Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2205598	02/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Covid Clinic, Inc	9585 Sw Washington Square, 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 COVID Clinic Tigard, located at 9585 SW Washington Square Road in Tigard, OR was performed on 02/01/2022. 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	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: 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: Surveyor: 37006 Based on review of written temperature records for this site and discussion with the Compliance Nurse on site at the time of survey 02/01/2022, the laboratory failed to follow the manufacturer's package insert for Accula rPCR and Indicaid rapid antigen COVID testing. Findings include: 1. The Phase Indicaid rapid antigen test for COVID 19 Information for Use (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 02/01/2022, COVID Clinic Tigard has not informed Oregon Health Authority to date of it's intention to run this test for COVID antigen. 2. The Accula IFU states: "Store reagents at room temperature (15C to 30C, 59F to 86F). Do not refrigerate or freeze". Upon review of the written temperature logs for December 2021 and January 2022 at this site, it was noted that the temperature in the temporary testing site chamber was out of temperature range five (5) days out of thirty one (31) days in December 2021 and one (1) day out of thirty one (31) days in

	January 2022. No written corrective action for either of these months when temperatures were out of range could be produced for review during on site survey 02 /01/2022. The Compliance nurse on site during survey confirmed there were no written records of corrective action for these temperature outliers. 3. The Accula rPCR assay IFU states: "Sample collection and handling procedures require specific training and guidance". Upon review of testing personnel (TP) records for the Accula rPCR test, the trainer for the Site Lead, (TP #1), could not be identified for this assay, nor could this trainer be identified by the Compliance nurse on site during survey. Further investigation revealed that TP # 2 signed off competencies for TP # 3 on 07/09/2021 whereas TP #2 had not been signed off as competent on this assay until 07/18/2021. 4. The Phase Indicaid for COVID antigen IFU states "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling". Review of training records of TP performing this test on site, TP# 5 had no training record for the Indicaid COVID antigen test yet signed off TP #4 competencies for this assay 07/13 /2021. 5. According to the IFU for the Abbott ID Now COVID test sytem: "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling". Upon review of training records during survey 2/01/2022, it was noted that TP #2 signed off TP #3 training record 07/09/2021. Further investigation revealed that TP#2 was not signed off as competent on the Abbott ID NOW assay until 07/18/2021 and TP# 5 had no training record for the Indicaid COVID antigen test yet signed off TP #4 competencies for this assay 07/06/2021.
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: This STANDARD is not met as evidenced by: Surveyor: 37006 Based on discussion with the Compliance nurse at this COVID Clinic Tigard 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 and reviewed / approved by the Laboratory Director. Findings include: 1. The ELR Coordinator submitted numerous examples of discrepent results submitted to OHA regarding COVID testing to this surveyor. No written or digital documentation of a corrected patient report could be produced during survey. 2. The Compliance nurse on site 02/01/2022 confirmed that no corrected/amended patient reports or Laboratory Director review /signature for discrepant COVID patient results existed to date. 3. Patient #1 went to

	this COVID ClinicTigard site for rapid antigen testing 11/27/2021. Patient received two (2) conflicting results in the same day. The test record reveals the COVID test for the Tigard location was collected at 16:08 pm, specimen number 00-2735254-13, resulted as NEGATIVE by the Indicaid rapid Antigen test at 16:43 pm. The second test result came to the patient by text the same day 11/27/2021 from a COVID Clinic lab in Palm Desert, CA, collected at 11:21 am, specimen number 00-2730035-06 and resulted as POSITIVE by the SOFIA rapid antigen test at 11:56 am. No corrected report or corrective action for this error has been made available for review as of 2/22 /2022. 4. The Compliance nurse on site during survey confirmed during interview at approximately 2:00 pm that no corrected/amended report had been created for this patient.