

TECHNICAL SHEET IDYLLA™ IDH1-2 MUTATION ASSAY KIT

The Idylla™ IDH1-2 Mutation Assay Kit performed on the Biocartis Idylla™ System, is a fully automated in vitro diagnostic assay for the qualitative detection of five IDH1 mutations in codon R132, four IDH2 mutations in codon R140 and six IDH2 mutations in codon R172.

The Idylla™ IDH1-2 Mutation Assay Kit uses extracted DNA from blood (EDTA) or human bone marrow (EDTA) from patients with Acute Myeloid Leukemia (AML) or DNA extracted from FFPE tissue from patients with glioma. The Kit is also compatible with FFPE samples from patients with glioma. The Assay is a **sample-to-result** real-time PCR, intended for research use only.

FEATURES

IDH1 Mutation Detection		
Codon 132	R132C	c.394C>T
	R132H	c.395G>A
	R132G	c.394C>G
	R132S	c.394C>A
	R132L	c.395G>T
IDH2 Mutation Detection		
Codon 140	R140Q	c.419G>A
	R140L	c.419G>T
	R140G	c.418C>G
	R140W	c.418C>T
Codon 172	R172K	c.515G>A
	R172M	c.515G>T
	R172G	c.514A>G
	R172S	c.516G>T
	R172S	c.516G>C
	R172W	c.514A>T



Specimen requirements	
Sample Type	Extracted DNA: 50 µl (concentration 10 µl/g)
	OR
	FFPE: It is recommended to use maximum 3 FFPE tissue sections.
Neoplastic cells	Extracted DNA: DNA should be extracted from samples with \geq 10% neoplastic cells. If less, an enrichment procedure is required.
	OR
	FFPE: ≥ 10% neoplastic cells. If less, macro-dissection is required.

Supported blood and bone marrow collection tubes

EDTA tubes

Total turnaround time	
Time	95 minutes
Result reporting	
Report	Qualitative genotype call + Cq Value
Catalog numbers	
Idylla™ IDH1-2 Mutation Assay (Vial)	A0181/6
ldylla™ DNA Cartridge	A0191/6

The Idylla™ IDH1-2 Mutation Assay Kit consists of a Cartridge and a Vial.



 $Idylla^{\mathsf{IM}} \mathsf{IDH1-2} \, \mathsf{Mutation} \, \mathsf{Assay} \, \mathsf{Kit} \, \mathsf{is} \, \mathsf{for} \, \mathsf{Research} \, \mathsf{Use} \, \mathsf{Only} \, (\mathsf{RUO}), \, \mathsf{not} \, \mathsf{for} \, \mathsf{use} \, \mathsf{in} \, \mathsf{diagnostic} \, \mathsf{procedures}. \, \mathsf{Idylla^{\mathsf{IM}}} \, \mathsf{Platform} \, \mathsf{is} \, \mathsf{available} \, \mathsf{as} \, \mathsf{an} \, \mathsf{IVD} \, \mathsf{in} \, \mathsf{Europe}, \, \mathsf{the} \, \mathsf{US} \, \mathsf{and} \, \mathsf{many} \, \mathsf{other} \, \mathsf{countries}. \, \mathsf{Biocartis} \, \mathsf{and} \, \mathsf{Idylla^{\mathsf{IM}}} \, \mathsf{arg} \, \mathsf{ergistered} \, \mathsf{trademarks} \, \mathsf{in} \, \mathsf{Europe}, \, \mathsf{the} \, \mathsf{US} \, \mathsf{and} \, \mathsf{many} \, \mathsf{other} \, \mathsf{countries}. \, \mathsf{The} \, \mathsf{Biocartis} \, \mathsf{and} \, \mathsf{Idylla^{\mathsf{IM}}} \, \mathsf{trademarks} \, \mathsf{and} \, \mathsf{logos} \, \mathsf{are} \, \mathsf{used} \, \mathsf{trademarks} \, \mathsf{owned} \, \mathsf{by} \, \mathsf{Biocartis}. \, \mathsf{Biocartis} \, \mathsf{and} \, \mathsf{logos} \, \mathsf{are} \, \mathsf{used} \, \mathsf{trademarks} \, \mathsf{owned} \, \mathsf{by} \, \mathsf{Biocartis}. \, \mathsf{and} \, \mathsf{logos} \, \mathsf{are} \, \mathsf{used} \, \mathsf{trademarks} \, \mathsf{owned} \, \mathsf{by} \, \mathsf{Biocartis}. \, \mathsf{and} \, \mathsf{logos} \, \mathsf{are} \, \mathsf{used} \, \mathsf{logos} \, \mathsf{are} \, \mathsf{logos} \, \mathsf{log$

 $IdyIla^{M}$ is available for sale in Europe, the US and many other countries. Please check availability with the local Biocartis representative. © July 2023, Biocartis NV. All rights reserved.

