

SPECIMEN REQUIREMENTS

IDYLLA™ IN VITRO DIAGNOSTIC TESTS



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

Minimum Tissue Specimen Requirements

	EGFR	IVDR	2 x 5-10 µm FFPE tissue sections Neoplastic cells ≥ 20% - if less, macrodissection is required
	EGFR	IVDD	1 x 5 µm FFPE tissue section Neoplastic cells ≥ 10% - if less, macrodissection is required
	GeneFusion	IVDD	1 x 5 µm FFPE tissue section if tissue area ≥ 20 mm ² 3 x 5 µm FFPE tissue sections if tissue area < 20 mm ² Neoplastic cells ≥ 10% - if less, macrodissection is required
	BRAF	IVDD	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	IVDD IVDD	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
	MSI	IVDD	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



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



Idylla™ EGFR Mutation Test (A0270/6) is CE-marked in Europe in compliance with the EU IVD Regulation 2017/746 (IVDR). Idylla™ EGFR (A0060/6), BRAF, KRAS, NRAS-BRAF Mutation Tests, Idylla™ GeneFusion Panel and Idylla™ MSI Test are CE-marked in Europe in compliance with the EU IVD Directive 98/79/EC. 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. © May 2025, Biocartis NV. All rights reserved.