



**EMERGENCY USE AUTHORIZED
PURCHASE AGREEMENT for END USERS
Flowflex COVID-19 Antigen Home Test**

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 Flowflex COVID-19 Antigen Home Test (“Tests”) are provided to Purchaser as described in the October 4, 2021, Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA) to ACON Laboratories, Inc. under the “*Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised): Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff*” issued May 11, 2020, and *The Viral Mutation Revision Letter* issued September 23, 2021.

The Flowflex COVID-19 Antigen Home Test (“Tests”) are provided to Purchaser by the Company per the requirements of ACON Laboratories, Inc.’s (EUA210269). Purchaser agrees all uses of the tests shall be consistent with the Policy, indications described in the EUA, and “Flowflex COVID-19 Antigen Home Test User Instructions” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>).

Purchaser understands the Tests are for emergency use test purposes only and:

- This product has not been FDA cleared or approved, but has been authorized by FDA under EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated, or authorization is 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 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.

Initials: _____

INVOICE #: _____



**EMERGENCY USE AUTHORIZED
PURCHASE AGREEMENT for END USERS
Flowflex COVID-19 Antigen Home Test**

Purchaser acknowledges the Tests are for non-prescription home use for the qualitative detection of nucleocapsid protein antigen from SARA-CoV-2 with:

- Self-collected direct anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first six days of symptom onset.
- Adult-collected anterior nasal swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first six days of symptom onset.
- Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

Individuals should provide all test results obtained with this product to their healthcare provider for public health reporting as described in the EUA. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC.

The EUA (EUA210494) 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: _____
PRINT

Carolina Liquid Chemistries, Corp: _____
PRINT

Purchaser: _____
SIGNATURE

Carolina Liquid Chemistries, Corp: _____
SIGNATURE

Date: _____

Date: _____

INVOICE #: _____