IDYLLA™ SPECIMEN REQUIREMENTS

One of the biggest challenges in oncology biomarker testing is the ability to obtain samples of sufficient size and quality. The Idylla™ System only needs a minimal amount of sample.

SOLID BIOPSY SPECIMEN REQUIREMENTS

IVD Tests		
	**MSI 510(k)**	1 x 4 µm FFPE tissue section → 62.5-750 mm^2 1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥ 33% - if less, macrodissection is required
	MSI-CDx (PMA)	1 x 4 µm FFPE tissue section → 62.5-750 mm^2 1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥ 33% - if less, macrodissection is required
RUO Assays		
	EGFR	1 x 5 µm FFPE tissue section → ≥ 1 mm^2 Neoplastic cells ≥10% - if less, macrodissection is required
	GeneFusion	1 x 5 µm FFPE tissue section → ≥ 20 mm^2 3 x 5 µm FFPE tissue sections → < 20 mm^2 Neoplastic cells ≥ 10% - if less, macrodissection is required
	BRAF	1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥50% - if less, macrodissection is required
	**KRAS** **NRAS-BRAF-EGFR S492R**	1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥10% - if less, macrodissection is required
	POLE-POLD1	1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥ 10% - if less, macrodissection is required
	IDH1-2	50 µl extracted DNA (concentration ≥ 10 ng/µl) 10 µl blood or bone marrow Maximum 3 FFPE tissue sections Neoplastic cells ≥ 10% - if less, macrodissection is required
	PIK3CA-AKT1	1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 Neoplastic cells ≥ 20% - if less, macrodissection is required

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LIQUID BIOPSY SPECIMEN REQUIREMENTS[1]

RUO Assays	
ctEGFR	2 ml plasma collected using EDTA tubes
ctKRAS **ctNRAS-BRAF-EGFR S492R**	1 ml plasma collected using either EDTA or Streck tubes

(1) K_2EDTA tubes: process within 4 hours. Streck Cell-Free DNA BCT® Tubes: process within 3 days.

Please refer to the product instructions for complete instructions on how to process samples on Idylla™.

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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