

TECHNICAL SHEET IDYLLA™ POLE-POLD1 MUTATION ASSAY



The **Idylla™ POLE-POLD1 Mutation Assay** performed on the Biocartis Idylla™ System, is a fully automated real-time polymerase chain reaction (PCR) test. It qualitatively detects 17 point mutations in the POLE gene across 4 exons: **Exon 9:** P286H, P286L, P286R, P286S, M295R, S297F; **Exon 11:** F367S, F367V, D368Y; **Exon 13:** V411L (c.1231 G>C and c.1231 G>T), L424I, L424V, P436R, M444K; **Exon 14:** A456P, S459F. Additionally, the assay detects one mutation in the POLD1 gene exon 12: S478N.

The Idylla™ POLE-POLD1 Mutation Assay is optimized for use with **formalin-fixed, paraffin-embedded (FFPE) tissue specimens**. It covers the entire process from **sample to result**, including integrated sample preparation, nucleic acid liberation, real-time PCR amplification and detection, data analysis, and result reporting.

FEATURES

POLE mutation detection		
Exon 9	P286H	c.857C>A
	P286L	c.857C>T
	P286S	c.856C>T
	P286R	c.857C>G
	M295R	c.884T>G
	S297F	c.890C>T
Exon 11	F367S	c.1100T>C
	F367V	c.1099T>G
	D368Y	c.1102G>T
Exon 13	V411L	c.1231G>C
	V411L	c.1231G>T
	L424I	c.1270C>A
	L424V	c.1270C>G
	P436R	c.1307C>G
	M444K	c.1331T>A
Exon 14	A456P	c.1366G>C
	S459F	c.1376C>T
POLD1 mutation detection		
Exon 12	S478N	c.1433G>A

Minimum specimen requirements

Sample type	1 x 5 µm FFPE tissue section if tissue area 50-600 mm ² 1 x 10 µm FFPE tissue section if tissue area 25-300 mm ²
Neoplastic cells	≥10%, if less, macrodissection is required

Total turnaround time

Time	Approx. 95 min
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Catalog number

Idylla™ POLE-POLD1 Mutation Assay	A0281/6
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