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Biocartis Announces Launch of the Brand-New Idylla™ POLE-POLD1 Mutation Assay

Mechelen, Belgium, 02 April 2025 – Biocartis NV ("Biocartis"), an innovative molecular diagnostics company, is pleased to announce the launch of the brand-new Idylla™ POLE-POLD1 Mutation Assay (RUO[1]), a fully automated, real-time polymerase chain reaction (PCR) Assay designed for the detection of the hypermutated phenotype associated with mutations in POLE and POLD1.

POLE and POLD1 are proteins that ensure proper DNA amplification. When these proteins malfunction due to pathogenic mutations, uncontrolled DNA replication occurs, leading to cancer. Mutations in POLE and POLD1 have been identified in endometrial cancers and beyond[2,3]. POLE-mutated endometrial cancers are considered a distinct subtype in the molecular classification of endometrial cancer samples, next to dMMR/MSI-H, p53abn and NSMP subtypes[4].

The Idylla™ POLE-POLD1 Mutation Assay, run on the Idylla™ Platform, qualitatively detects 17 point mutations in the *POLE* gene and one mutation in the *POLD1* gene, enabling it to detect 99% of the known POLE and POLD1 pathogenic mutations in a single cartridge. Optimized for use with formalin-fixed, paraffin-embedded (FFPE) tissue specimens, the Idylla™ POLE-POLD1 Mutation Assay offers fast and accurate results, with a hands-on time of under 3 minutes and a turnaround time of approximately 95 minutes, enabling laboratories to go from sample to result in less than 2 hours.

Sigurd F. Lax, Professor and Head of Department of General Hospital Graz II[5], commented on the new Assay, stating: *"The Idylla™ POLE-POLD1 Mutation Assay has the potential to provide an on-demand, fast, and accurate solution, making molecular testing in endometrial cancer samples easier and more accessible than ever."*

At the Association for Molecular Pathology (AMP) 2024 Annual Meeting, Biocartis (Barault et al., 2024[6]) presented the results of a multi-center study to retrospectively detect POLE mutations in endometrial cancer tissue samples (cfr. Press Release 23 October 2024). More than 450 clinical samples were tested using a prototype version of the Idylla™ POLE-POLD1 Mutation Assay, comparing its accuracy against NGS, Sanger sequencing, and qPCR. This prototype study demonstrated 98.2% overall accuracy, highlighting the Assay's potential. The Assay has since been further enhanced by incorporating additional POLE and POLD1 mutations, achieving a 99% mutation coverage with an impressive 97.2% positive percent agreement and 99.2% negative percent agreement.

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[1] For Research Use Only (RUO), not for use in diagnostic procedures.

[2] Barbari, S. R., & Shcherbakova, P. V. (2017). Replicative DNA polymerase defects in human cancers: Consequences, mechanisms, and implications for therapy. *DNA repair, 56*, 16–25. https://doi.org/10.1016/j.dnarep.2017.06.003

[3] Ambrosini, M. et al. (2024). Immune checkpoint inhibitors for POLE or POLD1 proofreading-deficient metastatic colorectal cancer. *Annals of Oncology, 35* (7), 643– 655. https://doi.org/10.1016/j.annonc.2024.03.009

[4] Kommoss, S. et al. (2018). Final validation of the ProMisE molecular classifier for endometrial carcinoma in a large population-based case series. *Annals of Oncology, 29*(5). https://doi.org/10.1093/annonc/mdy058

[5] Department of Pathology, Hospital Graz II, Graz, Austria & School of Medicine, Johannes Kepler University, Linz, Austria.

[6] Barault, L. et al (2024). The Idylla *POLE* Mutation Assay: A New Tool for Direct Mutation Detection from FFPE Tissue. *The Journal of Molecular Diagnostics, 26*(11), S139.

For more information about the newly available Idylla™ POLE-POLD1 Mutation Assay, please visit the Biocartis website or contact the Biocartis team.

Roger Moody, Chief Executive Officer of Biocartis, commented: "We *are pleased to introduce the Idylla™ POLE-POLD1 Mutation Assay, which empowers laboratories to streamline molecular profiling for endometrial cancer."*

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About Biocartis

With its revolutionary and proprietary Idylla™ Platform, Biocartis aspires to enable personalized medicine for patients around the world through universal access to molecular testing, by making molecular testing actionable, easy, fast and suitable for any lab. The Idylla™ Platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) based system designed to offer in-house molecular biomarker testing in only 3 hours, allowing fast and optimal treatment selection. Idylla™'s continuously expanding menu of molecular diagnostic tests and research assays addresses key unmet clinical needs. Today, Biocartis offers tests supporting lung, skin, thyroid, colorectal, endometrial, blood, brain and breast cancer. More information: www.biocartis.com. Follow us on LinkedIn, Facebook and X (Twitter).

Disclaimers

Idylla™ Platform is CE-marked in Europe in compliance with EU IVD Regulation 2017/746, listed as a class II device in the US under establishment registration 3009972873, and registered in many other countries. Idylla™ POLE-POLD1 Mutation Assay is for Research Use Only (RUO), not for use in diagnostic procedures. Biocartis and Idylla™ are registered trademarks in Europe, the US and many other countries. The Biocartis and Idylla™ trademarks and logos are used trademarks owned by Biocartis NV.