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ASIA EDITION

Gencurix wins FDA EUA for COVID-19 test kit

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Enhanced performance and high throughput screening up to 384 samples simultaneously

A Korean molecular diagnostic company, Gencurix, Inc., has announced that they have received U.S. Food and Drug Administration (FDA)'s Emergency Use Authorization (EUA) for its GenePro SARS-CoV-2 Test.

It is the second RT-PCR test that Gencurix has launched following the first test assay, GenePro COVID-19 Detection Test released last March.

Key advantages of GenePro SARS-CoV-2 test include simultaneous monitoring of up to 384 samples which would allowhigh t hroughput screening of the novel coronavirus. With the FDA's EUA, Gencurix is now able to provide its COVID-19 detection tests the U.S. nationwide.

Gencurix's GenePro SARS-CoV-2 Test has the flexibility in the number of samples it can test simultaneously depending on the different PCR platforms.

When most of RT-PCR tests have been developed to be used with 96-well plates, GenePro SARS-CoV-2 test can be used with 384-well plate which can quadruple the number of test samples. "According to a joint review with a CLIA lab inSalt Lake City, Utah, we found that you can test up to 6,000 people with just a couple of RNA prep and RT-PCR instruments," said Gencurix's representative.

Another important advantage of GenePro SARS-CoV-2 Test is the versatility of the RNA Extraction Kit. The lack of RNA Extraction Kit has become one of the biggest obstacles in carrying out coronavirus test in the U.S. Gencurix anticipates that it will be able to solve the problem as it has been approved with RNA Extraction Kits that are relatively well-supplied.