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Seasun Biomaterials set to launch COVID-19 rapid kit

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The kit obtained CE-IVD marking in March



South Korea based SEASUN BIOMATERIALS has announced that they are about to release their second COVID-19 assay "AQ-TOP COVID-19 Rapid Detection Kit" just after the completion of FDA EUA (April-27) of their U-TOP COVID-19 Real-Time Detection Kit.

Analytical Speed, Sensitivity and Specificity of the conventional molecular methods were enhanced with AQ-TOP technology through the combination of isothermal amplification and PNA (Peptide Nucleic Acid) detection probe, which has high accurate binding efficiency to the target nucleic acid.

This kit targets ORF1ab gene of SARS-CoV-2 with an endogenous control human RNase P gene. The kit obtained CE-IVD marking in March, and now examinations of an export approval of MFDS (Korea's Ministry of Food & Drug Safety) and the FDA EUA are underway.

CEO Hee-Kyung Park said, "Customers don't need to purchase an additional equipment. The existing real-time PCR instrument which is frequently used for COVID-19 diagnosis can be used as it is. The average number of specimens that can be tested per unit (12 hours per day) is 3,400, which is 5-6 times faster than before. Currently, as COVID-19 is rapidly spreading globally and re-infection is reported frequently, we will produce more than 200,000 tests per day to deliver as fast as possible. As soon as the permit for the AQ-TOP COVID-19 Rapid Detection Kit has been completed, the kit will be provided globally and with the advantage that the rapid COVID-19 diagnosis will contribute to quick follow-up."

SEASUN BIOMATERIALS is currently distributing its real-time PCR based "U-TOP COVID-19 Detection Kit" which acquired CE-IVD marking, Certificate of Free Sales of MFDS (in February) and the FDA-EUA (on April-27), to overseas including Europe and the Middle Eastern countries.