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Lepu Medical Technology (Beijing) Co., Ltd.

Reminding Announcement on the SARS-CoV-2 Antigen Rapid Test Kit

(Colloidal Gold Immunochromatography) was Shortlisted in Export "White

List"

The company and all members of the Board of Directors hereby guarantee that

the information presented in this Announcement is true, accurate and complete

with no false or misleading statement or material omission. The English version

of this Announcement is for reference only.

The subsidiary company Beijing Lepu Medical Technology Co., Ltd. (hereinafter

brief as "Lepu Diagnostics") of Lepu Medical Technology (Beijing) Co., Ltd.

(hereinafter brief as "Lepu Medical") is always devoted to the research and

development and manufacturing of products in the IVD field. The announcement is

given that the Lepu Diagnostics self-developed SARS-CoV-2 Antigen Rapid Test Kit

(Colloidal Gold Immunochromatography) was shortlisted in export "White List"

recently. This is a new product getting the EU market access qualification again after

independently developed SARS-CoV-2 Antibody Test (colloidal gold

immunochromatography) got the EU market access qualification in March 2020.

The SARS-CoV-2 Antigen Rapid Test Kit, which is different with the antibody test kit,

is intended for the qualitative detection of antigen against SARS-CoV-2 in clinical

samples (nasal swab). The test card is based on the specific antibody-antigen reaction

and immunoanalysis technology. The test card contains colloidal gold labeled

SARS-CoV-2 N protein monoclonal antibody which is pre-coated on the combination

pad, matched SARS-CoV-2 N protein monoclonal aotibody immobilized on the Test

area (T) and corresponding antibody in the quality control area (C) to realize more

Cninf 多 巨潮资讯 rapid and accurate test. The clinical performance characteristics of the test kit has been evaluated in a clinical study in the Islamabad Diagnostic Center, Pakistan, with a diagnostic sensitivity of 97.47% and a diagnostic specificity of 95%.

The listing of the test kit in export "white list" will provide faster, more accurate and convenient on-site detection methods for the global COVID-19 suspected patients, patients who requires isolation or medical observation, and other people who require COVID-19 diagnoses. Lepu Diagnostics will increase productivity, actively ensure the safety and effectiveness of products, and prepare for the fight against the COVID-19, and make contribution to human health.

The Board of Directors

Lepu Medical Technology (Beijing) Co., Ltd.

November 10, 2020