

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.

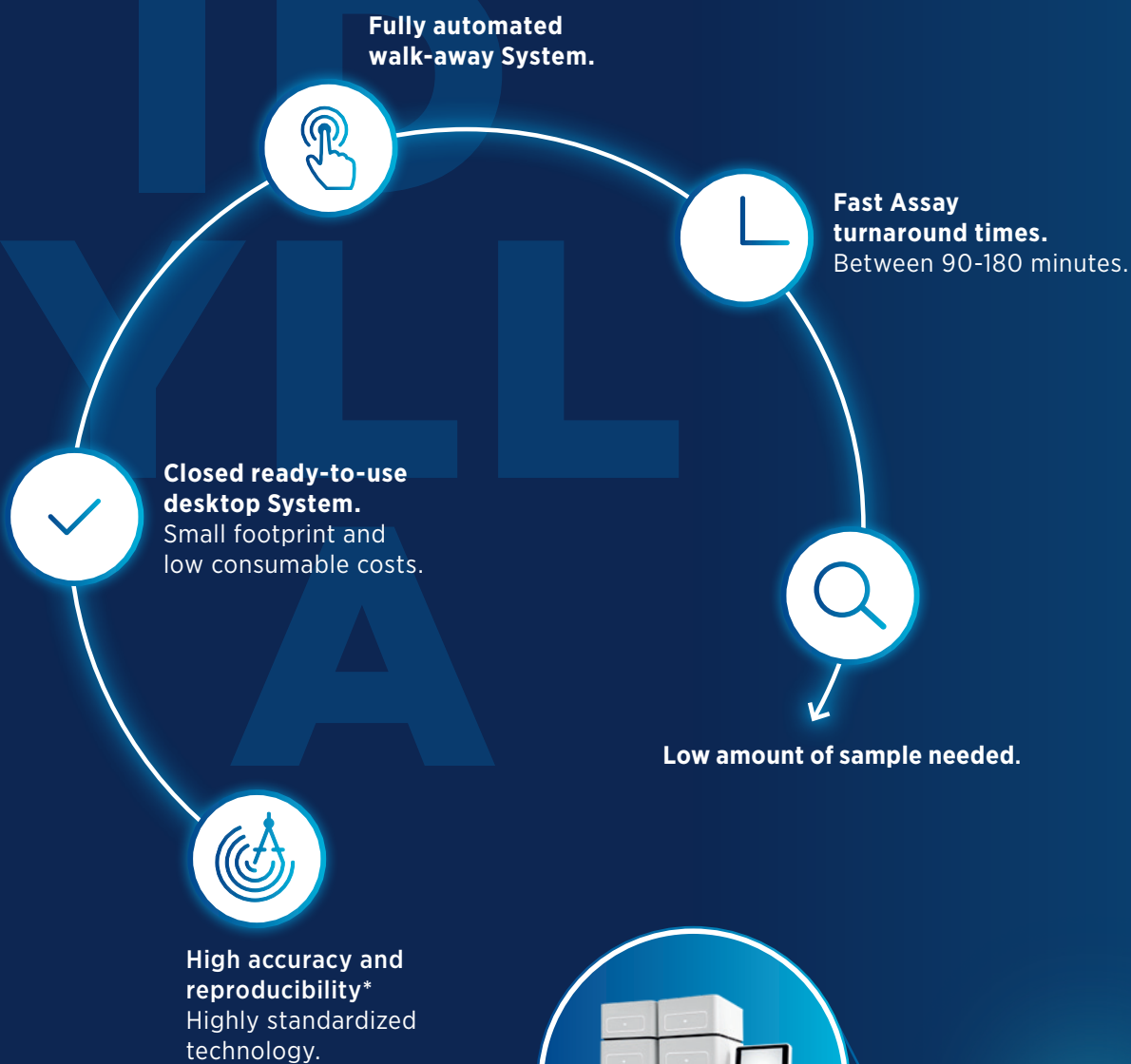
[biocartis.com/us](https://biocartis.com/us)





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.



\*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



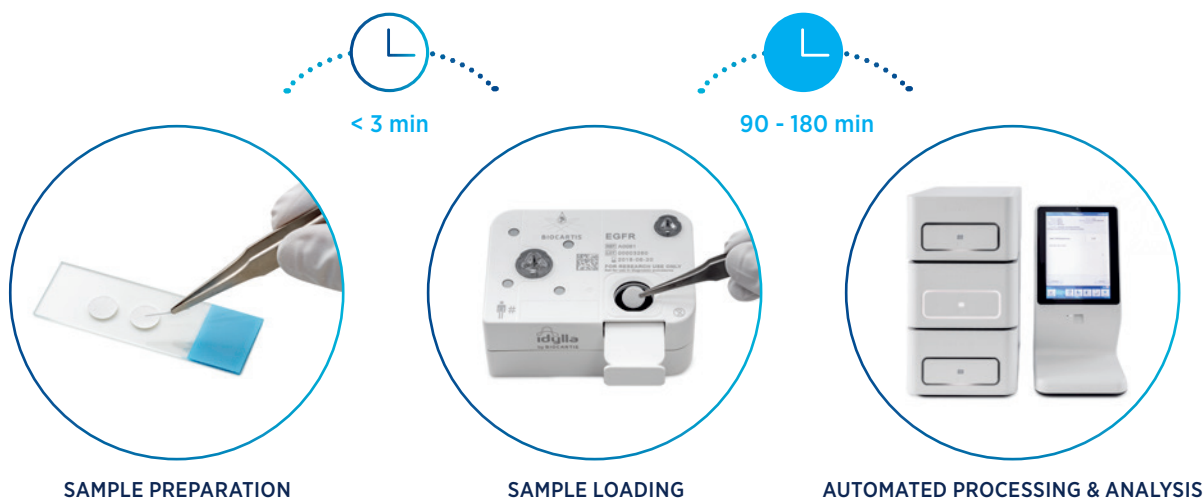
### **IDYLLA™ PROVIDES AN ULTRA-RAPID ACTIONABLE SOLUTION COMPLEMENTING COMPREHENSIVE NGS PROGRAMS**

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

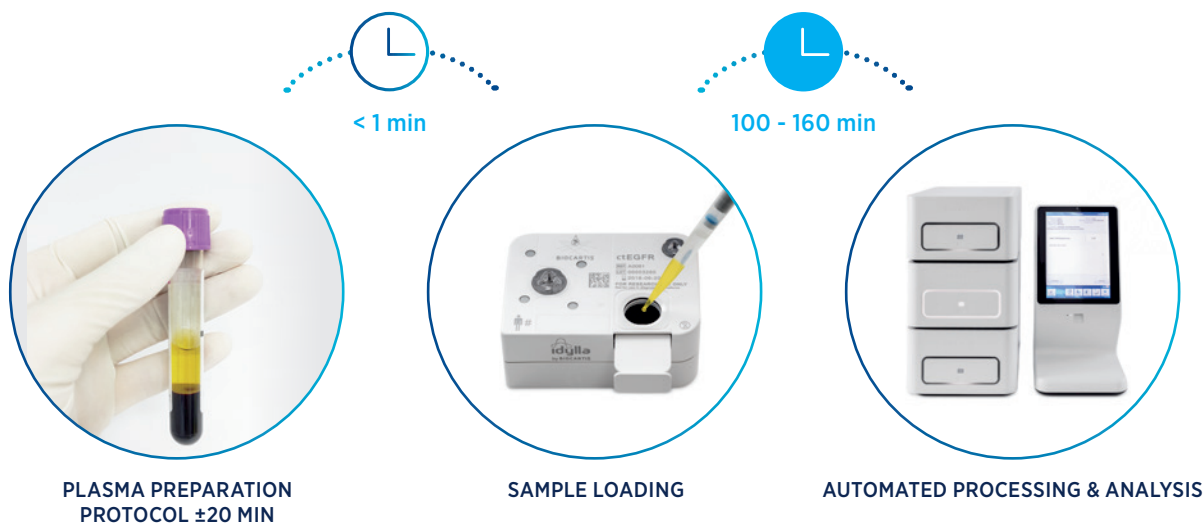


# THE REVOLUTIONARY IDYLLA™ WORKFLOW

## STANDARD SOLID BIOPSY WORKFLOW

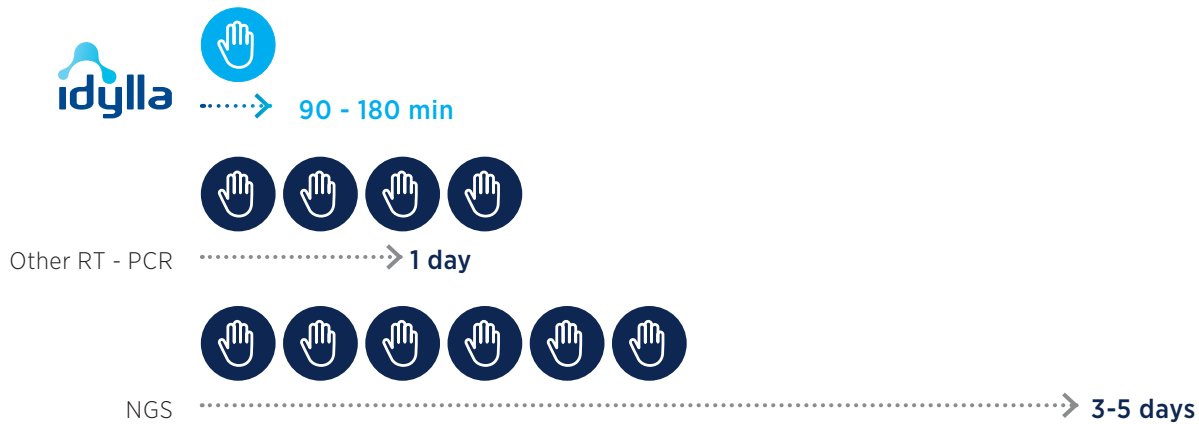


## LIQUID BIOPSY WORKFLOW










# IDYLLA™ COMPARED TO OTHER TECHNOLOGIES

## MINIMAL HANDS-ON AND ASSAY TURNAROUND TIMES



## REDUCED NUMBER OF INSTRUMENTS AND CONSUMABLES NEEDED

	OTHER RT-PCR	NEXT GENERATION SEQUENCING
<b>INSTRUMENTS</b> 		
<b>CONSUMABLES</b> 		
<b>LAB INFRASTRUCTURE (# OF ROOMS)</b> <div data-bbox="487 1690 568 1774">1</div>	<div data-bbox="771 1690 852 1774">3</div>	<div data-bbox="1161 1690 1242 1774">4</div>

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 TEST

#### MSI 510(k)

- 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 cell content ≥ 33%
- If < 33%, macrodissection needed

### RUO ASSAYS

#### EGFR

- 1 x 5 µm FFPE tissue section ≥ 1 mm<sup>2</sup>
- Neoplastic cell content ≥ 10%
- If < 10%, macrodissection needed

#### GeneFusion

- 1 x 5 µm FFPE tissue section 20 - 100 mm<sup>2</sup>
- 3 x 5 µm FFPE tissue section < 20 mm<sup>2</sup>
- Neoplastic cell content ≥ 10%
- If < 10%, macrodissection needed

#### BRAF

- 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 cell content ≥ 50%
- If < 50%, macrodissection needed

#### KRAS, NRAS-BRAF-EGFR S492R

- 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 cell content ≥ 10%
- If < 10%, macrodissection needed

#### POLE-POLD1

- 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 cell content ≥ 10%
- If < 10%, 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 mm<sup>2</sup>
- 1 x 10 µm FFPE tissue section 25-300 mm<sup>2</sup>
- 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:



#### **K<sup>2</sup>EDTA 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



Biocartis US Inc.  
2 Pierce Place, Suite 1510  
Itasca, IL 60143 - US  
+1 (844) 443-9552

### REQUEST A DEMO



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Idylla™ Platform is listed as a class II device in the US under establishment registration 3009972873. Idylla™ MSI Test is cleared in the US under K211181 for Lynch Syndrome. Idylla™ EGFR, ctEGFR, BRAF, KRAS, ctKRAS, NRAS-BRAF-EGFR S492R, ctNRAS-BRAF-EGFR S492R, POLE-POLD1 & PIK3CA-AKT1 Mutation Assays; Idylla™ GeneFusion 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](https://www.biocartis.com/en/license-statements).

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