

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2205595	(X3) Date Survey Completed 02/07/2022
Name of Provider or Supplier Covid Clinic, Inc	Street Address, City, State 729 Ne Oregon Street, Portland, 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 Portland COVID Clinic located at 729 NE Oregon St. in Portland, OR was performed on 2/07/2022. 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 Oregon Health Authority records and discussion with the Compliance nurses on site (2) during survey 02/07/2022, the laboratory failed to follow the manufacturer's package insert. Findings include: 1. 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 the survey date, 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.</p>
D8201	<p>INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b)</p> <p>(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</p>

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 Compliance nurse on site at time of survey 02/07/2022 , 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 02/07/2022, this surveyor inquired about incorrect results having been given to patients during interview with the LPN and Compliance nurse on site at approximately 2 pm. Both personnel stated that there was no process in place to amend or correct reports and there was no documentation of Laboratory Director review of any of the incorrectly reported patient results. ELR Coordinator for Oregon Health Authority (OHA) provided documentation of one hundred twenty four(124) conflicting patient results from 11/5/2021 - 1/31/2022 for this site. 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 reports. 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). 3. No corrective action for any of the erroneous patient results could be produced during survey or at any time to date. 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 11/3/2021 through 02/07/2022 when one thousand two hundred eighty seven (1287) patient results were not reported to OHA by COVID Clinics.