COMING SOON IDYLLA[™] POLE-POLD1 MUTATION ASSAY

For the detection of the hypermutated phenotype associated with mutations in POLE and POLD1





Idylla™ POLE-POLDI Mutation Assay is currently under development and will be launched as Research Use Only (RUO), not for use in diagnostic procedures.

IDYLLA[™] POLE-POLD1 MUTATION ASSAY



EXPECTED BY BEGINNING OF 2025



Qualitative detection of > 95% of the POLE mutations associated with the hypermutated phenotype in endometrial and colorectal cancer samples^{1,2}

- Exon 9: P286H, P286L, P286R, P286S, M295R, S297F
- Exon 11: F367S, F367V, D368Y
- Exon 13: V411L, L424I, L424V, P436R, M444K
- Exon 14: A456P, S459F

Additionally, one mutation in POLD1 is detected: S478N



For use on the **fully automated** Idylla[™] Platform **On-demand testing** (no sample batching required)



Directly from FFPE tissue sections



Results in **only 2 hours**

Approximately 3 minutes hands-on-time

REFERENCES

León-Castillo, A. et al. (2020). Clinicopathological and molecular characterisation of 'multiple-classifier' endometrial carcinomas. *The Journal of pathology*, *250*(3), 312–322. https://doi.org/10.1002/path.5373
Ambrosini, M. et al. (2024). Immune checkpoint inhibitors for POLE or POLD1 proofreading-deficient metastatic colorectal cancer. *Ann Oncol.*, *35*(7), 643-655. https://doi.org/10.1016/j.annonc.2024.03.009

Biocartis NV Generaal De Wittelaan 11B 2800 Mechelen, Belgium +32 15 632 888 Biocartis US Inc. 2 Pierce Place Suite 1510 Itasca, IL 60143, US +1 (844) 443-9552 Follow us on fxin www.biocartis.com customerservice@biocartis.com customerserviceUS@biocartis.com

Idylla[™] POLE-POLD1 Mutation Assay is currently under development and will be launched as Research Use Only (RUO), not for use in diagnostic procedures. 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. 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. Idylla[™] is available for sale in Europe, the US and many other countries. Please check availability with a Biocartis representative.