



PURCHASING AGREEMENT

RightSign COVID-19 IgG/IgM Rapid
Test Cassette

PUBLIC HEALTH EMERGENCY TEST DEVICE PURCHASE AND USE AGREEMENT

This Public Health Emergency Test Device Purchase Agreement (“Agreement”) is entered into by and between NexScreen, LLC, a Colorado limited liability company (“Company”) and the purchaser identified below (“Purchaser”), is effective as of date of the Purchaser’s signature and remains in effect until the Agreement is no longer required or the COVID-19 test device receives full regulatory clearance for the United States market.

The Purchaser agrees that the COVID-19 Rapid Test Devices purchased from the Company (“Tests”) falls within the scope of laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 41 U.S.C. 263a, that meet the requirements to perform moderate or high complexity tests which allows such tests to be sold into the US market for professional use only, including healthcare professionals at point-of-care sites provided they are done so with the following reporting requirements:

- 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.
- Authorized laboratories using this product 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.
- Authorized laboratories will use the product 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 the product are not permitted.
- Authorized laboratories that receive this product will notify the relevant public health authorities of their intent to run the product prior to initiating testing.
- Authorized laboratories using this product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and (info.use@biotests.com.cn) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All laboratory personnel using this product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product 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.

The Purchaser shall comply with the product labeling and report requirements. The tests are limited to use by moderate or highly complex laboratories, or by healthcare workers at point-of-care sites covered by the laboratory’s CLIA certificate.

Tests cannot be marketed or sold to the public for home use. Anyone caught selling for home use will be cited with a cease and desists order letter. For distributors, you are furthermore required to obtain your own Customer Agreement Letter from each customer prior to fulfillment of orders.

ACCEPTANCE

By signing this agreement, 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.

Purchaser Signature: _____ Date_____

Company Name:_____ Location: _____

*This form is required. Please email completed form to: operations@nexscreen.com