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	
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 ≥ 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	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
MSI	1 x 5 µm FFPE tissue section → 50-600 mm^2 1 x 10 µm FFPE tissue section → 25-300 mm^2 CRC: Neoplastic cells ≥ 20% - if less, macrodissection is required EC: Neoplastic cells ≥ 40% - 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	Extracted DNA: 50 µl (concentration ≥ 10 ng/µl) Blood & Bone Marrow: 10 µl FFPE: maximum 3 FFPE tissue sections Neoplastic cells ≥ 10% - if less, macrodissection 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, macrodissection is required

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Liquid Biopsy Specimen Requirements*

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

*NOTE:
1. K_2EDTA tubes: process within 4 hours
2. 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 CE-marked in Europe in compliance with EU IVD Regulation 2017/746. Idylla™ EGFR, ctEGFR, BRAF, KRAS, ctKRAS, NRAS-BRAF-EGFR S492R, ctNRAS-BRAF-EGFR S492R, POLE-POLD1 & PIK3CA-AKT1 Mutation Assays; Idylla™ MSI & GeneFusion Assays; and Idylla™ IDH1-2 Mutation Assay Kit are available for Research Use Only (RUO), not for use in diagnostic procedures. Idylla™ is available for sale in Europe, the US and many other countries. Please check availability with a Biocartis representative. 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. © November 2026, Biocartis NV. All rights reserved.

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