Curetis Begins Offering BGI’s CE-IVD Rapid Test Kit for Coronavirus in Europe

- Rapid real-time PCR test allows testing for SARS-CoV2 in only a few hours
- Test kit to be made available via Curetis’ European sales channels
- Synergies with Curetis Unyvero HPN panel for pneumonia testing for bacterial co-infections in Covid-19 patients

Holzgerlingen, Germany, March 16, 2020, 08:00 am CET - Curetis N.V. (the "Company" and together with its subsidiaries "Curetis"), a developer of next-level molecular diagnostic solutions, today announced that it starts offering a CE-IVD certified real-time PCR test kit for SARS-CoV2 (also known as 2019-nCov), the causal pathogen of Corona Virus Disease 2019 (Covid-19). The test kit was developed and is manufactured by Curetis’ strategic partner BGI (Shenzhen, China) and was cleared by Chinese authorities in January 2020. In compliance with European regulations for in-vitro-diagnostics (IVD) tests, the test kit was CE-IVD certified on February 28, 2020.

The BGI 2019-nCoV RT-qPCR Kit enables diagnostic laboratories to perform SARS-CoV2 testing of nasopharyngeal swabs and bronchoalveolar lavage fluid of patients suspected to suffer from Covid-19. The test kit is compatible with standard methods for extracting the virus’ nucleic acid from the sample such as the QIAamp Viral RNA Mini Kit (QIAGEN) and can be performed on standard real-time PCR instruments such as the Applied Biosystems 7500 Real-Time PCR System (ThermoFisher Scientific) that are available in many molecular diagnostic laboratories in Europe. The test kit includes all necessary reagents and controls to test up to 48 patients in just a few hours.

The test will be made available to diagnostic laboratories in Europe through Curetis network of distribution partners but - owing to the special circumstances of the global SARS-CoV2 outbreak - also directly by Curetis in countries where Curetis’ distribution partners are not set up to supply the test kit themselves at short notices.

Offering the BGI 2019-nCoV RT-qPCR Kit is highly synergistic with Curetis' Unyvero product line as patients hospitalized with Covid-19 are at risk of co-infections with bacterial pathogens that are often resistant to one or more antibiotics. The Unyvero HPN Panel for pneumonia allows for rapid testing of a broad spectrum of bacterial or fungal pathogens commonly involved in lower respiratory tract infections such as severe and life-threatening cases of pneumonia. It also provides key information on genetic resistance markers often carried by such pathogens and thereby allows for earlier and better informed treatment decisions for hospitalized patients suffering from severe pneumonia.

“The strong synergies in offering BGI’s SARS-CoV2 test alongside our Unyvero HPN application make it an obvious move to leverage our sales channels to make coronavirus testing available as broadly as possible in Europe,” said Oliver Schacht, PhD, CEO of Curetis. “We sincerely hope that in this way we can contribute to containing the outbreak and improving the outcomes of Covid-19 patients by way of a comprehensive offering of diagnostic solutions for severe and life-threatening respiratory tract infections.”
For Diagnostic Laboratories

To place and order directly with Curetis or to be referred to Curetis’ distribution partner in your country, please contact us at:

   Email:   orders@curetis.com
   Phone:  +49-7031-49195-61

For Medical Professionals

Curetis does not offer SARS-CoV2 testing of patients directly. Please contact your local diagnostic laboratory to inquire about their ability to offer SARS-CoV2 testing for human diagnostic use.

For Patients

Curetis does not offer SARS-CoV2 testing of patients directly. Please contact your general practitioner/family doctor by phone if you believe you could be infected by SARS-CoV2 or suffer from Covid-19.

About Curetis

Curetis N.V.’s (Euronext: CURE) goal is to become a leading provider of innovative solutions for molecular microbiology diagnostics designed to address the global challenge of detecting severe infectious diseases and identifying antibiotic resistances in hospitalized patients.

Curetis’ Unyvero System is a versatile, fast and highly automated molecular diagnostic platform for easy-to-use, cartridge-based solutions for the comprehensive and rapid detection of pathogens and antimicrobial resistance markers in a range of severe infectious disease indications. Results are available within hours, a process that can take days or even weeks if performed with standard diagnostic procedures, thereby facilitating improved patient outcomes, stringent antibiotic stewardship and health-economic benefits. Unyvero in vitro diagnostic (IVD) products are marketed in Europe, the Middle East, Asia and the U.S.

Curetis’ wholly owned subsidiary Ares Genetics GmbH is developing next-generation solutions for infectious disease diagnostics and therapeutics. The ARES Technology Platform combines the presumably most comprehensive database worldwide on the genetics of antimicrobial resistances, ARESdb, with advanced bioinformatics and artificial intelligence.

For further information, please visit www.curetis.com and www.ares-genetics.com.

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