randomly selected patient records, and interview with the laboratory director (LD) and laboratory personnel (LP) on August 6, 2024, a.m., the laboratory failed to document corrective action taken when the QC perfumed was out of range and testing fails. The findings include: 1. Review of 14 randomly chosen SARS-CoV-2 (Covid-19) and multiplex (Covid-19, Influenza A&B, and respiratory syncytial virus) test records results ranging from 12/24/2020 to 2/3/2023; the laboratory QC failed on 09/09/2022 in the Quant Studio #5 and on January 27, 2023, in the Quant-Studio #6 instrument. Retesting may have been performed; however, no records of any corrective action documentation was available. Therefore, the accuracy of the patients' Covid-19 and multiplex results performed on the above two dates cannot be affirmed. 2. The LP confirmed that the laboratory did not document any corrective actions taken after QC failed. 3. The LD declared by interview on the day of the survey 8/6/2024 that the laboratory processed and reported on 9/9/2022 the total of 446 Covid-19 samples of which four (4) samples were reported positive and on 1/27/203 nineteen (19) multiplex samples all reported negative for which QC failure corrective action was not documented.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on the lack of laboratory's policies, review of randomly selected patient test records, and interview with the laboratory director (LD); it was determined that the laboratory failed to have a policy for turn-around time (TAT) for all tests performed in the laboratory. 1. The laboratory failed to provide TAT of testing for fourteen (14) out of fourteen (14) randomly selected patients at the time of the survey (August 6, 2024). The laboratory did not provide a TAT policy which may adversely impact patient management. 2. The laboratory LD on August 6, 2024, at approximately 1:00 p.m. affirmed that the laboratory did not have a TAT policy to notify any delay on testing to the physician. 3. The laboratory's testing declaration form, signed by the laboratory director on August 6, 2024, stated that the laboratory performs 1,200 Virology tests annually for which a TAT policy was not available.

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 the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing: Laboratory Director was not met. The laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored (see D6082); quality control programs were established and maintained to assure the quality of laboratory services and to identify failures in quality as they occur (see D6093); quality assessment programs were established and maintained (see D6094); and the establishment and maintenance of acceptable level of analytical performance for each test system. (see D6103).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyors' review of policies and procedures, fourteen (14) randomly chosen patients' test results and interviews with the laboratory personnel on August 6, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D3031, D5291, D5301, D5311, D5391, D5781, D5815.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of random patient testing records, quality control data, and interviews with the laboratory director and laboratory personnel; it was determined that the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify and correct failures in quality control as they occur. See D5781.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)

	The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the surveyors' team review of laboratory's policies and procedures, lack of quality assessment policy and records, and interview with the laboratory director and laboratory personnel on August 6, 2024, the laboratory director failed to ensure that the laboratory maintained and documented quality assessment activities. The findings include See D5391.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must 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 review of the laboratory's policies and procedures, unable to retrieve QC records of failed runs where acceptable QC run was performed before patient testing and reporting and patient PCR test run documentation and interview with the laboratory director, and laboratory perdonnel; it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance. See D5291 and D5781