

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2205686	(X3) Date Survey Completed 01/12/2022
Name of Provider or Supplier Covid Clinic, Inc	Street Address, City, State 293 Valley River Center, Eugene, 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
D0000	A special survey of the Curative Lab Eugene, located at 293 Valley River Center in Eugene, OR was performed on 01/12/ 2022. The Laboratory was found to be in substantial compliance with the CLIA Condition-level regulation (42 CFR, Part 493.41) pertaining to COVID-19 reporting requirements. No deficiencies were cited.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of written laboratory records and discussion with the Site Supervisor during survey 01/12/2022, 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 293 Valley River Drive in Eugene, OR 97401 Oregon CLIA # 38D2205686 2.. The Instructions for use (IFU) using the Accula SARS CoV-2 PCR test state "Firmly rotate the swab against the nasal wall ten (10) times. Using the same swab, repeat this sampling procedure in the other nostril". For patient self collection, as of January 27, 2022, the COVID Clinic website patients use to register for testing states "COVID Clinic's nasal swab tests are used to detect the presence COVID-19. The tip of a cotton swab is inserted into one nostril. The swab is rotated in a circle around the entire inside edge of the nostril at least three times", which is in conflict with the Accula IFU. 3. The Instructions for use (IFU) using the Accula SARS CoV-2 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 the Site Supervisor at approximately 11:00 am on 1/12/2022. 4. The IFU for the</p>

Accula 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 December 2021 and January 2022 revealed that the temperature was out of acceptable range (lower than 59 degrees F or 15 degrees C) thirteen (13) out of thirty one (31) days in December 2021 and seventeen (17) days out of thirty one (31) days in January 2022. 5. As of January 27, 2022, The COVID Clinic website patients use to register for testing states "COVID Clinic's nasal swab tests are used to detect the presence COVID-19. The tip of a cotton swab is inserted into one nostril. The swab is rotated in a circle around the entire inside edge of the nostril at least three times", which is in conflict with the Abbott ID NOW IFU. The IFU for the Abbott ID NOW test system says "To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril". 6. 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) of three (3) testing personnel (TP) performing the Abbott ID NOW test for COVID 19 have no training records signed off by an authorized person. 7. 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) of three (3) TP performing the Accula PCR test for COVID 19 have no training records signed off by an authorized person. 8. The Indicaid IFU states: The INDICAID (Trademark) COVID-19 Rapid Antigen Test is intended for use by trained clinical laboratory personnel and medical and healthcare personnel in Point of Care (POC) settings". During survey written record review, one (1) of three (3) TP performing patient testing using the Indicaid COVID-19 Rapid Antigen test system had no records of training for this test system during survey 1/12/2022. 9. The Indicaid rapid antigen IFU states: "Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing". As of 1/12/2022, the Oregon Health Authority (OHA)/CLIA Compliance had not been informed of the intent to test with the Phase Indicaid rapid antigen test at any COVID Clinic location in Oregon.

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 discussion with the Site Supervisor at this facility , discussion with the

Electronic Laboratory Reporting (ELR) Coordinator for Oregon Health Authority (OHA) and review of patient records shared by the ELR Coordinator, the laboratory failed to ensure accurate and timely test results were submitted to the patient and to OHA and when appropriate, an amended report was created. Findings include: 1. During survey 1/12/2022, this surveyor inquired about incorrect results having been given to patients. The Site Supervisor confirmed incorrect results were given to three (3) patients in November 2021 and December 2021. No documentation of correction or amended reports could be produced, though requested multiple times both on site during survey and post survey. 2. Electronic Inquiry with COVID Clinic's Vice President of Compliance Nurse on record as of 1/28/2022 asked for proof of an amended patient report for the three (3) patients with erroneous results demonstrated during survey and the day after. The Compliance Nurse failed to yield any documentation thereof for either Corrective Action (CA) or amended patient reports signed off by the Laboratory Director (LD). One of the erroneous results was reported to the Compliance Nurse by the Site Supervisor 12/17/2021, though the incorrect test result had been reported by the patient to the Site Supervisor on November 29, 2021. 3. No corrective action for any of the three (3) erroneous patient results could be produced during survey 1/12/2022 or at any time thereafter. The Site Supervisor for this site stated during interview 1/12/2022 that no corrective action had been initiated or completed by COVID Clinic regarding the three (3) erroneous results to her knowledge. No laboratory procedure for correcting patient results was available to staff nor was the Site Supervisor aware if such a procedure existed during survey. 4. OHA ELR Coordinator has expressed concerns via email about missing patient reports on multiple occasions to COVID Clinic and now to this State Agency CLIA surveyor, including a window of time from 12/6/2021 through 12/19/21 when no patient results were reported by COVID Clinics. Once the electronic reporting issue was resolved, submission began again but the facility failed to follow up with the missing test results from 12/6/2021 - 12/19/21 requested by OHA ELR Coordinator multiple times. Result reporting from COVID Clinic failed again beginning 12/31/2021. 5. The ELR Coordinator provided documentation of 1287 results not reported to OHA from 11/03/2021 - 02/07/2022.