



EMERGENCY USE AUTHORIZED PURCHASE AGREEMENT

DiaSure Assure COVID-19 IgG/IgM Rapid Test Device

This Emergency Use Test Purchase Agreement (“Agreement”) is entered into by and between True Diagnostics, Inc. a Nevada 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 Assure Tech.’s (Hangzhou Co., Ltd) Emergency Use Authorization (EUA) issued on July 6, 2020, 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.

Authorized Laboratories - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests.

1. Authorized laboratories using the Assure COVID-19 IgG/IgM Rapid Test Device 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.

Initials _____

2. Authorized laboratories will use the Assure COVID-19 IgG/IgM Rapid Test Device 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 COVID-19 IgG/IgM 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 COVID-19 IgG/IgM 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 will collect information on the performance of the COVID-19 IgG/IgM Rapid Test Cassette and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAREporting@fda.hhs.gov) and Assure Tech. (via email: contact@direagent.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 laboratory personnel using Assure COVID-19 IgG/IgM Rapid Test Device must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use Assure COVID-19 IgG/IgM Rapid Test Device 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 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 Assure Tech.'s (Hangzhou Co., Ltd) EUA for Assure COVID-19 IgG/IgM Rapid Test Device.

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 (Print Name)	True Diagnostics (Print Name)

Purchaser (Signature)	True Diagnostics (Signature)

Date	Date