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		
	KRAS NRAS-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 ≥ 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
	EGFR	1 x 5 µm FFPE tissue section Neoplastic cells ≥ 10% - if less, macrodissection is required
	GeneFusion	1 x 5 μm FFPE tissue section if tissue area \ge 20 mm ² 3 x 5 μm FFPE tissue sections if tissue area < 20 mm ² Neoplastic cells \ge 10% - if less, macrodissection is required
	MSI	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™. OUS.FL026.EN.R5.05/2022