

NOTHING
IS SIMPLE
IN ONCOLOGY.
NOTHING
BUT
THIS.



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

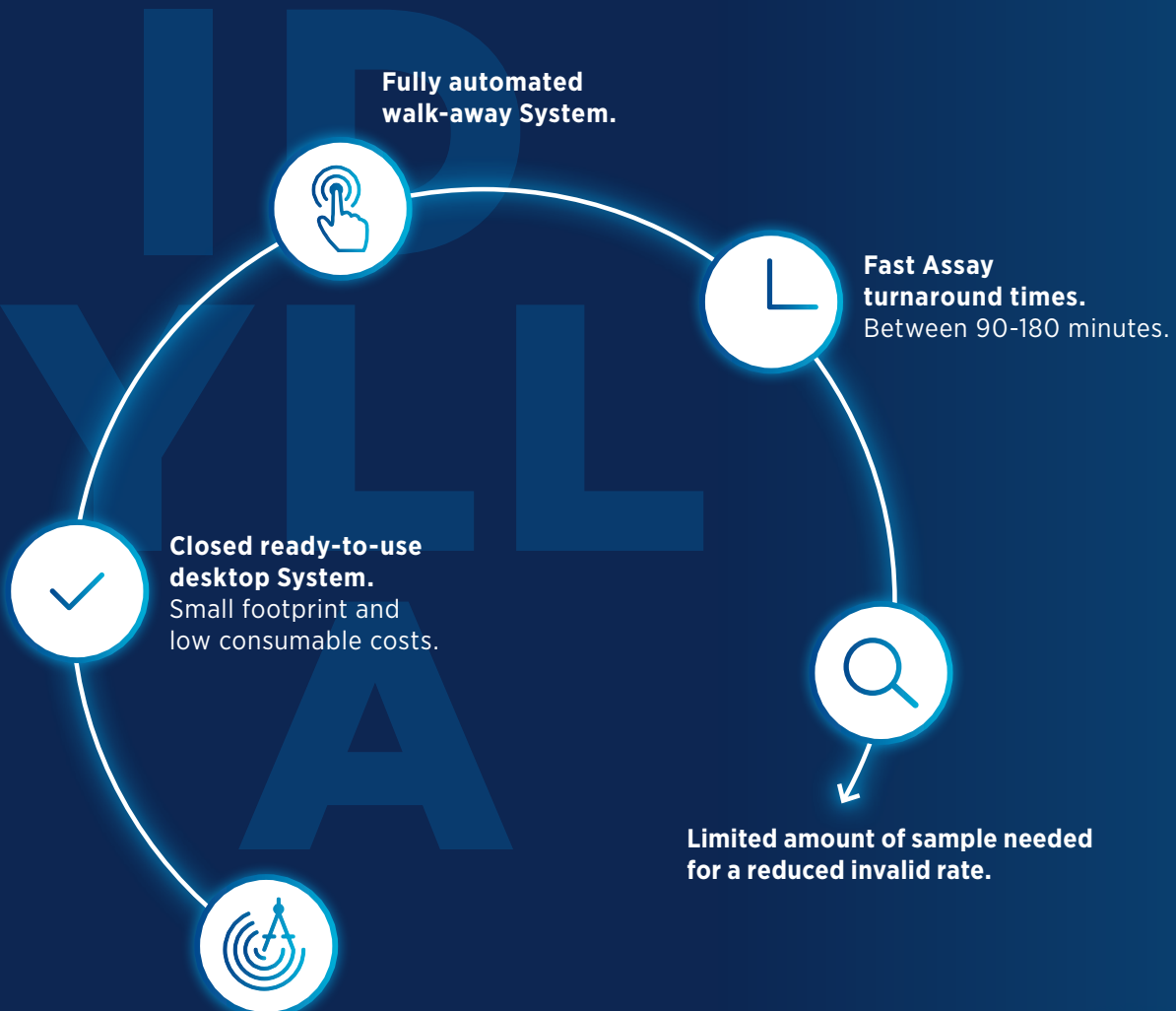
biocartis.com/us





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

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



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.

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
- No external controls needed



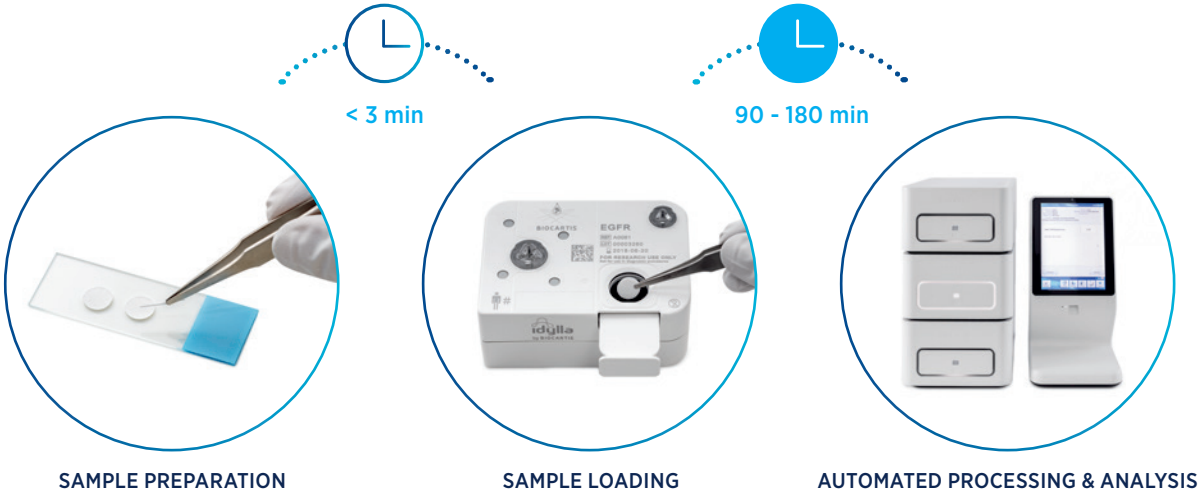
IDYLLA™ PROVIDES AN ULTRA-RAPID ACTIONABLE SOLUTION COMPLEMENTING COMPREHENSIVE NGS PROGRAMS

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

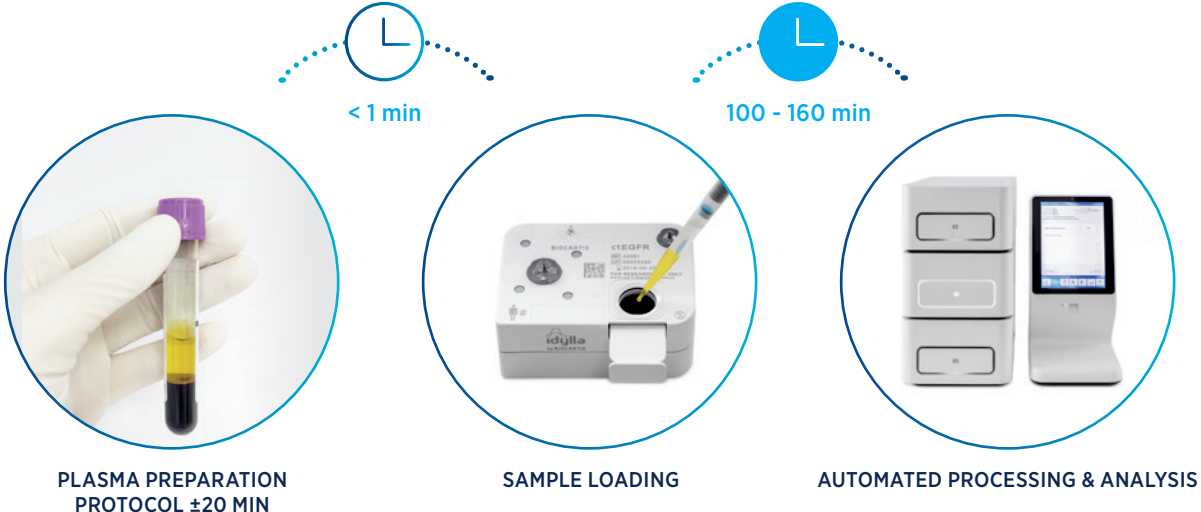


THE REVOLUTIONARY IDYLLA™ WORKFLOW

STANDARD SOLID BIOPSY WORKFLOW



LIQUID BIOPSY WORKFLOW



IDYLLA™ COMPARED TO OTHER TECHNOLOGIES

MINIMAL HANDS-ON AND ASSAY TURNAROUND TIMES



REDUCED NUMBER OF INSTRUMENTS AND CONSUMABLES NEEDED

	idylla	OTHER RT-PCR	NEXT GENERATION SEQUENCING
INSTRUMENTS			
CONSUMABLES			
LAB INFRASTRUCTURE (# OF ROOMS)	1	3	4

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 62.5 – 750 mm²
- 1 x 5 µm FFPE tissue section 50 – 600 mm²
- 1 x 10 µm FFPE tissue section 25 – 300 mm²
- Neoplastic cell content ≥ 33%
- If < 33%, macrodissection needed

RUO ASSAYS

EGFR

- 1 x 5 µm FFPE tissue section ≥ 1 mm²
- Neoplastic cell content ≥ 10%
- If < 10%, macrodissection needed

GeneFusion

- 1 x 5 µm FFPE tissue section 20 - 100 mm²
- 3 x 5 µm FFPE tissue section < 20 mm²
- Neoplastic cell content ≥ 10%
- If < 10%, macrodissection needed

KRAS, NRAS-BRAF-EGFR S492R

- 1 x 5 µm FFPE tissue section 50 – 600 mm²
- 1 x 10 µm FFPE tissue section 25 – 300 mm²
- Neoplastic cell content ≥ 10%
- If < 10%, macrodissection needed

BRAF

- 1 x 5 µm FFPE tissue section 50 – 600 mm²
- 1 x 10 µm FFPE tissue section 25 – 300 mm²
- Neoplastic cell content ≥ 50%
- If < 50%, macrodissection needed

IDH1-2

- Extracted DNA: 50 µl (concentration > 10 ng/µl)
DNA should be extracted from samples with a neoplastic cell content ≥ 10%
- If < 10%, enrichment procedure needed
- FFPE: It is recommended to use maximum 3 FFPE tissue sections.
Neoplastic cell content ≥ 10%
- If < 10%, macrodissection needed

PIK3CA-AKT1

- 1 x 5 µm FFPE tissue section 50-600 mm²
- 1 x 10 µm FFPE tissue section 25-300 mm²
- Neoplastic cell content ≥ 20%
- If < 20%, macrodissection needed



LIQUID BIOPSY SPECIMEN REQUIREMENTS

RUO ASSAYS

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



K²EDTA tubes

process within 4 hours



Streck Cell-free DNA BCTs

process within 3 days

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



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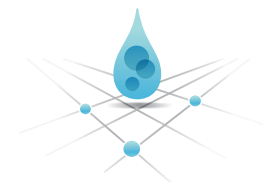
Idylla™ MSI Test and Idylla™ System are cleared in the US under K211181.

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

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