

Macrogen obtains CE-IVD mark for COVID-19 test kit

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Korean biotech company Macrogen has recently announced that it has obtained the CE marking for Europe's In-Vitro Diagnostic (CE-IVD) devices for its coronavirus disease 2019 (COVID-19) test kit 'Axen™ COVID-19 RT'. Europe's CE-IVD is an essential certification for the distribution of in-vitro diagnostic reagents, as it is considered as a 'passport' that allows entry into the European market, and the products with this certification are subject to distribution in the markets throughout Europe without any restriction.

Macrogen plans to make major inroads into the European market following this acquisition of CE-IVD, and supply test kits to government agencies and medical institutions through its local corporations and branches as well as diagnostic agent distributors. Since the test kit has now become available for export to entire Europe and many countries that recognize the certification as well as Latin America with which agreements will soon be signed, Macrogen is projected to dramatically increase its export across the globe.

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.