BIOCARTIS

NOTHING
IS SIMPLE
IN ONCOLOGY.

NOTHING BUT THIS.



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Idylla™ A revolutionary,
fully automated system that makes
molecular testing convenient and fast.
Suitable for any lab.

WE AIM
TO PROVIDE
RAPID ACCESS
TO HIGH-LEVEL
MOLECULAR TESTING
ANYTIME,
ANYWHERE.

THE IDYLLA™ SOLUTION - MOLECULAR TESTING SUITABLE FOR VIRTUALLY ANY LAB.

Fully automated walk-away System.

Fast Assay turnaround times.
Between 90-180 minutes.

Low amount of sample needed.

High accuracy and reproducibility*
Highly standardized technology.

Closed ready-to-use desktop System.
Small footprint and low consumable costs.



THE IDYLLA™ SYSTEM. BUILT FOR YOUR NEEDS.

Idylla™ is a modular instrument ready to accommodate your lab's throughput even as it changes over the years.

*For Idylla™ IVD Tests.

IDYLLA™ FITS ANY SIZE LAB

IDYLLA™ IS A COST-EFFECTIVE IN-HOUSE SOLUTION EVEN FOR SMALL SAMPLE VOLUMES

- Easy to implement and maintain
- No molecular infrastructure needed
- No batching needed

IDYLLA™ PROVIDES AN ULTRA-RAPID ACTIONABLE SOLUTION COMPLEMENTING COMPREHENSIVE NGS PROGRAMS

- Short turnaround time and minimal hands-on time
- Minimal sample input requirements
- On-demand testing
- Seamless integration into virtually any laboratory workflow



THE REVOLUTIONARY IDYLLA™ WORKFLOW

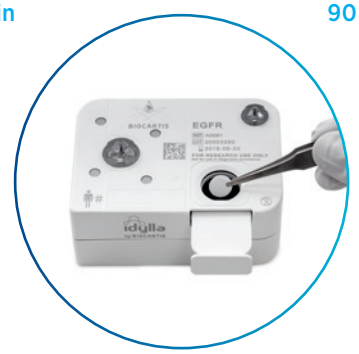
STANDARD SOLID BIOPSY WORKFLOW

< 3 min

90 - 180 min



SAMPLE PREPARATION



SAMPLE LOADING



AUTOMATED PROCESSING & ANALYSIS

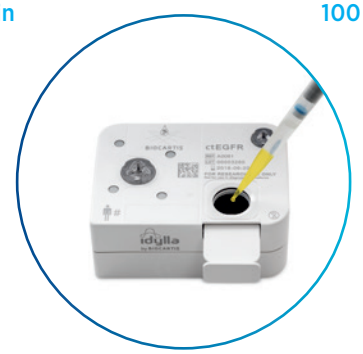
LIQUID BIOPSY WORKFLOW

< 1 min

100 - 160 min



PLASMA PREPARATION PROTOCOL ±20 MIN



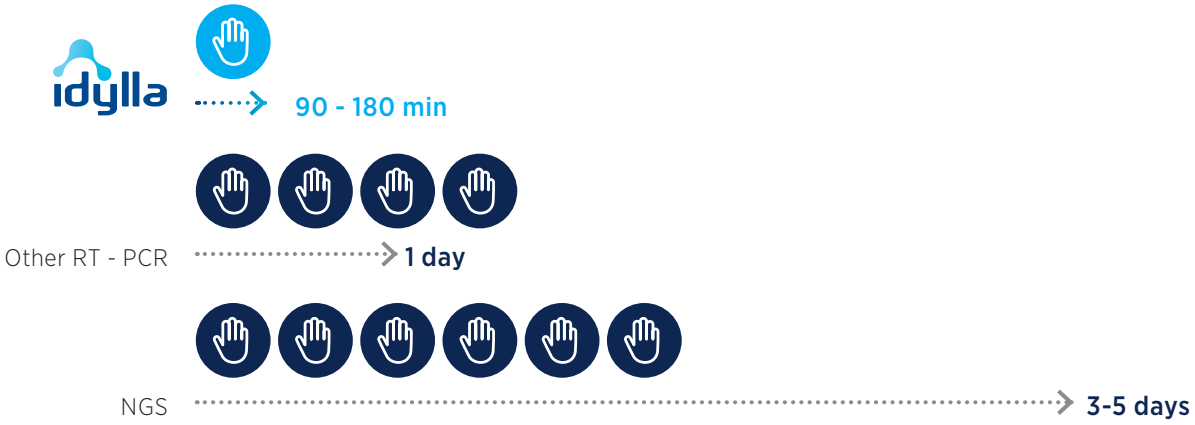
SAMPLE LOADING



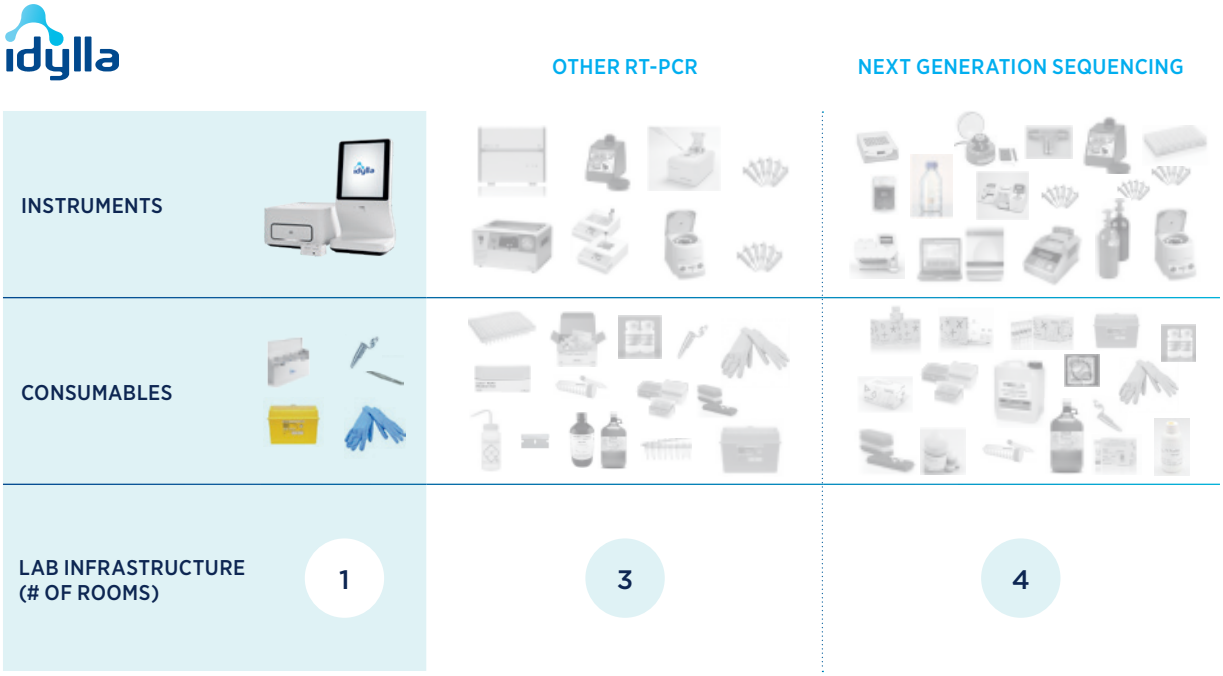
AUTOMATED PROCESSING & ANALYSIS

IDYLLA™ COMPARED TO OTHER TECHNOLOGIES

MINIMAL HANDS-ON AND ASSAY TURNAROUND TIMES



REDUCED NUMBER OF INSTRUMENTS AND CONSUMABLES NEEDED



Based on workflow exercise in real-life laboratory setting. Reference technologies used: Illumina MiSeq® and Qiagen Therascreen®.

THE IDYLLA™ ASSAYS. MINIMAL SAMPLE REQUIREMENTS AND VERSATILE SAMPLE TYPES.

SOLID BIOPSY SPECIMEN REQUIREMENTS

IVD TESTS

MSI (510(k))	• 1 x 4 µm FFPE tissue section • 1 x 5 µm FFPE tissue section • 1 x 10 µm FFPE tissue section • Neoplastic cells ≥ 33% - if less, macrodissection is required	→ 62.5-750 mm^2 → 50-600 mm^2 → 25-300 mm^2
MSI-CDx (PMA)	• 1 x 4 µm FFPE tissue section • 1 x 5 µm FFPE tissue section • 1 x 10 µm FFPE tissue section • Neoplastic cells ≥ 33% - if less, macrodissection is required	→ 62.5-750 mm^2 → 50-600 mm^2 → 25-300 mm^2

RUO ASSAYS

EGFR	• 1 x 5 µm FFPE tissue section • Neoplastic cells ≥ 10% - if less, macrodissection is required	→ ≥ 1 mm^2
GeneFusion	• 1 x 5 µm FFPE tissue section • 3 x 5 µm FFPE tissue sections • Neoplastic cells ≥ 10% - if less, macrodissection is required	→ 20-100 mm^2 → < 20 mm^2
BRAF	• 1 x 5 µm FFPE tissue section • 1 x 10 µm FFPE tissue section • Neoplastic cells ≥ 50% - if less, macrodissection is required	→ 50-600 mm^2 → 25-300 mm^2
KRAS, NRAS-BRAF-EGFR S492R	• 1 x 5 µm FFPE tissue section • 1 x 10 µm FFPE tissue section • Neoplastic cells ≥ 10% - if less, macrodissection is required	→ 50-600 mm^2 → 25-300 mm^2
MSI	• 1 x 5 µm FFPE tissue section • 1 x 10 µm FFPE tissue section • CRC: Neoplastic cells ≥ 20% - if less, macrodissection is required • EC: Neoplastic cells ≥ 40% - if less, macrodissection is required	→ 50-600 mm^2 → 25-300 mm^2
POLE-POLD1	• 1 x 5 µm FFPE tissue section • 1 x 10 µm FFPE tissue section • Neoplastic cells ≥ 10% - if less, macrodissection is required	→ 50-600 mm^2 → 25-300 mm^2
IDH1-2	• 50 µl extracted DNA (concentration ≥ 10 ng/µl) • 10 µl blood or bone marrow • Maximum 3 FFPE tissue sections • Neoplastic cells ≥ 10% - if less, macrodissection is required	
PIK3CA-AKT1	• 1 x 5 µm FFPE tissue section • 1 x 10 µm FFPE tissue section • Neoplastic cells ≥ 20% - if less, macrodissection is required	→ 50-600 mm^2 → 25-300 mm^2

LIQUID BIOPSY SPECIMEN REQUIREMENTS

RUO ASSAYS

- 1 or 2 ml plasma (depending on Assay) and two validated tube types:



K^2EDTA tubes
process within 4 hours



Streck Cell-Free DNA BCT® Tubes
process within 3 days

- Used in the following Idylla™ Assays: Idylla™ ctKRAS, ctEGFR and ctNRAS-BRAF-EGFR S492R Mutation Assays (RUOs)



CONTACT US

REQUEST A DEMO

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Idylla™ System is listed as a class II device in the US under establishment registration 3009972873. Idylla™ MSI Test (A0160/6) is cleared in the US under K211181 for Lynch Syndrome. Idylla™ CDx MSI Test (A0220/6) is approved in the US under P250005. Idylla™ EGFR, ctEGFR, BRAF, KRAS, ctKRAS, NRAS-BRAF-EGFR S492R, ctNRAS-BRAF-EGFR S492R, POLE-POLD1 & PIK3CA-AKT1 Mutation Assays; Idylla™ GeneFusion & MSI Assay; and Idylla™ IDH1-2 Mutation Assay Kit are for Research Use Only, not for use in diagnostic procedures. 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.
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