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To Whom it may concern,

We, Hangzhou Lysun Biotechnology Co.,Ltd ,as the manufacturer of Lysun COVID-19 antigen Rapid Test Device（colloidal Gold) states that the tests are based on the N protein of COVID-19 as the detection target which showed good sensitivity and specificity in detecting Covid-19 virus .

*B.1.1.7: This variant was initially detected in the UK;

*B.1.351: This variant was initially detected in the South Africa in December 2020;

*P.1: This variant was initially identified in Travelers from Brazil, who were tested during routine screening at an airport in Japan, in early January;

*B.1.617: This variant was initially detected in India.

*B.1.1.529：This variant was initially detected in the South Africa in November 2021

BA.4 and BA.5 were initially detected in January ,2022 which are two sub-lineages of the Omicron clade (B.1.1.529). They share the same mutation profile in the spike gene. The main mutations of Omicron mainly happened in the S-protein region alone . The variant BA.4 and BA.5 didn't affect the normal rate of Lysun COVID-19 antigen Rapid Test Device（colloidal Gold）.

Certified by Clinical Performance Evaluation Report from Uniwesyteckie Centrum Kliniczne in May 2022, Speically in the clinic purpose of evalution on Omicron and Delta .The results proved that the following major Sars-Cov-2 variants can be detected by Lysun COVID-19 antigen Rapid Test Device（colloidal Gold).

Your sincerely

Chen Jungang

CEO of Hangzhou Lysun Biotechnology Co.,Ltd.

杭州联晟生物科技有限公司
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