EMERGENCY USE AUTHORIZED PURCHASE AGREEMENT
Status™ COVID-19/Flu A&B Antigen Test
(P/N – 33225)

This Emergency Use Test Sales 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 by Company 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 Princeton BioMeditech Corp's Emergency Use Authorization (EUA) issued on February 4, 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 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.

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.

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Authorized Laboratories - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use 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.

Authorized Laboratories agree to the following conditions as described in the EUA which may be accessed via the FDA In Vitro Diagnostics EUAs @ FDA.gov:

1. Authorized laboratories using the *Status*™ COVID-19/ Flu A&B Antigen Test must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

2. Authorized laboratories using the *Status*™ COVID-19/ Flu A&B Antigen Test must use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use the *Status*™ COVID-19/ Flu A&B Antigen Test are not permitted.

3. Authorized laboratories that receive the *Status*™ COVID-19/ Flu A&B Antigen Test must notify the relevant public health authorities of their intent to run the product prior to initiating testing.

4. Authorized laboratories using the *Status*™ COVID-19/ Flu A&B Antigen Test must 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 *Status*™ COVID-19/ Flu A&B Antigen Test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and you (via email technical@lifesignmed.com, or via phone by contacting LifeSign Customer Support Services at 800-526-2125 or 732-246-3366) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the *Status*™ COVID-19/ Flu A&B Antigen Test of which they become aware.

6. All operators using the *Status*™ COVID-19/ Flu A&B Antigen Test must be appropriately trained in performing and interpreting the results of the product, use appropriate personal protective equipment when handling this kit, and use the product in accordance with the authorized labeling.

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7. Princeton BioMeditech Corp and authorized laboratories using *Status*™ COVID-19/ Flu A&B Antigen Test will 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.

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.

The labeling entitled "Status COVID-19/Flu" Instructions for Use and "Quick Reference Instructions Status COVID-19/Flu Nasopharyngeal Swab", Fact Sheet for Healthcare Providers, and Fact Sheet for Patients may be accessed via the FDA website at: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/vitro-diagnostics-euas)

The Purchaser agrees not to resell or distribute the product.

Duration of Authorization

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:_____

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