EMERGENCY USE AUTHORIZED TEST PURCHASE AGREEMENT
DiaCarta, Inc., QuantiVirus™ SARS-CoV-2 Test Kit and QuantiVirus SARS-CoV-2 Multiplex Test Kit

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 Purchaser agrees that the tests purchased by Purchaser from the Company ("Tests") are for emergency use test purposes only and have not been approved, cleared or licensed for sale or use in the U.S. by the U.S. Food and Drug Administration ("FDA"). The Tests are provided by Company to Purchaser pursuant to the Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency issued on the web on March 16, 2020 and updated on May 11, 2020, by U.S. Food and Drug Administration ("FDA") which may be found here https://www.fda.gov/media/135659/download (collectively the "Policy").

All uses of the tests by the Purchaser shall be consistent with the Policy. The Purchaser shall comply with the Policy guidance including, but not limited to, validation, FDA notification, reporting of results, Emergency Use Authorization ("EUA"), clinical testing and distribution. Collection and interpretation of the Tests shall only be performed by medical professionals. The Tests shall not be made available, sold, distributed, or marketed, directly or indirectly, to the general public.

Authorization of use for this test is limited to high complexity laboratories. You confirm your laboratory is licensed to perform high complexity tests and further agree to the following conditions for use of this product as described in DiaCarta Inc.'s, EUAs for QuantiVirus SARS-CoV-2 Test kit and QuantiVirus SARS-CoV-2 Multiplex Test Kit.

1. Authorized laboratories using the product will include with result reports of the product, 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 using the product will use the product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the product are not permitted.
3. Authorized laboratories that receive the product will notify the relevant public health authorities of their intent to run the product prior to initiating testing.
4. Authorized laboratories using the product 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 product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and CLC (via email: Techsupport@carolinachemistries.com or via phone: 336-722-8910, option 2) 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 the product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling.

Initials_____

INVOICE #: _____

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.

In accordance with CLIA, tests offered under these policies are considered high complexity by default until or unless they are authorized and deemed to be appropriate, through an EUA authorization or general FDA review processes, to be performed as moderate or waived complexity tests.

Laboratories using tests being marketed under the FDA's EUA policy should be mindful of CLIA requirements which are enforced by CMS and certain State authorities, and CMS guidance for laboratories during the COVID-19 public health emergency. Under CMS guidance, if a facility has the appropriate CLIA certificates and follows applicable CLIA regulations, state regulations and guidelines, the laboratory's CLIA certificate can be extended to cover testing in areas outside of the designated primary site or home base such as contiguous buildings, or any other designated temporary overflow location in its facility or temporary remote location, such as a parking lot.

At any point in time, Purchaser should be able to provide the location and disposition or assist with the traceability of the kits. The Purchaser agrees not to resell or distribute the product.

This product is a medical device for prescription use only and cannot not be used for home testing.

"If the FDA alters the Policy of May 11, 2020 or determines that this test is no longer authorized under the Policy, Purchaser understands that a recall shall be conducted, and the Purchaser shall be notified. The Purchaser acknowledges that no refunds for purchase of the Tests will be issued in the event of a recall."

Account Name: _____

Purchaser: _____
PRINT

Carolina Liquid Chemistries, Corp: _____
PRINT

Purchaser: _____
SIGNATURE

Carolina Liquid Chemistries, Corp: _____
SIGNATURE

Date: _____

Date: _____

INVOICE #: _____