Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2251969	03/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Covid Clinic, Inc	12000 Se 82nd Ave, Happy Valley, OR	

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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: Based on physical inspection of the COVID Clinic temporary testing site in Happy Valley, OR, the Laboratory failed to post the correct CLIA certificate. Findings include: 1. During physical/visual on site inspection of the laboratory testing site located in the parking lot at 12000 SE 82nd Avenue in Happy Valley, OR, the facility failed to display the correct CLIA certificate for this site. 2. The CLIA certificate displayed in the testing area is for this COVID Clinic is the certificate for the site located in Tigard, OR at Washington Square Mall. 38D2205598 3. During interview with testing personnel (TP) #1 on 3/23/2022 at approximately 1230 pm, she said did not know anything about the certificates and that there was no other certificate that she was aware of.
D1001	CERTIFICATE OF WAIVER TESTS

CFR(s): 493.15(e)

Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

This STANDARD is not met as evidenced by:
Based on review of written laboratory records and interview with Testing Personnel (TP) during survey 03/23/2022, the laboratory failed to follow the manufacturer's instructions for performing COVID testing. Findings include: 1. The COVID Clinic testing site under investigation in this complaint is located at 12000 SE 82nd Ave. Suite 1093, Happy Valley (Portland), OR 97266 2. The Instructions for use (IFU) using the Accula rapid PCR test state "Testing site personnel must provide a physical or digital copy of the Self-Collection Quick Reference Guide to the patient prior to collection". No written or digital copy of the Self Collection Quick guide is/was given to patients prior to collection. This was confirmed during interview with testing personnel (TP) #1 at approximately 1130 am on 03/23/2022. 3. The IFU for the Accula rapid PCR test system states "Store reagents at room temperature (15C to 30C or 59F to 86F). Do not refrigerate or freeze". Upon review of the temperature charts for storage of reagents and testing supplies at this location for February and March 2022 revealed that the temperature was out of acceptable range (lower than 59 degrees F or 15 degrees C) five (5) out of ten (10) days in February 2022 and eight (8) out of seventeen (17) days in March of 2022. The temperature logs were approved as acceptable by a Site Supervisor 03/15/2022 with no corrective action or acknowledgement of temperature outliers. 4. The IFU for the Accula rapid PCR test states "The Accula SARS-CoV-2 Test is intended for use by trained operators who are proficient in performing tests on the Accula Dock and Silaris Dock". During survey written record review, two (2) TP performing the Accula rapid PCR test for COVID 19 had no training records available for review and signed off by an authorized person. 5. The IFU for the Abbott ID NOW states "The ID NOW COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument". During written survey record review, two (2) TP performing the Abbott ID NOW test for COVID 19 had no training records available for review and signed off by an authorized person. 6. The Indicaid rapid Antigen testing kit IFU states on page six (6): Materials Required but not Provided Timer External Positive and Negative Controls (sold separately) - P/N: 2110410/2110420 250 L single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives) 250 L single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives). During interview with testing personnel (TP) at approximately 1130 am, TP#1 said she was unaware of external controls being required for this assay nor had she ever performed external Quality Control (QC) for this test system. 7. The Indicaid IFU on page seven (7) states: "Positive and negative controls should be run once with every new lot, shipment, and each new user, using the test procedure provided in this Instructions for Use". The laboratory could not provide Indicaid untrained operator QC from 2/16/2022 - 3/22/2022. During interview with TP #1 and TP#2 at approximately 12:00 pm, admitted they had never performed any external QC for the Indicaid testing system since testing began at this site 02/16/2022. 8. All three test systems in place as of survey date 3/23/2022 state that it is the responsibility of the laboratory to report COVID test results to the Public Health Authority. During survey, this surveyor counted eighty one (81) patients tested for COVID using the test systems mentioned above for test dates 02/16/2022 - 03/23/2022. Oregon Health

	Authority Electronic Laboratory Reporting Coordinator reports only sixty four (64) COVID patient test results have been reported to OHA as of survey date. 9. Upon inspection of reagents and collection test kits during survey, the laboratory was found to have four (4) cases or a total of two hundred plus (200+) tubes of Bartels viral transport media that were outdated as of 02/10/2022. Further investigation revealed that this media was received by this laboratory a day after expiration, which was 02/11 /2022, but still put into use. The pre-assembled collection kits using this media for COVID testing sent out of state and kept in an Igloo at room temperature, not chilled, were also expired and of the same lot number FT0012B. 10. The temperature gauge on the Bartels viral transport media says store at 2 - 8 degrees Celcius. The four (4) cases of transport media and the media in the pre-assembled collection kits were all stored at room temperature. Upon interview with TP #1, she stated that they do not have a refrigerator to store any testing supplies. The one small refrigerator in the 5th wheel used as a testing site is used by TP for food storage.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of written laboratory records, manufacturer's instructions, Quality Control records, temperature logs, patient test results and interview with testing personnel #1 and #2, the laboratory is performing testing in a manner that constitutes an imminent and serious risk to public health as specified in standard 493.1775. see D8201
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on review of written laboratory records, manufacturer's instructions, Quality Control records, temperature logs, patient test results and interview with testing personnel #1 and #2, the laboratory is performing testing in a manner that constitutes an imminent and serious risk to public health. Findings include: 1. The COVID Clinic testing site under investigation in this complaint is located at 12000 SE 82nd Ave. Suite 1093, Happy Valley, OR 2. The Instructions for use (IFU) using the Accula rapid PCR test state "Testing site personnel must provide a physical or digital copy of

the Self-Collection Quick Reference Guide to the patient prior to collection". No written or digital copy of the Self Collection Quick guide is/was given to patients prior to collection. This was confirmed during interview with testing personnel (TP) #1 at approximately 1130 am on 03/23/2022. 3. The IFU for the Accula rapid PCR test system states "Store reagents at room temperature (15C to 30C or 59F to 86F). Do not refrigerate or freeze". Upon review of the temperature charts for storage of reagents and testing supplies at this location for February and March 2022 revealed that the temperature was out of acceptable range (lower than 59 degrees F or 15 degrees C) five (5) out of ten (10) days in February 2022 and eight (8) out of seventeen (17) days in March of 2022. The temperature logs were approved as acceptable by a Site Supervisor 03/15/2022 with no corrective action or acknowledgement of temperature outliers. 4. The IFU for the Accula rapid PCR test states "The Accula SARS-CoV-2 Test is intended for use by trained operators who are proficient in performing tests on the Accula Dock and Silaris Dock". During survey written record review, two (2) TP performing the Accula rapid PCR test for COVID 19 had no training records available for review and signed off by an authorized person. 5. The IFU for the Abbott ID NOW states "The ID NOW COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument". During written survey record review, two (2) TP performing the Abbott ID NOW test for COVID 19 had no training records available for review and signed off by an authorized person. 6. The Indicaid rapid Antigen testing kit IFU states on page six (6): Materials Required but not Provided Timer External Positive and Negative Controls (sold separately) - P/N: 2110410/2110420 250 L single-use COVID-19 Antigen Positive Control Vials (non-infectious recombinant SARS-CoV-2 antigen in buffered solution with preservatives) 250 L single-use COVID-19 Antigen Negative Control Vials (buffered solution with preservatives). During interview with testing personnel (TP) at approximately 1130 am, TP#1 said she was unaware of external controls being required for this assay nor had she ever performed external Quality Control (QC) for this test system. 7. The Indicaid IFU on page seven (7) states: "Positive and negative controls should be run once with every new lot, shipment, and each new user, using the test procedure provided in this Instructions for Use". During interview with TP #1 and TP#2 at approximately 12:00 pm, admitted they had never performed any external QC for the Indicaid testing system since testing began at this site 02/16/2022. The laboratory could not provide Indicaid untrained operator QC from 2/16/2022 - 3/22/2022. 8. All three test systems in place as of survey date 3/23/2022 state that it is the responsibility of the laboratory to report COVID test results to the Public Health Authority. During survey, this surveyor counted eighty one (81) patients tested for COVID using the test systems mentioned above for test dates 02/16/2022 - 03/23/2022. Oregon Health Authority Electronic Laboratory Reporting Coordinator reports only sixty four (64) COVID patient test results have been reported to OHA as of survey date. 9. Upon inspection of reagents and collection test kits during survey, the laboratory was found to have four (4) cases or a total of two hundred plus (200+) tubes of Bartels viral transport media that were outdated as of 02/10/2022. Further investigation revealed that this media was received by this laboratory a day after expiration, which was 02/11 /2022, but still put into use for patient testing. The pre-assembled COVID collection kits using this media for COVID testing sent out of state and kept in an Igloo at room temperature, not chilled, were also expired and of the same lot number FT0012B. 10. The temperature gauge on the Bartels viral transport media says store at 2 - 8 degrees Celcius. The four (4) cases of transport media and the media in the pre-assembled collection kits were all store at room temperature. Upon interview with TP #1, she stated that they do not have a refrigerator to store any testing supplies. The one small refrigerator in the 5th wheel used as a testing site is used by TP for food storage.