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Macrogen obtains export approval for COVID-19 test kit

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Currently, Macrogen is preparing to obtain Emergency Use Authorization (EUA) from the U.S. FDA and Europe's CE In-Vitro Diagnostics (CE-IVD)



The Korean biotech company Macrogen, announced that it obtained export approval for COVID-19 test kit 'Axen™ COVID-19 RT' from the Ministry of Food and Drug Safety (MFDS).

Macrogen's COVID-19 test kit is a product that uses RT-PCR, and can confirm whether the person is infected with COVID-19 in just two hours, which allows for conducting a large number of tests quickly and efficiently. As the kit detects ORF1ab and E genes, two genes related to COVID-19, it has a high level of accuracy and target detection. Hence, the test kit is evaluated as more appropriate to screen patients with trace amounts of COVID-19.

Earlier, Macrogen collected samples from the upper airway (nose, mouth, neck, etc.) and lower airway (bronchus, etc.) of COVID-19 patients, and conducted a clinical trial with its test kit Axen™ COVID-19 RT. Macrogen confirmed 100% consistency in 20 samples each in the positive and negative groups and reported these results to the MFDS.

Macrogen applied various guidelines including a Draft International Standard by the International Organization for Standardization's (ISO) technical committees of medical devices, and completed its self-development of the test kit Axen™ COVID-19 RT last month. Macrogen, is recognized as a company with reliable diagnostic technology and an accuracy, obtained enough raw materials to produce at least 100,000 tests per week and completed the kit production system and process in accordance with GMP regulations.

Even before this export approval, a surge of inquiries about how to purchase Macrogen's test kit rushed in from many countries including Brazil and Uruguay. This suggests that Macrogen has been acknowledged for its technology based on its 24 years of genome analysis expertise, and diagnostic reagent development experience. Macrogen has targeted the global market with its glocalization strategies and maintained a high level of recognition and customer trust in research, clinical diagnostics, personal genome, and microbiome. In particular, Macrogen boasts an all-encompassing business portfolio, which includes Korea's leading virus research in the face of the outbreak of novel viruses, such as MERS and SARS as well as its

manufacture of oligo, the key material in a diagnostic reagent, and production of model mice for therapeutics and vaccine development.

Currently, Macrogen is preparing to obtain Emergency Use Authorization (EUA) from the U.S. FDA andEurope's CE In-Vitro Diagnostics (CE-IVD). These authorizations are expected to increase Macrogen's exports across the U.S. andEurope as well as Brazil and Uruguay, in which the test kit is currently under negotiation.