

Biocartis Announces Market Release of SeptiCyt[®] RAPID test on Idylla[™]

Mechelen, Belgium, 6 October 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the market release of SeptiCyt[®] RAPID on Idylla[™] as a CE-marked IVD test. SeptiCyt[®] RAPID is a host-response test¹ that distinguishes sepsis from non-infectious systemic inflammation in patients suspected of sepsis and provides actionable results in about one hour. The test was developed by Biocartis' partner [Immunexpress Pty Ltd](#) ('Immunexpress'), a Seattle-based (US) molecular diagnostics company, and is now being released as part of Biocartis' exclusive commercialization² of SeptiCyt[®] RAPID on Idylla[™] in Europe.

Sepsis is the body's life-threatening response to infection, which can lead to tissue damage, organ failure, and death³. A recent scientific publication by The Lancet estimated that in 2017 there were 48.9 million cases and 11 million sepsis-related deaths worldwide, which accounted for almost 20% of all global deaths⁴. Early and rapid diagnosis of sepsis is furthermore essential to avoid unnecessary hospital costs or overuse of antibiotics, which leads to greater antibiotic resistance among vulnerable patient populations.

Current diagnostic tests to aid in the diagnosis of sepsis are often unreliable and slow. At the virtual e-ISICEM symposium⁵ held between 15-18 September 2020, Immunexpress presented [clinical validation data](#)⁶ which demonstrated comparable and reproducible results between Immunexpress' existing US FDA-cleared test, SeptiCyt[®] LAB, and SeptiCyt[®] RAPID on Idylla[™]. These data are the first validation of a rapid, fully-integrated, reproducible, immune response-based sepsis diagnostic test⁶.

Herman Verrelst, Chief Executive Officer of Biocartis, reacted: *"Together with our partner Immunexpress, the SeptiCyt[®] and Idylla[™] technologies joined forces in a single one-step, sample-to-result test that, thanks to the Idylla[™] platform, can now be rolled out globally. As the exclusive distributor of SeptiCyt[®] RAPID in Europe, we are very pleased to offer this test to our existing and new customer base within our well-established European laboratory and hospital network. I believe we can make a real difference with this test that now enables⁷ clinicians to detect the likelihood of sepsis early on and provides actionable results in approximately one hour for critically-ill patients suspected of sepsis, where every second counts."*

SeptiCyt[®] RAPID on Idylla[™] as CE-marked IVD test is now available⁸ for ordering. More info can be found on the [Biocartis website](#).

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¹ By testing whole blood directly, the assay is able to detect the response of the patient's immune system to an infection earlier, faster and more accurately than finding the pathogen

² As announced on 26 March 2020

³ Source: <https://www.sepsis.org/>, last consulted on 24 September 2020

⁴ Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievian DR, et al. Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. *Lancet* (London, England). 2020;395(10219):200-11

⁵ International Symposium on Intensive Care and Emergency Medicine

⁶ Source: [Immunexpress website](#) and on <https://www.prnewswire.com/news-releases/immunexpress-presents-data-on-clinical-validation-of-septicyte-rapid-for-diagnosing-sepsis-at-e-isicem-301130702.html>, last consulted on 24 September 2020

⁷ Used in conjunction with clinical assessments, vital signs and laboratory findings

⁸ Available to select countries within the EU and European region. Check availability with your local Biocartis representative

About Biocartis

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis is developing and marketing a continuously expanding test menu addressing key unmet clinical needs, with a focus in oncology, which represents the fastest growing segment of the MDx market worldwide. Today, Biocartis offers tests supporting melanoma, colorectal and lung cancer. More information: www.biocartis.com. Follow us on [Twitter](https://twitter.com/Biocartis_): @Biocartis_.

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