

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 Tests¹			
MSI (510(k))	Microsatellite Instability detection at 7 MSI loci	 A0160/6	
MSI-CDx (PMA)		 A0220/6	
RUO Assays²			
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
POLE-POLD1	17 mutations in <i>POLE</i> gene and 1 mutation in <i>POLD1</i> gene	 A0281/6	
IDH1-2 ⁴	5 mutations in <i>IDH1</i> gene and 10 mutations in <i>IDH2</i> gene	 A0181/6 (Vial)  A0191/6 (Cartridge)	
PIK3CA-AKT1	13 mutations in <i>PIK3CA</i> gene and 1 mutation in <i>AKT1</i> 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.



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**REQUEST
A DEMO**



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Idylla™ Platform 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 Assay; 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.

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