乐普诊断
LEPU TECHNOLOGY

Statement on FDA Recall of Lepu Leccurate SARS-CoV-2 Antibody Rapid Test Kit and SARS-CoV-2 Antigen Rapid Test Kit

Lepu Medical has two types of products related to SARS-CoV-2 detection, including the antibody or antigen detection systems that assist the users to test if they have infected with COVID-19 and the neutralization antibody detection that evaluates the effectiveness and duration of the COVID-19 vaccine. The products that were mentioned by FDA involved the antibody and antigen test kits. The antibody test kit (product name: Leccurate SARS-CoV-2 antibody Rapid Test Kit) is designed to detect the antibody of the users, functioning as a complementary method for SARS-CoV-2 detection. The antigen test kit (product name: SARS-CoV-2 Antigen Rapid Test Kit) is designed to detect the antigen of the users, functioning as another complementary method for SARS-CoV-2 detection.

Lepu developed the Leccurate SARS-CoV-2 antibody Rapid Test Kit in early 2020, and passed the USA Notification list（Listing D378763）application successfully on March 25, 2020, which means the product could be used in clinical institutions in the U.S.. After that, we tried to apply for EUA (EUA200069) but revoked the application on June 19, 2020.

The Notification List turned invalid with the revocation as well. Therefore, the Leccurate SARS-CoV-2 antibody Rapid Test Kit has not been allowed to sell in the U.S. since June 19, 2020. As for the SARS-CoV-2 Antigen Rapid Test Kit, U.S. is not our target market and thus we have never intended to apply for any registrations in the U.S.. The SARS-cov-2 Antigen Rapid Test Kit has received related approvals in Europe, which is its major market.

In summary, due to the alteration of the products' registration status in the U.S., since June 19, 2020, Lepu has been taking actions and informing related distributors of the alteration accordingly. Nevertheless, some distributors might still have sold our products remaining in the U.S. market out of personal interest. Countering this situation, we have been taking efforts to further recall the products. On April 29, 2021, the FDA updated the information on the recall of EUA over 264 companies, including Lepu's antibody test kit.

According to the recall notification from FDA on May 29, 2021, a total of 8,419,545 our antibody test kits should be recalled. Lepu has been coordinating closely with FDA for almost a month to verify the accurate number, with the aid of the customs data starting from March 20, 2020. Lepu has also investigated all the distributors and found that 8,154,550 of them were products ought to be shipped to South America with transit via the U.S. with nearly 260,000 entering into the U.S. market. At this point, we are verifying the stock of the 260,000 products that went to distributors and clinical centers. Moreover, we are assisting FDA with the recall procedure based on the regulations proactively.

Regarding the antigen test kit, Lepu has never tried to sell the product in the U.S. market, while according to the customs data there have been 200,000 kits in the U.S. market. They might have been shipped to other countries, transited via the U.S., or might have entered into U.S. market. At this point, we are probing and verifying the logistics of the products that went to distributors. Moreover, we are assisting FDA with the recall procedure based on the regulations as well.

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Beijing Lepu Medical Technology Co., Ltd.

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