THE IDYLLA™ MENU

Gene content selected from relevant industry guidelines, key opinion leaders, and pharmaceutical research.

		Catalog # for solid biopsies	Catalog # for liquid biopsies
IVD Tests[1]			
MSI (510(k))	Microsatellite instability detection at 7 MSI loci	A0160/6	
MSI-CDx (PMA)		A0220/6	
RUO Assays[2]			
EGFR	46 mutations in EGFR exons 18, 19, 20 and 21	A0061/6	
	49 mutations in EGFR exons 18, 19, 20 and 21		A0111/6
GeneFusion	ALK, ROS1, RET, NTRK1/2/3 fusions & MET Exon 14 skipping	A0121/6	
BRAF	7 mutations in BRAF exon 15	A0011/6	
KRAS	21 mutations in KRAS exons 2, 3 and 4	A0021/6	A0081/6
NRAS–BRAF[3]	23 mutations in NRAS exons 2, 3, 4 and BRAF exon 15	A0031/6	A0091/6
MSI	Microsatellite instability detection at 7 MSI loci	A0101/6	
POLE-POLD1	17 mutations in *POLE* gene and 1 mutation in *POLD1* gene	A0281/6	
IDH1-2[4]	5 mutations in *IDH1* gene and 10 mutations in *IDH2* gene	A0181/6 (Vial) A0191/6 (Cartridge)	
PIK3CA-AKT1	13 mutations in *PIK3CA* gene and 1 mutation in *AKT1* gene	A0171/6	

(1) For in vitro diagnostic use.
(2) For Research Use Only. Not for use in diagnostic procedures.
(3) Included in the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay.
(4) The Idylla™ IDH1-2 Mutation Assay Kit consists of a Cartridge and a Vial.

THE IDYLLA™ SYSTEM. BUILT FOR YOUR NEEDS.

Idylla™ is a revolutionary, fully automated system that makes molecular testing convenient, affordable and fast.
Idylla™ delivers accurate results from a minimal amount of specimen and is suitable for any lab.



CONTACT US

REQUEST A DEMO

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BIOCARTIS

Idylla™ System is listed as a class II device in the US under establishment registration 3009972873. Idylla™ MSI Test (A0160/6) is cleared in the US under K211181 for Lynch Syndrome. Idylla™ CDx MSI Test (A0220/6) is approved in the US under P250005. Idylla™ EGFR, ctEGFR, BRAF, KRAS, ctKRAS, NRAS-BRAF-EGFR S492R, ctNRAS-BRAF-EGFR S492R, POLE-POLD1 & PIK3CA-AKT1 Mutation Assays; Idylla™ GeneFusion & MSI Assays; and Idylla™ IDH1-2 Mutation Assay Kit are for Research Use Only, not for use in diagnostic procedures. For more information on the acceptable use and licenses of Idylla™ products, please visit www.biocartis.com/en/license-statements. 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.
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