Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2254682	03/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
United Providers Of Health, Llc - Peach Durham	800 N Mangum St, Durham, NC	

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**
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 manufacturer instructions for use (IFU), surveyor observation, review of laboratory records, interviews with testing personnel (TP) and Managing Partner 3/28/22, and email correspondence 4/7/22, the laboratory failed to follow manufacturer's instructions for test performance, failed to document TP training, failed to monitor and document room temperatures for storage and testing areas, failed to provide fact sheets to patients and failed to have a procedure for the reporting of positive SARS-CoV-2 patient results to the state health department. Findings: The laboratory began testing for SARS-CoV-2 using the iHealth COVID-19 Antigen Rapid Test Pro on February 16, 2022. The laboratory failed to have manufacturer's IFU for the iHealth COVID-19 Antigen Rapid Test Pro available on-site during the survey. Findings: 1. The laboratory failed to follow manufacturer's instructions for the performance of the iHealth COVID-19 Antigen Rapid Test Pro. Review of manufacturer's instructions revealed "Do not use the COVID-19 Test Card if the pouch is damaged or if the seal is broken. Once the COVID-19 Test Card is removed from the pouch, perform the test as soon as possible, but no more than one hour after opening the pouch." At approximately 11:00 a.m. surveyor observed approximately 25 iHealth COVID-19 cassettes, "Test Cards" in a small, clear plastic storage container. All test cards within the container had been removed from their original pouch. Interview with TP at approximately 11:00 a.m. confirmed the test cards had been removed from their original pouch and were then stored in the plastic container. TP stated she removes the test card from their original pouch when she receives a new box of tests. She stated it was easier to do beforehand than at time of testing. 2. The

	laboratory failed to document TP training for the performance of the iHealth COVID-19 Antigen Rapid Test Pro. Review of IFU for the iHealth COVID-19 Antigen Rapid Test Pro revealed "CONDITIONS OF AUTHORIZATION FOR LABORATORIES... All operators using your product must be appropriately trained in performing and interpreting the results of your product...". Review of training documentation submitted via email on April 7, 2022 revealed "Lateral flow immunoassay (COVID-19 Antigen/Antibodies Rapid Test)". The training documentation is signed January 11, 2022 and fails to document training for the iHealth COVID-19 Antigen Rapid Test Pro which the facility began using on February 16, 2022. Review of email submitted April 7, 2022 confirmed the laboratory began using the iHealth COVID-19 Antigen Rapid Test Pro on February 16, 2022. 3. The laboratory failed to monitor and document room temperature and storage room temperature for the iHealth COVID-19 Antigen Rapid Test Pro. Review of manufacturer's instructions revealed "Store iHealth COVID-19 Antigen Rapid Test Pro in a dry location between 36-56 degrees Fahrenheit (F) (2-30 degrees Celcius (C)). Ensure all test components are at room temperature 65-86 degrees F (18-30 degrees C) before use.". Review of laboratory records revealed no documentation the laboratory was monitoring and recording the room temperature of the testing location or the room temperature of the storage location. Interview with TP at approximately 11:00 a.m. confirmed the laboratory was not monitoring and recording the temperature of the room in which testing occurred. Phone interview with Managing Partner at approximately 11:15 a.m. confirmed boxes of iHealth COVID-19 Antigen Rapid Test Pro kits were stored at a climate controlled storage facility until delivered to a testing location. The Managing Partner also confirmed there was no documentation of the monitoring and recording of the storage facilty temperatures. 4. The laboratory failed to provide fact sheets to patients for the SARS-CoV-2 testing performed. Findings: Review of IFU for the iHealth COVID-19 Antigen Rapid Test Pro revealed "CONDITIONS OF AUTHORIZATION FOR LABORATORIES...Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets." During interview with TP at approximately 11:00 a.m. TP stated she is aware of fact sheets in the test kits, but she does not distribute them when a patient is tested. Phone interview with Managing Partner at approximately 11:30 a.m. confirmed the laboratory does not include fact sheets with patient test reports or at the time patient is tested. He stated he was unaware of this requirement. 5. The laboratory failed to have a procedure for the reporting of positive SARS-CoV-2 test results to the state health department. Findings: Review of laboratory records revealed no procedure for the reporting of positive SARS-CoV-2 test results to the state health department. Review of IFU for the iHealth COVID-19 Antigen Rapid Test Pro revealed "Laboratories within the United States and its territories are required to report results to the appropriate public health authorities." Phone interview with Managing Partner at approximately 11:15 a.m. confirmed the laboratory did not have a written procedure for the reporting of positive SARS-CoV-2 test results. He stated they have been reporting to the state, but they did not have a written procedure for how the results are reported.