BECAUSE TIME MATTERS

IDYLLA™ POLE-POLD1 MUTATION ASSAY

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

idylla
by BIOCARTIS

THINK IDYLLA™
BECAUSE TIME MATTERS

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

INTRODUCING THE IDYLLA™ POLE-POLD1 MUTATION ASSAY!

Qualitative detection of **17 POLE** pathogenic mutations across 4 exons:

- Exon 9: P286H, P286L, P286R, P286S, M295R, S297F
- Exon 11: F367S, F367V, D368Y
- Exon 13: V411L (G>C; G>T), L424I, L424V, P436R, M444K
- Exon 14: A456P, S459F

Additionally, **1 POLD1** mutation is detected in exon 12: S478N

Fully automated molecular testing platform
On-demand testing, without the need for sample batching

Under 3 minutes hands-on time
Assay turnaround time (TAT) of approx. **95 minutes**

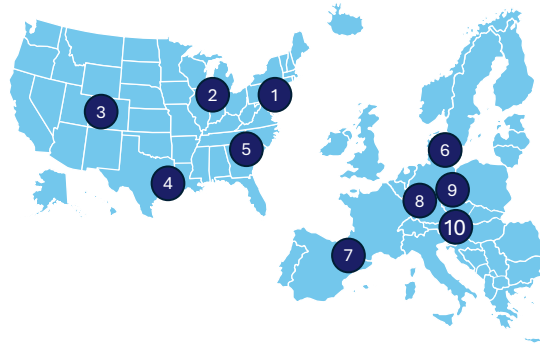
Directly from 1 **FFPE** tissue section

SPECIMEN REQUIREMENTS

- 50-600mm^2 tissue area for 5 µm FFPE tissue sections
- 25-300mm^2 tissue area for 10 µm FFPE tissue sections
- ≥ 10% neoplastic cells

A MULTI-CENTER STUDY HIGHLIGHTS THE ASSAY'S POTENTIAL IN ENDOMETRIAL CANCER RESEARCH

A retrospective, multi-center study was conducted to evaluate the Assay's potential by comparing it to NGS, Sanger of qPCR using a cohort of endometrial cancer samples[1] (Barault et al., 2024).



1: MSKCC (USA), 2: Compunet (USA); 3: CMOCO (USA); 4: Methodist (USA); 5: Augusta (USA); 6: Hvidovre (DK); 7: Arnau de Vilanova (ES); 8: Ludwigsburg (DE); 9: Kassel (DE); 10: Graz (AT)

IDYLLA™ DEMONSTRATED 98.6% ACCURACY WITH ENDOMETRIAL CANCER SAMPLES

434 tissue samples met all inclusion criteria[2] and generated valid results with Idylla™ and the reference methods.

Table 1. Aggregated results comparing Idylla™ and the reference methods.

		Reference methods		
		Mutated	Wild Type	Total
Idylla™	Mutated	175	2*	177
	Wild Type	4**	253	257
	Total	179	255	434

* 2/2 false positive results were potentially due to the use of a lower sensitivity reference method (Sanger).

** 4/4 false negative results were obtained with a low amount of amplifiable DNA.

Table 2. Concordance rates of Idylla™ with the reference methods.

	All samples (n=434)	Without low input samples (n=386)
PPA	97.7%	100%
NPA	99.2%	99.2%
OPA	98.6%	99.5%

PPA: positive percent agreement, NPA: negative percent agreement, OPA: overall percent agreement.

(1) The assay used during this prototype study included 12 POLE mutations. Five POLE mutations (L424V, F367V and P286H/L/S) as well as the POLD1 mutation (S478N) were added after data collection to increase mutation coverage.

(2) $\geq$ 10% tumor cells, $\geq$ 0.25 mm^3 tissue area.

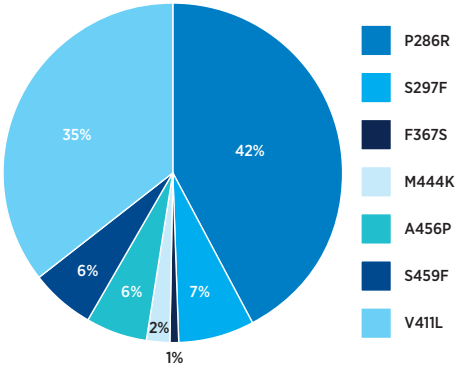


Figure 1. Distribution of the detected mutations for the 175 mutated samples[3].

CONCLUSION

Fully automated solution to detect 99% of the known pathogenic POLE and POLD1 mutations

Demonstrated 98.6% accuracy with 434 endometrial cancer tissue samples

The Idylla™ POLE-POLD1 Mutation Assay provides a rapid and reliable solution to close an important gap in oncology research by enabling molecular classification of endometrial cancer samples.

REFERENCES

Barault, L. et al. (2024). The Idylla™ POLE Mutation Assay, A New Tool For Direct Mutation Detection From FFPE Tissue. *AMP 2024 Annual Meeting*.

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
www.biocartis.com
customerservice@biocartis.com
customerserviceUS@biocartis.com

(3) Idylla™ reports the different mutations per exon.

WW.086.EN.N.03/2025