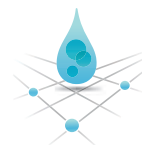


Biocartis NV

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BIOCARTIS

Idylla: high-precision diagnostics for high-precision medicine

Biocartis' molecular diagnostics make precision medicine simple.

Personalized or precision medicine is a fast-growing area that relies on targeted medicines supported by fast, reliable, sensitive and cost-effective *in vitro* diagnostics to ensure that doctors are able to get the right drugs to the right patients on the right timescale while tracking their response to treatment. Belgian company Biocartis NV, founded in 2007, aims to provide next-generation diagnostic solutions for improving clinical practice for the benefit of patients, clinicians, payers and industry. Idylla is Biocartis' fully automated, real-time PCR-based molecular diagnostics system, designed to offer fast and easy access to clinical molecular diagnostic information virtually anywhere and any time. Idylla was commercially launched in September 2014, and its track record so far has convinced key opinion leaders in pathology, oncology and infectious disease across the world of its abilities.



The Biocartis team: Hilde Windels (left) and Erik Vossenaar (right).

Creating fast and accurate molecular diagnostics

Molecular diagnostics is one of the fastest growing segments of the *in vitro* diagnostics market, predicted to be worth around US\$8 billion worldwide by 2018.

Clinical molecular testing currently involves a series of complex, labor-intensive and relatively costly steps, including preparation of clinical samples; isolation of genetic material, such as DNA; amplification, detection and quantification of the genetic material; result delivery; and—finally—interpretation by the pathologist. Driven by the conviction that easier, more effective and near-patient use can help doctors select a targeted therapy, Biocartis has developed the CE-IVD-marked Idylla diagnostics system. It is a rapid, highly sensitive, automated real-time system that can be used on demand and at point of need. All this in combination with its capability to detect up to 30 molecular targets in standard mode creates new possibilities. The Idylla system consists of a console with a touch-screen connected to an instrument that allows Idylla cartridges to perform specific tests. The cartridge includes all reagents and is designed to handle a wide variety of different clinical sample types, including tissue samples, blood, urine, sputum, swabs and fine needle aspirates. With an average hands-on time of just 2 minutes and a turnaround time of 35–150 minutes, depending on the complexity of the test, Idylla can be considered a fully automated PCR system.

Because of the current complexity of molecular diagnostics (MDx), only a small subset of hospitals are able to perform (complex) MDx tests

in-house. For most hospitals, the test volume is too small to justify investment in the infrastructure, equipment and personnel needed to perform today's MDx tests. With the Idylla platform, this hurdle can be overcome: there is no need for dedicated pre- and post-amplification rooms, and handling is reduced to a level of such simplicity that no specific skills in MDx are required, as no complex steps or other equipment are involved. In addition, with Idylla samples can be analyzed one by one, whereas most current systems require batches of samples for analysis. These features could bring MDx within the reach of smaller hospitals, so that they would no longer have to send samples to centralized labs and could thus save time in the diagnostics process, which is a crucial advantage. For larger labs, Idylla offers the ability to run samples between batches, decreasing labor costs related to the execution of tests, reducing user-induced variability between tests and offering a much faster turnaround time. Idylla does this without sacrificing quality. Idylla truly creates new opportunities for hospitals and laboratories.

Today Biocartis is rapidly expanding its test menu to address key unmet clinical needs in oncology and infectious diseases. Biocartis recently made significant progress in the field of liquid biopsies. In June 2015, Biocartis presented positive results of a research study, conducted in collaboration with Bart Neyns from the University Hospital Brussels, at the annual meeting of the American Society for Clinical Oncology, demonstrating that levels of *BRAF*-mutant tumor DNA in the circulating blood of

metastatic melanoma patients were associated with disease progression. This opens up the possibility of making patient monitoring easier and less invasive.

Biocartis' vision: growing into the future

Currently employing over 200 people, Biocartis has plans for growth. Over the next few years, the company aims to ramp up its release of MDx tests to four or five a year, through a combination of in-house development and collaboration. Biocartis' direct sales team currently covers 16 European countries, and this reach will expand worldwide as the company launches more products and Idylla gains regulatory approval in the United States, Japan and China.

Hilde Windels (deputy CEO), Erik Vossenaar (VP of business development) and Rudi Pauwels (founder and CEO) are aware of the advantages of good collaborations and strategic partnerships. "Small and larger partners have contributed to the success of Idylla, and the Idylla platform has enabled partners to bring their innovation to a new level. Biocartis is looking forward to partnering with teams with the same drive and mind-set, creating new opportunities in the fields of MDx and high-precision medicine," explained Vossenaar.

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