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02 September 2020

ASX Announcement
TBG Biotechnology Corp. Receives US FDA Emergency Use Authorisation (EUA) of the COVID-19 Antibody Rapid Test Kits

TBG Diagnostics Limited ("TDL" or "Company") is pleased to announce that its wholly owned subsidiary TBG Biotechnology Corp. ("TBG Taiwan") has received an Emergency Use Authorisation (EUA) from the United States Food and Drug Administration (FDA) for its TBG SARS-CoV-2 IgG / IgM Rapid Test Kit.

The TBG SARS-CoV-2 IgG / IgM Rapid Test Kit is a lateral flow immunochromatography based diagnostic kit that uses colloidal gold technology to detect the presence of antibodies against N and S proteins of the SARS-CoV-2 virus in a test card. It is commonly used to confirm prior infection of the SARS-CoV-2 virus from serum and plasma samples. This test is manufactured by TBG Biotechnology Corp. in Taiwan and will be exported from Taiwan.

The United States FDA has made the Test Kit available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. Since the Test Kit is made available under an EUA, it has not undergone the same type of review as an FDA-approved or cleared IVD.

The EUA for the Test Kit is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

Under the EUA, the TBG SARS-CoV-2 IgG / IgM Rapid Test Kit is only authorised for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests

The FDA concluded that the Test Kit met the criteria for issuance of the EUA which are listed in Section I on page 2 of the Letter of Authorization. A full copy of the Letter of Authorization from the FDA, which includes the conditions attached to the EUA, is available on the FDA website at https://www.fda.gov/media/141770/download

The Fact Sheets for Healthcare Providers and Patients for the Test Kit and the Instructions for Use are also available from the FDA website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

The Testing Kit is one of 41 in vitro diagnostics test kits for detecting antibodies against the novel coronavirus and one of 13 that uses the lateral flow immunochromatography rapid test platform that have received FDA EUAs to date.

Authorised by the Board of Directors
Jitto Arulampalam
Chairman