

# 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



<b>EGFR</b>	<b>IVDR</b>	2 x 5-10 µm FFPE tissue sections Neoplastic cells ≥ 20% - if less, macrodissection is required
<b>EGFR</b>	<b>IVDD</b>	1 x 5 µm FFPE tissue section Neoplastic cells ≥ 10% - if less, macrodissection is required
<b>GeneFusion</b>	<b>IVDD</b>	1 x 5 µm FFPE tissue section if tissue area ≥ 20 mm <sup>2</sup> 3 x 5 µm FFPE tissue sections if tissue area < 20 mm <sup>2</sup> Neoplastic cells ≥ 10% - if less, macrodissection is required
<b>BRAF</b>	<b>IVDD</b>	1 x 5 µm FFPE tissue section → 50-600 mm <sup>2</sup> 1 x 10 µm FFPE tissue section → 25-300 mm <sup>2</sup> Neoplastic cells ≥ 50% - if less, macrodissection is required
<b>KRAS</b> <b>NRAS-BRAF</b>	<b>IVDD</b> <b>IVDD</b>	1 x 5 µm FFPE tissue section → 50-600 mm <sup>2</sup> 1 x 10 µm FFPE tissue section → 25-300 mm <sup>2</sup> Neoplastic cells ≥ 10% - if less, macrodissection is required
<b>MSI-CDx</b>	<b>IVDR</b>	1 x 4 µm FFPE tissue section → 62.5-750 mm <sup>2</sup> 1 x 5 µm FFPE tissue section → 50-600 mm <sup>2</sup> 1 x 10 µm FFPE tissue section → 25-300 mm <sup>2</sup> Neoplastic cells ≥ 33% - if less, macrodissection is required
<b>MSI</b>	<b>IVDD</b>	1 x 5 µm FFPE tissue section → 50-600 mm <sup>2</sup> 1 x 10 µm FFPE tissue section → 25-300 mm <sup>2</sup> Neoplastic cells ≥ 20% - if less, macrodissection is required





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

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