EMERGENCY USE AUTHORIZED PURCHASE AGREEMENT
FaStep by Assure Tech COVID-19 IgG/IgM Rapid Test Device
(AZCOVID-19W)

This Emergency Use Test Purchase Agreement ("Agreement") is entered into by and between Carolina Liquid Chemistries Corp, a Delaware corporation ("Company") and the purchaser identified below ("Purchaser") and is effective as of the date set forth next to the Purchaser's signature.

The Tests are provided to Purchaser pursuant to Section 546 of the Federal Food, Drug, and Cosmetic Act.

Per the requirements of Assure Tech.'s (Hangzhou Co., Ltd) Emergency Use Authorization (EUA) issued on September 23, 2020, the Purchaser agrees all uses of the tests shall be consistent with the Policy and understands the tests purchased by Purchaser ("Tests") are for emergency use test purposes only and:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The Purchaser shall not alter, modify, remove, or deface the labeling on the Tests. The Purchaser agrees to indemnify, defend and hold harmless Company and its officers, directors, shareholders, employees, agents, representatives, successors and assigns from any and all claims, demands, losses, liabilities, judgments, awards and costs (including attorney's) fees arising out of or relating to the breach of this Agreement by the Purchaser or any person affiliated with the Purchaser.

The Purchaser agrees not to resell or distribute the product. At any point in time, Purchaser should be able to provide the location and disposition or assist with the traceability of the kits and ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

_____

Initials

INVOICE #: _____

313 Gallimore Dairy Road, Greensboro, NC 27409
877-722-8910 tel • 336-722-8915 fax • carolinachemistries.com

Authorized Laboratories - Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

1. Authorized laboratories using the Assure COVID-19 IgG/IgM Rapid Test Device will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories will use the Assure COVID-19 IgG/IgM Rapid Test Device as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive the COVID-19 IgG/IgM Rapid Test Cassette will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using the COVID-19 IgG/IgM Rapid Test Cassette will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of the COVID-19 IgG/IgM Rapid Test Cassette and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and Assure Tech. (via email: contact@direagent.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which they become aware.
6. All laboratory personnel using Assure COVID-19 IgG/IgM Rapid Test Device must be appropriately trained in immunochromatographic techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the device in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product. Authorization of use for this test is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests. This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

You confirm your laboratory is licensed to perform CLIA Waived tests and further agree to the above conditions for use of this product as described in Assure Tech.'s (Hangzhou Co., Ltd) EUA for the COVID-19 IgG/IgM Rapid Test Device.

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Account Name: _____

Purchaser: _____ Carolina Liquid Chemistries, Corp: _____
PRINT *PRINT*

Purchaser: _____ Carolina Liquid Chemistries, Corp: _____
SIGNATURE *SIGNATURE*

Date: _____ Date: _____

INVOICE #: _____

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