



PRESS RELEASE

26 June 2020, 07:00 CEST

US Multicenter Study Shows Idylla™ Allows Rapid and Accurate Mutation Testing Results Across Different Laboratory Settings

Mechelen, Belgium, 26 June 2020 – Biocartis Group NV (the 'Company' or 'Biocartis'), an innovative molecular diagnostics company (Euronext Brussels: BCART), today announces the publication of a [new multicenter study](#)¹ led by researchers from Dartmouth's and Dartmouth-Hitchcock's Norris Cotton Cancer Center (Lebanon, New Hampshire, US) in the 'American Journal of Clinical Pathology'. The study showed that, compared to current standard-of-care testing methods, Biocartis' molecular diagnostics platform Idylla™ can substantially improve turnaround time of the results of mutation testing, independent of the size of the laboratory.

The new multicenter study included 20 laboratories of different types and sizes throughout the US and Puerto Rico, and data from almost 800 colorectal cancer samples. Consequently, it is one of the largest studies performed involving Idylla™. Contrary to other studies that often research the assay (test) turnaround time, this study focused on the full sample journey, or the turnaround time between ordering the test and receiving the results, including steps such as sample transport to the laboratory, or pathologist sign off time. Researchers found that the average turnaround time for test results could be cut by more than 50% from 15 days to 5 days, with some results available in a single day, with Idylla™.

The study, using the Idylla™ KRAS Mutation Assay (RUO²) and the Idylla™ NRAS-BRAF Mutation Assay (RUO), also concluded that the simplicity and ease of use of Idylla™ compared with other molecular techniques make it suitable for integration into laboratories of any size, including those that may not have much molecular expertise. Finally, the study addressed the use of minimal tissue from the samples, showing that even smaller tissue-based specimens can be successfully analyzed by Idylla™.

Herman Verrelst, Chief Executive Officer of Biocartis, stated: "We are very pleased with this large new multicenter study focusing on the full sample journey. Results show that Idylla™ performs very strongly in terms of delivering highly accurate, rapid results, but also in terms of its simplicity, making Idylla™ suitable even for smaller laboratory settings."

Gregory Tsongalis, PhD, HCLD, CC, Professor and Vice Chair of Research in the Department of Pathology and Laboratory Medicine at Dartmouth's Geisel School of Medicine, reacted: "Our results are in line with findings of other studies showing successful analyses with Idylla™, using very small tissue amounts, including those deemed too small for standard molecular testing methods. Idylla™'s simplicity and ease of use compared with other molecular techniques make it suitable for routine laboratory testing."

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¹ Tsongalis et al., "Comparison of Tissue Molecular Biomarker Testing Turnaround Times and Concordance Between Standard of Care and the Biocartis Idylla Platform in Patients With Colorectal Cancer", Am J Clin Pathol. 2020 Jun 11;aqaa044. doi: 10.1093/ajcp/aqaa044. Online ahead of print.

² RUO = Research Use Only, not for use in diagnostic procedures

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. This 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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