

BECAUSE
TIME MATTERS

IDYLLA™ POLE-POLD1 MUTATION ASSAY

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



THINK IDYLLA™
BECAUSE TIME MATTERS

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

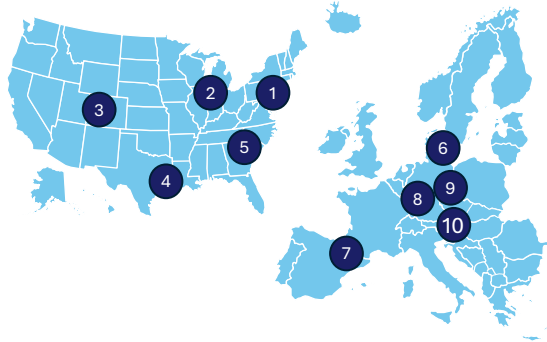
SPECIMEN REQUIREMENTS

- 50-600mm² tissue area for 5 µm FFPE tissue sections
- 25-300mm² 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 samples¹ (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 98.3% ACCURACY WITH ENDOMETRIAL CANCER SAMPLES

435 tissue samples met all inclusion criteria² 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	5**	253	258
	Total	180	255	435

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

** 4/5 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=435)	Without low input samples (n=387)
PPA	97.2%	99.3%
NPA	99.2%	99.1%
OPA	98.3%	99.2%

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) ≥ 10% tumor cells, ≥ 0.25 mm³ tissue area.

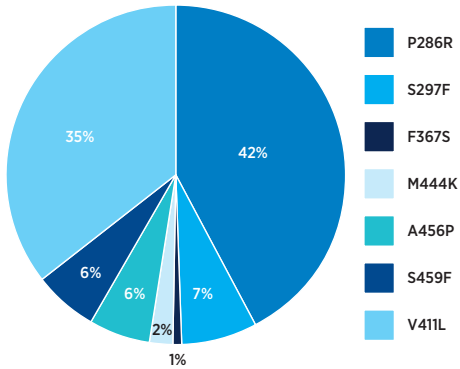


Figure 1. Distribution of the detected mutations for the 175 mutated samples³.

CONCLUSION



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



Demonstrated 98.3% accuracy with 435 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*.

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

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