

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

Shuwen Biotech announced that it was recently granted the CE-IVD Mark for its SARS-COV-2 RT-PCR Kit.

DEQING, CHINA, January 5, 2021 /EINPresswire.com/ -- Shuwen Biotech announced that it was recently granted the CE-IVD Mark for its SARS-COV-2 RT-PCR Kit. Shuwen has also obtained



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Jay Z. Zhang, CEO and Chairman of Shuwen Biotech

clearance from the relevant Chinese government agency for export of the kit. The kit is now immediately available for distribution in Europe and other territories recognizing CE certification.

The kit is a real-time reverse transcription PCR (rRT-PCR) test used for the qualitative detection of nucleic acids from SARS-CoV-2 in upper and lower respiratory specimens and can confirm whether the person is infected with COVID-19 in hours. Specifically, the kit is compatible with nasal, nasopharyngeal and oropharyngeal swab specimens to detect active infections and has been validated on almost

all world leading real-time PCR platforms (ABI 7500, ABI 7500Fast, QuantStudio Dx, Cobas® Z480, LightCycler® 480II, CFX96, Rotor-Gene Q, SIAN-96S) and laboratory workflows, enabling more tests to be performed in a day.

The assay contains specific primers and probes for conserved ORF1ab and N genes of SARS-CoV-2, thus demonstrating its reliability in ruling out closely-related viruses such as CoV 229E, CoV HKU1, CoV NL63, SARS-CoV, MERS and CoV OC43. In addition, the kit also detects the newly emerging mutants (S. 501Y. V2, VUI-202012/01).

"Receiving the CE IVD Mark for our Quick SARS-CoV-2 assay means we can better support COVID-19 testing and supporting lives of patients on a global level in a cost effective way, something that Shuwen has been deeply committed to since the start of the pandemic," said Jay Z. Zhang, CEO and Chairman of Shuwen Biotech.

Shuwen plans to make major inroads into the global market following this acquisition of CE-IVD, and supply test kits to government agencies and medical institutions through its network of distributors.

About Shuwen Biotech

Shuwen Biotech is a China-based diagnostic company founded on the principles of innovation, patent protection, and international collaboration as its strategic platforms for growth. Since 2011, Shuwen established strategic partnerships with numerous outstanding academic and commercial institutions to commercialize first-in-class diagnostic technologies and patents and has developed a range of novel diagnostics in the fields of cancer, women's health, and health screening among others. Shuwen has also developed quality companion diagnostics and provided central lab biomarker testing services to leading pharmaceutical developers. Shuwen houses an in-house development team, CAP-accredited central labs, and ISO13485-certified IVD manufacturing facilities, all in line with global standards to continue to deliver transformational products and services to its customers globally and open new possibilities in the advancement of health.

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