EMERGENCY USE AUTHORIZED PURCHASE AGREEMENT
Sienna-Clarity COVID-19 Antigen Rapid Test Cassette

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 the *Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency* issued on March 16, 2020 (Revised May 11, 2020) by U.S. Food and Drug Administration ("FDA").

Per the requirements of Salofa Oy's Emergency Use Authorization (EUA) issued on May 20, 2021, 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

1. Authorized laboratories using the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette 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 Sienna-Clarity COVID-19 Antigen Rapid Test Cassette 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 Sienna-Clarity COVID-19 Antigen 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 Sienna-Clarity COVID-19 Antigen 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 must collect information on the performance of the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and Salofa Oy (via email: info@salofa.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 operators using Sienna-Clarity COVID-19 Antigen Rapid Test Cassette must be appropriately trained in performing and interpreting the results of Sienna-Clarity COVID-19 Antigen Rapid Test Cassette, use appropriate personal protective equipment when handling the kit, and use Sienna-Clarity COVID-19 Antigen Rapid Test Cassette in accordance with the authorized labeling.

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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