

SPECIMEN REQUIREMENTS IDYLLA™ RESEARCH ASSAYS



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

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, macro-dissection 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, macro-dissection is required
EGFR	1 x 5 µm FFPE tissue section
	Neoplastic cells ≥ 10% - if less, macro-dissection is required
GeneFusion	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, macro-dissection 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, macro-dissection is required
IDH1-2	Extracted DNA: 50 µl (concentration ≥ 10 ng/µl)
	Blood & Bone Marrow: 10 µl
	FFPE: maximum 3 FFPE tissue sections
	Neoplastic cells ≥ 10% - if less, macro-dissection is required
PIK3CA-AKT1	1 x 5 µm FFPE tissue section if tissue area 50-600 mm ²
	1 x 10 µm FFPE tissue section if tissue area 25-300 mm ²
	Neoplastic cells ≥ 20% - if less, macro-dissection is required



Fine Needle Aspirate (FNA) Specimen Requirements



ThyroidPrint

FNA from an indeterminate thyroid nodule collected in ThyroidPrint® Collection Buffer

Liquid Biopsy Specimen Requirements*



ctKRAS

ctNRAS-BRAF-EGFR S492R

1 ml plasma collected using either EDTA or Streck tubes

ctEGFR

2 ml plasma collected using EDTA tubes

***NOTE:**

1. K₂EDTA tubes: process within 4 hours
2. Streck Cell-free BCTs: process within 3 days



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

Idylla™ KRAS, NRAS-BRAF-EGFR S492R, BRAF, EGFR, PIK3CA-AKT1, ctKRAS, ctNRAS-BRAF-EGFR S492R and ctEGFR Mutation Assays; Idylla™ GeneFusion, MSI and ThyroidPrint® Assays; and Idylla™ IDH1-2 Mutation Assay Kit are available for Research Use Only and are not for use in diagnostic procedures.

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