

NOTHING
IS SIMPLE
IN ONCOLOGY.
**NOTHING
BUT
THIS.**



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



BIOCARTIS' MISSION

IS TO ENABLE UNIVERSAL ACCESS
TO **PERSONALIZED MEDICINE**
FOR PATIENTS AROUND THE WORLD
BY MAKING MOLECULAR TESTING
CONVENIENT, FAST AND SUITABLE
FOR **ANY LAB.**

THE NEED FOR IMPROVED, STANDARDIZED AND FAST DIAGNOSTICS

Cancer can hit anyone at any time and treatment remains a real challenge. Because cancer doesn't follow rules. It fights back against therapies. It adapts. It changes its path. It does whatever it can to stay ahead of us.

At the advanced edge of oncology, **rapid access** to **accurate data** about relevant cancer mutations and treatment resistance is vital and creates the opportunity for early disease interception^{1,2} reducing the anxiety while waiting for results and the time before starting the best possible treatment.

Current technologies in molecular oncology are complex, require a lot of hands-on time and are often difficult to implement in the local laboratory. As a consequence, most laboratories do not perform molecular tests in-house, but send them out to specialized centers, where samples are batched in order to optimize costs.³⁻⁵

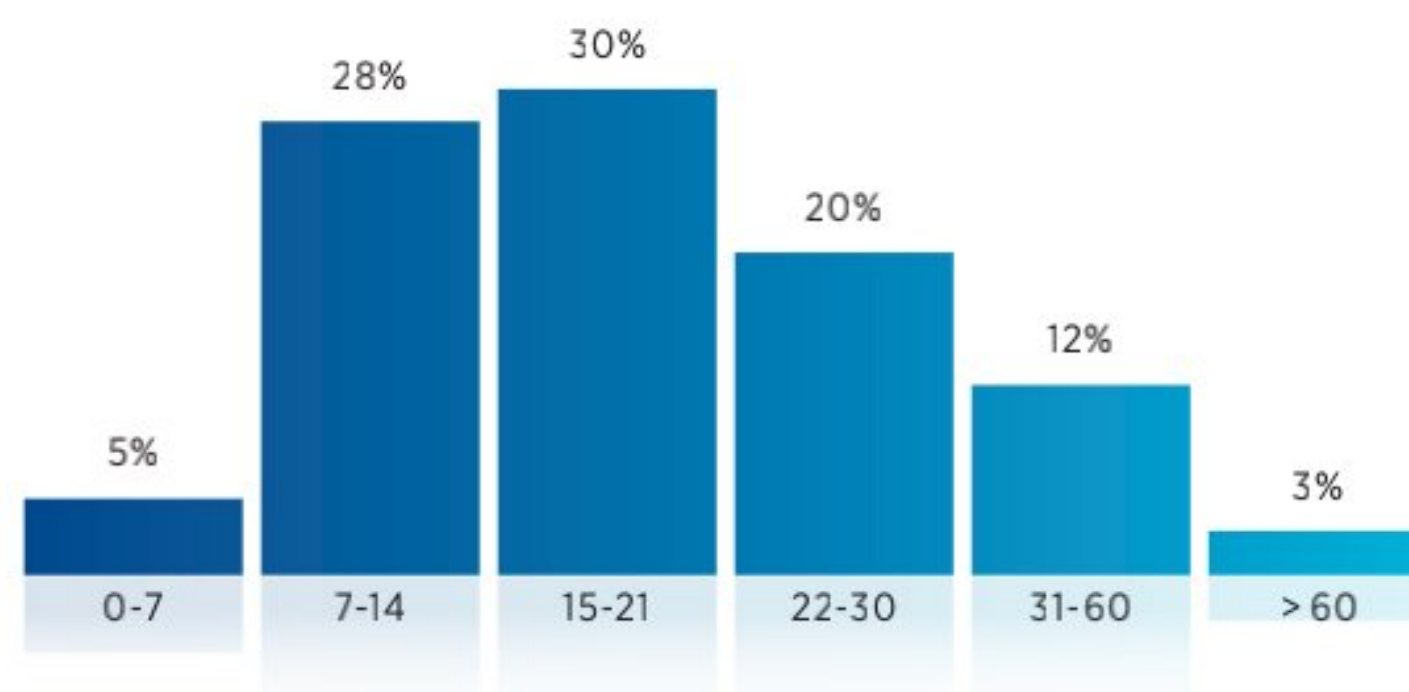
This causes delay to the fast delivery of results, preventing rapid initiation of correct therapy. In the meantime the tumor grows, which is detrimental in case of aggressively growing cancers.

THE NEED FOR A RAPID TREATMENT INITIATION RESPONSE TOWARDS PATIENTS

Fast initiation of immunotherapy or targeted therapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates.⁶⁻¹⁰ Timely detection of biomarkers therefore is very important.

Today, turnaround times of reference technologies are on average 18 days, with 14% of patients waiting longer than a month to be able to start treatment. Ninety-five percent of the patients have to wait more than a week in order to receive the biomarker results.¹¹

This means that precious time is lost whereas treatment initiation could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.



TOTAL TURNAROUND TIME OF REFERENCE TECHNOLOGIES (IN DAYS)

IDYLLA™, THE NEXT LEVEL IN DISEASE INTERCEPTION

Idylla™, a **fully automated**, sample-to-result PCR based **molecular diagnostics** system, provides **same-day** results helping physicians to make **timely decisions** on patients' therapy.

Idylla™ can be used with **multiple sample types**, including **solid** and **liquid biopsies**. This flexibility allows use of the system for **diagnostic**, **research**, and potentially future **monitoring** applications.

Idylla™, with its **compact scalable design** and **outstanding ease of use**, overcomes the traditional barriers of molecular diagnostics, allowing it to be used in virtually **any laboratory setting**.



IDYLLA™ IS THE FIRST AND ONLY MOLECULAR DIAGNOSTIC SYSTEM THAT COMBINES



FAST RESULTS

- < 3 minutes hands-on time
- Short turnaround time from 90 to 180 minutes



ACCURATE RESULTS

- High sensitivity
- Highly standardized technology
- Contamination-controlled design



ACCESSIBLE

- Access on demand - no need for batching



MULTIPLEXING CAPABILITY

- Detection of up to 51 relevant mutations in one cartridge
- Multiple genes and loci detection in one cartridge



EASE OF USE

- Fully automated sample-to-result process
- Walk-away system (no need for any intervention during the automatic process)



SAMPLE VERSATILITY

- For solid and liquid biopsy



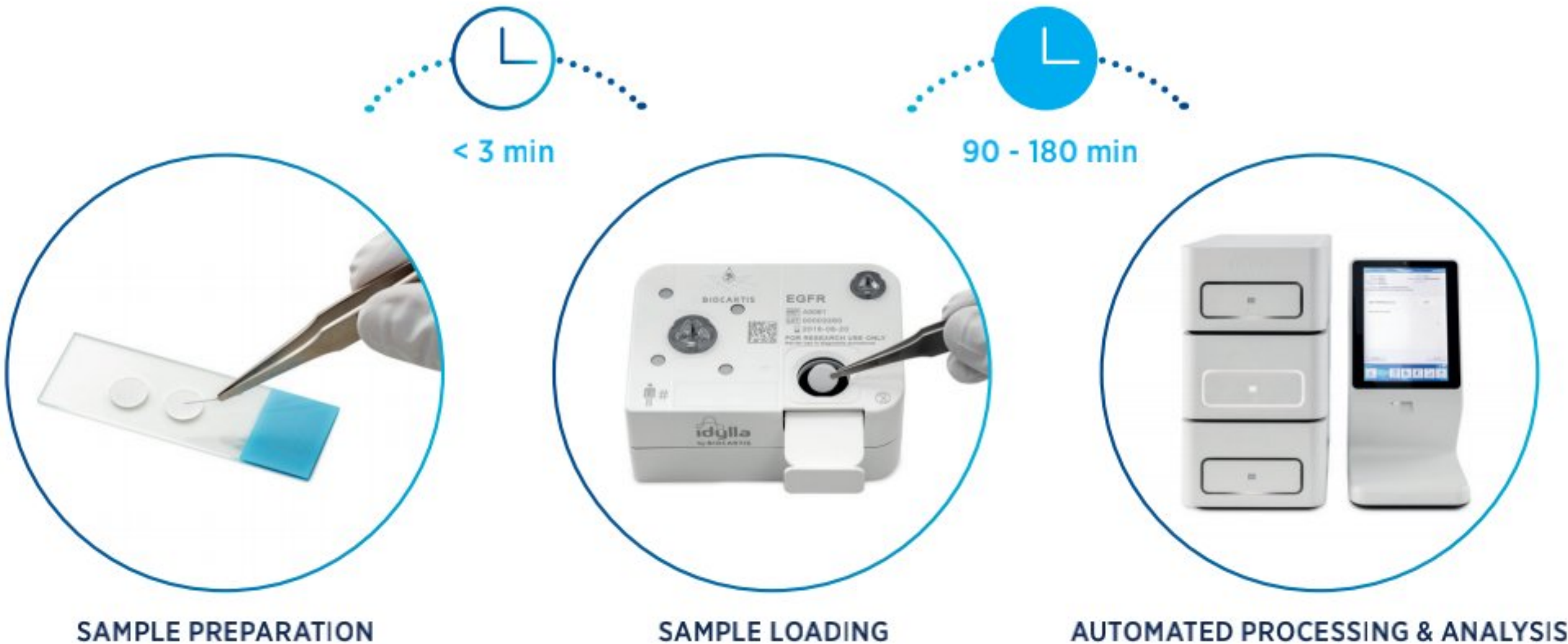
CONNECTIVITY

- Remote assistance, monitoring and upgrading
- Bi-directional LIS

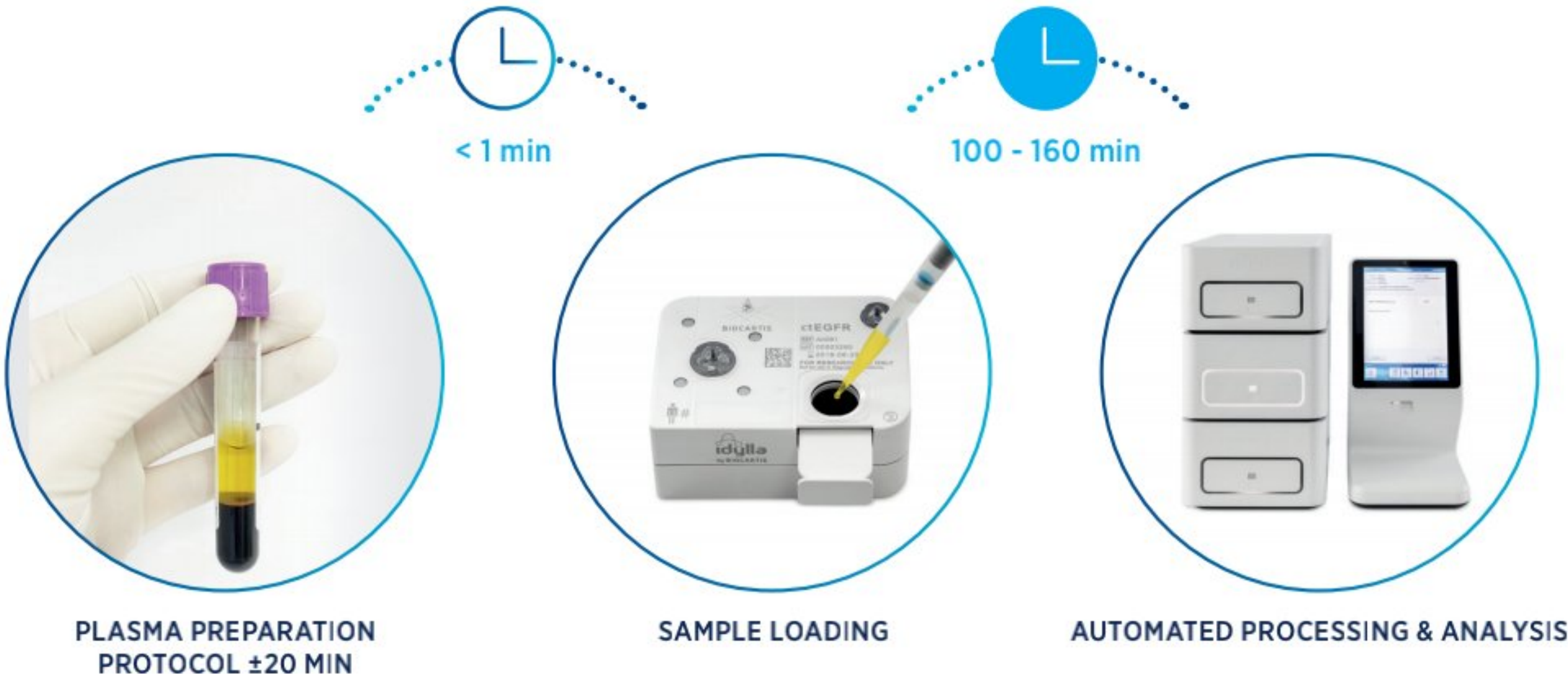


THE REVOLUTIONARY IDYLLA™ WORKFLOW

STANDARD SOLID BIOPSY WORKFLOW



STANDARD LIQUID BIOPSY WORKFLOW

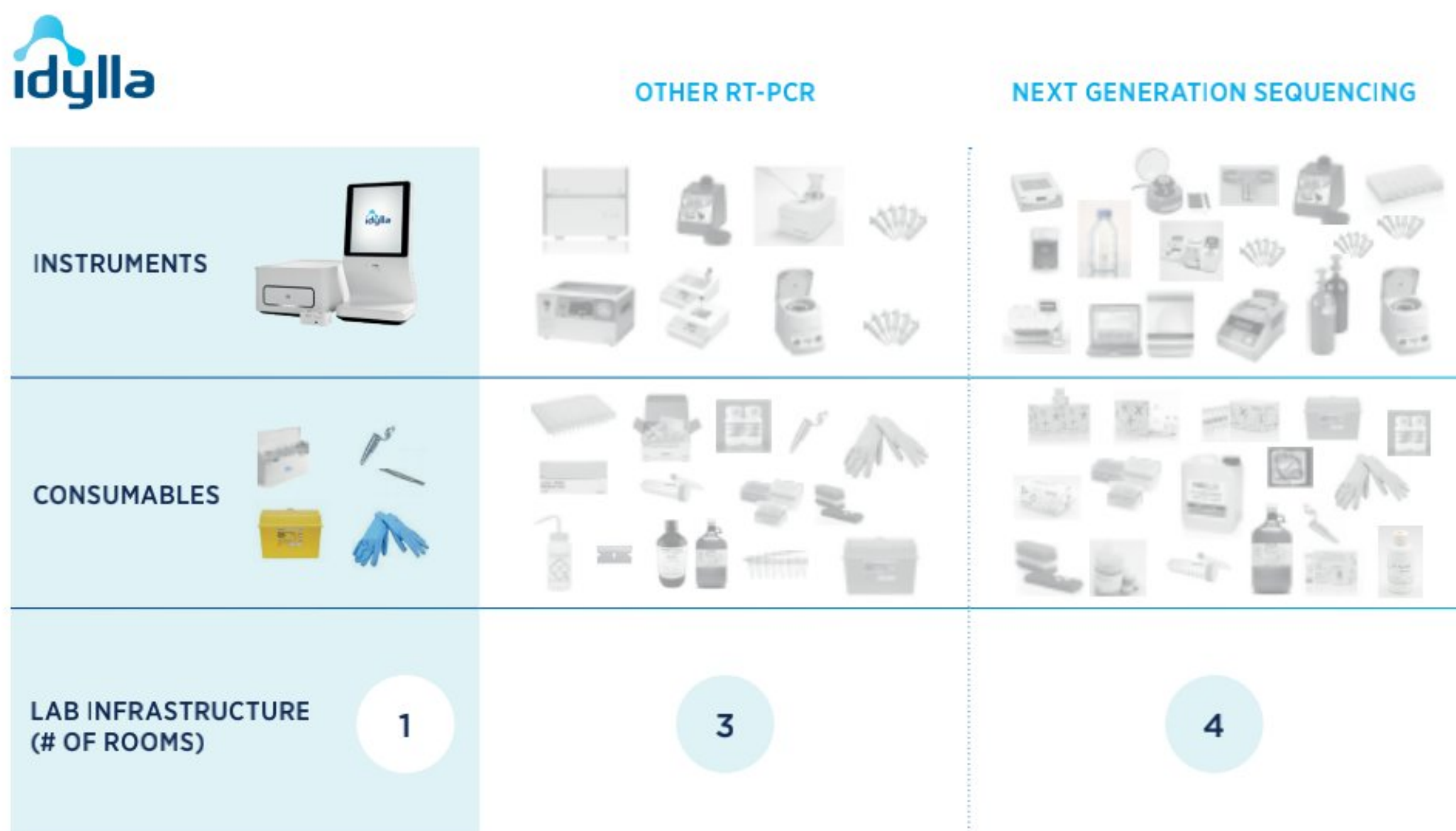


IDYLLA™ COMPARED TO OTHER TECHNOLOGIES

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.

EGFR **ctEGFR**

IDYLLA™ EGFR MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*

Lung cancer is the most common cancer worldwide, contributing for 13% of all cancer types. 85% of lung cancers are non-small cell lung cancers (NSCLC), of which histologically adenocarcinoma is the most prevalent.

EGFR mutations are mainly observed in lung cancer. *EGFR* mutation testing in exons 18-21 is recommended in all patients with advanced NSCLC of a non-squamous subtype. Activating mutations in the *EGFR* gene have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.^{8,9} Exon 19 deletion and exon 21 (L858R, L861Q), exon 18 (G719X), and exon 20 (S768I) mutations are associated

with sensitivity to Tyrosine Kinase Inhibitors (TKIs). Exon 20 insertion mutation may predict resistance to TKIs. *EGFR* T790M mutation is the main indicator of the patient's resistance to TKI therapy and has been reported in about 55% of patients with disease progression after initial response to 1st or 2nd generation TKIs.^{8,9}

The prevalence of *EGFR* mutations in NSCLC adenocarcinomas is 10-15% of Western and up to 50% of Asian patients. Sensitizing *EGFR* mutations are predictive for response to *EGFR* tyrosine kinase inhibitors.^{8,9,12}

*Idylla™ EGFR Mutation Test is validated for metastatic NSCLC

DIAGNOSTIC PRODUCT

Idylla™ EGFR Mutation Test (CE-IVD)

EGFR

Diagnostic use

approx. 150 min sample-to-result | < 2 min hands-on time | 51 mutations in exons 18, 19, 20, 21



FFPE

Directly on 1 FFPE tissue section (5 µm) from **metastatic non-small-cell lung cancer**



Qualitative genotype call + Cq values



Mutation detection to support **treatment assessment**

RESEARCH PRODUCT

Idylla™ ctEGFR Mutation Assay (RUO)

ctEGFR

Research Use Only, not for diagnostic use

approx. 160 min sample-to-result | ± 2 min hands-on time | 49 mutations in exons 18, 19, 20, 21



plasma

Directly on 2 ml plasma



Qualitative genotype call + Cq values + Quality status



Applicable in NSCLC harboring *EGFR* mutations

"Today, EGFR testing is a cumbersome process and it often takes several weeks before results are analyzed. This may lead to the administration of anti-EGFR therapy as second-line agents, which is less efficient than their use in first-line therapy. The Idylla™ EGFR Mutation Test technology has the potential to change that: it is a cost-effective solution, ensuring reliable and fast detection of all relevant mutations"

Prof Giancarlo Troncone, University of Napoli Federico II, Naples

GeneFusion

IDYLLA™ GENEFUSION DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION

Gene rearrangements represent an important class of somatic alterations in cancer. Due to their inherent expression in tumor tissue alone, rearrangements involving ALK, ROS1, RET, MET exon 14 and NTRK1/2/3 have become important biomarkers for cancer diagnosis, prognosis, and targeted therapies.¹³⁻¹⁵

The Idylla™ GeneFusion Panel (CE-IVD)* detects ALK, ROS1, RET & MET exon 14 rearrangements and the Idylla™ GeneFusion Assay (RUO) additionally detects NTRK1/2/3 rearrangements. Both assays use two different detection technologies. Specific detection of ALK, ROS1, RET and MET exon 14 rearrangements

is combined with expression imbalance detection for ALK, ROS1 and RET (& NTRK1/2/3 in the Idylla™ GeneFusion Assay). Expression imbalance detects gene fusions, irrespective of the fusion partner, based on the 3' kinase overexpression caused by the partner gene. Expression imbalance results are indicative for the presence of a fusion and should be confirmed with another technology.

Discovery and further understanding of fusion genes across multiple cancer types like NSCLC, CRC, thyroid cancer, pediatric cancers, ... may in the future provide more effective therapies for cancer patients.

*Idylla™ GeneFusion Panel is validated for use in NSCLC

DIAGNOSTIC PRODUCT

Idylla™ GeneFusion Panel (CE-IVD)

GeneFusion

Diagnostic use



Directly on 1-3 FFPE tissue sections (5-10 µm) from NSCLC



Qualitative genotype call for every biomarker + Quality status



Fusion detection in NSCLC

RESEARCH PRODUCT

Idylla™ GeneFusion Assay (RUO)

GeneFusion

Research Use Only, not for diagnostic use



Directly on 1-3 FFPE tissue sections (5-10 µm)



Qualitative genotype call for every biomarker + Cq values + Quality status



Fusion detection applicable in multiple cancer types

IDYLLA™ KRAS MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*

Activating mutations in the *RAS* genes are observed in 9-30% of all cancers and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.¹⁶ Cancers in which *KRAS* mutations are observed include: colorectal cancer, lung cancer and pancreatic cancer.

According to ESMO⁶, NCCN¹⁷, ASCO¹⁸ and CAP/AMP/ASCO guidelines¹⁹, genotyping of clinically actionable mutations at a sensitivity of 5% in *RAS* genes exon 2 (codons 12 and 13), exon 3 (codons 59 and 61) and exon 4 (codons 117 and 146) is now mandatory on tumor tissue (either primary or metastasis) of all metastatic colorectal cancers, since the presence of these mutations correlate with the lack of response to

certain anti-EGFR antibody therapies⁶. About 46% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *KRAS* gene.²⁰ Several studies are ongoing to define the predictive impact of *KRAS* mutations on therapy decision for non-small-cell lung cancer (NSCLC) patients.²¹⁻²³ Currently there is evidence that *KRAS* in lung cancer has a prognostic value, indicating poor survival for patients with NSCLC, compared to the absence of *KRAS* mutations.⁸

Using liquid biopsies for *KRAS* testing is minimally invasive, fast and easy to perform and provides an excellent solution to study the presence of *KRAS* mutations in different cancer types.

*Idylla™ *KRAS* Mutation Test is validated for use in mCRC

DIAGNOSTIC PRODUCT

Idylla™ **KRAS** Mutation Test (CE-IVD)

KRAS

Diagnostic use



Directly on FFPE tissue sections (5-10 μm) from **metastatic colorectal cancer**



Qualitative genotype call



Mutation detection for **baseline treatment**

RESEARCH PRODUCT

Idylla™ **ctKRAS** Mutation Assay (RUO)

ctKRAS

Research Use Only, not for diagnostic use



Directly on 1 ml plasma



Qualitative genotype call + Cq values



Applicable in multiple cancers harboring *KRAS* mutations

Beatriz Bellosillo
Laboratori de Biologia Molecular,
Hospital del Mar, Barcelona

"Idylla™ allows very quick results with little hands-on time"

NRAS-BRAF **ctNRAS3**

IDYLLA™ NRAS MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*

Activating mutations in the *RAS* genes are observed in 9-30% of all cancers and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.¹⁶ Cancers in which *NRAS* mutations are observed include colorectal, lung, thyroid cancers and melanoma.

According to ESMO⁶, NCCN¹⁷, ASCO¹⁸ and the CAP/AMP/ASCO guidelines¹⁹, genotyping of clinically actionable mutations at a sensitivity of 5% in *RAS* genes exon 2 (codons 12 and 13), exon 3 (codons 59 and 61) and exon 4 (codons 117 and 146) is now mandatory on tumor tissue (either primary or metastasis) of all metastatic colorectal cancers, since the presence of these mutations correlate with the lack of response to certain anti-EGFR antibody

therapies.⁶ About 5% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *NRAS* gene.²⁰

In metastatic colorectal cancer *BRAF* mutation status should be assessed alongside the assessment of tumor *RAS* mutational status for prognostic assessment (the presence of a *BRAF* mutation indicates poor prognosis). Using liquid biopsies for *NRAS* testing is minimally invasive, fast and easy to perform and provides an excellent solution to study these mutations in different cancer types and lesions. Recent research data^{24,25} suggest that in about 16% of patients, mutations may develop in codon 492 of the *EGFR* gene as a mechanism of resistance, to the anti-EGFR antibody therapies such as cetuximab.

*Idylla™ NRAS-BRAF Mutation Test is validated for use in mCRC

NRAS-BRAF

DIAGNOSTIC PRODUCT

Idylla™ NRAS-BRAF Mutation Test (CE-IVD)

Diagnostic use

 approx. 120 min sample-to-result
  < 2 min hands-on time
  18 mutations in NRAS codons 12, 13, 59, 61, 117, 146

 5 mutations in BRAF codon 600
  FFPE
 Directly on FFPE tissue sections (5-10µm) from metastatic colorectal cancer

 **Qualitative genotype call + Cq values**

 Mutation detection for **baseline treatment**

ctNRAS3


RESEARCH PRODUCT

Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay (RUO)

Research Use Only, not for diagnostic use

 approx. 110 min sample-to-result
  < 1 min hands-on time
  18 mutations in NRAS codons 12, 13, 59, 61, 117, 146

 5 mutations in BRAF codon 600
  2 mutations in EGFR codon 492
 Directly on 1 ml plasma


 **Semi-quantitative genotype call + Cq values**

 **Applicable in multiple cancers** harboring NRAS, BRAF or EGFR S492R mutations

MSI

IDYLLA™ MSI DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION*

Microsatellite instability (MSI) is defined as a length variation of DNA repeat regions found in microsatellites or homopolymers. MSI is caused by deficiency of the DNA mismatch repair system (dMMR) resulting in a distinct accumulation of insertions and deletions in microsatellite and homopolymeric regions.²⁶

MSI can be sporadic or hereditary. MSI-high (MSI-H) is detected in 15% of all colorectal cancers; 3% are associated with Lynch syndrome (LS), the other 12% have sporadic disease.²⁷

Clinical trials and pathophysiological studies indicate a wide distribution of MSI-H across tumor types.²⁸

In addition to CRC, high incidences are observed in endometrial cancer (20-30%), and gastric cancer (15-20%).²⁹

Guidelines recommend assessing the MSI status for all patients with colorectal or endometrial carcinomas for screening for Lynch syndrome as well as for prognostic stratification and potential response to certain immunotherapies.³⁰⁻³³

Research studies have shown that MSI-H patients respond favorably to immune checkpoint inhibitors, and checkpoint blockade therapy has recently been incorporated into clinical care for gastrointestinal cancers.^{34,35}

*Idylla™ MSI Test is only validated for CRC

DIAGNOSTIC PRODUCT

Idylla™ MSI Test (CE-IVD)

MSI

Diagnostic use

 approx. 150 min
sample-to-result

 < 3 min
hands-on time

7 novel MSI Bio-markers*



FFPE

Directly on FFPE tissue sections (5-10 µm) from colorectal cancer. **No need for paired normal tissue sections**



Qualitative MSI call + MSI score



Determination of **MSI status** in **colorectal cancer**

*ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2

“We are delighted with the performance of the Idylla™ MSI Test providing high quality results from minimal amount of tissue. The ease of use allows even laboratories with minimal histopathology experience to perform MSI testing in-house.”

*Sarah L. McCarron
Cancer Molecular Diagnostics,
St. James' Hospital, Dublin, Ireland*

PIK3CA-AKT1

IDYLLA™ PIK3CA-AKT1 MUTATION DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION

Mutations in *PIK3CA* and *AKT1* are detected in multiple cancers including HR+/HER2- metastatic breast cancer. Collectively, mutations in *PIK3CA* and *AKT1* occur frequently, affecting up to 40% of patients with advanced HR+/HER2- breast cancer. They have become important biomarkers for emerging and approved targeted therapies.³⁶⁻³⁸

The Idylla™ PIK3CA-AKT1 Mutation Assay allows for the qualitative detection of 13 mutations in the *PIK3CA* gene (N345K, C420R, E542K, E545K, E545G, E545D (c.1635G>T), E545A, Q546K, Q546R, Q546E, H1047R, H1047L, H1047Y) and one mutation in the *AKT1* gene (E17K) in formalin-fixed, paraffin-embedded (FFPE) human tissue sections. The assay covers 99% of the druggable mutations in HR+/HER2- breast cancer.

PIK3CA-AKT1

RESEARCH PRODUCT

Idylla™ PIK3CA-AKT1 Mutation Assay (RUO)

Research Use Only, not for diagnostic use



FFPE

Directly on FFPE tissue sections



Qualitative genotype call
+ Cq values



Applicable in multiple cancers
harboring *PIK3CA* and *AKT1*
mutations

BRAF

IDYLLA™ BRAF MUTATION DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION*

Activating mutations in the *BRAF* gene are observed in about 8% of all cancers³⁹ and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.

Cancers in which *BRAF* mutations are observed include: melanoma, colorectal cancer, thyroid cancer, lung cancer, hairy cell leukemia and ovarian cancer.

BRAF testing is recommended in all patients with metastatic melanoma and metastatic colorectal

cancer (mCRC). About 50% of all metastatic melanoma patients harbor mutations in the *BRAF* gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy.⁴⁰ In mCRC, BRAF mutation status should be assessed alongside the assessment of tumor *RAS* mutational status for prognostic assessment (the presence of a *BRAF* mutation indicates poor prognosis). The prevalence of *BRAF* in mCRC is about 8-15%.⁶

*Idylla™ BRAF Mutation Test is validated for use in metastatic melanoma

DIAGNOSTIC PRODUCT

Idylla™ BRAF Mutation Test (CE-IVD)

BRAF

Diagnostic use



FFPE

Directly on FFPE tissue sections (5-10 µm) from **metastatic melanoma**



Qualitative genotype call



Mutation detection for **baseline treatment**

“The Idylla™ system has the potential to allow the start of targeted therapy within a time window of less than 24 hours following the diagnosis of metastasis, thereby saving precious time”

*Prof. B. Neyns, M.D., Ph.D
Medical Oncology,
UZ Brussels, Belgium*

IDH1-2

IDYLLA™ IDH1-2 MUTATION DETECTION

BACKGROUND INFORMATION

Mutations in *IDH1* and *IDH2* are detected in multiple cancers such as glioma, Acute Myeloid Leukemia (AML) and cholangiocarcinoma. Due to their inherent occurrence in cancer, IDH1 and IDH2 mutations have become important biomarkers for tumor classification, prognosis, and emerging targeted therapies.

The Idylla™ IDH1-2 Mutation Assay Kit (RUO) qualitatively detects five IDH1 mutations in codon R132 (R132C/H/G/S/L), four IDH2 mutations in codon R140 (R140Q/L/G/W) and six IDH2 mutations in codon R172 (R172K/M/G/S/W). The Idylla™ IDH1-2 Mutation Assay Kit is compatible with FFPE tissue sections, human whole blood and bone marrow, and DNA extracted from all of these sample types.

RESEARCH PRODUCT

Idylla™ IDH1-2 Mutation Assay (RUO)

IDH1-2

Research Use Only, not for diagnostic use



Directly from 50 µl extracted DNA
Directly from 10 µl whole blood or bone marrow
Directly from FFPE tissue sections



Qualitative genotype call
+ Cq values



Applicable in multiple cancers
harboring IDH1-2 mutations

IDYLLA™ CONNECT ENGAGE IN THE FUTURE

IDYLLA™ EXPLORE

ADVANCED SERVICES



ADVANCED SERVICES TO ENSURE CONTINUITY IN YOUR LABORATORY WORKFLOW



AUTOMATIC SOFTWARE UPDATES

New releases of Assay and Console Software are sent to your Idylla™ Console and can be installed with a single touch on the screen.



IMMEDIATE AND REMOTE SERVICE AND SUPPORT

Idylla™ System parameters and error logs can be analyzed at anytime and anywhere to ensure swift actions and solutions.

MORE INSIGHT INTO YOUR DATA WITH IDYLLA™ EXPLORE



Get connected and enjoy **the advantages of Idylla™ Explore**, a web-based application that allows you to analyze your data by providing

- Visualization of PCR curves from Idylla™ Test Results
- Cq values per target
- Direct Access to Console result reports

Idylla™ Explore can be accessed anywhere and anytime from your PC or tablet through the following link: <https://idyllaexplore.biocartis.com>

Subscribe today and **join the Idylla™ Explore community** by sending an email to explore@biocartis.com

Sample ID	State	Sample ID	Test type	Run date	Results
Sample 1	✓	Sample 1	KRAS	15 Jul 2016 08:15:12	MUTATION DETECTED IN KRAS CODON 12
Sample 2	✓	Sample 2	KRAS	18 Jul 2016 17:24:01	NO MUTATION DETECTED IN KRAS CODON 12, 13, 15, 61, 111, 146
Sample 3	✓	Sample 3	BRAF	22 Jul 2016 11:02:07	NO MUTATION DETECTED IN BRAF CODON 600
Sample 4	✓	Sample 4	KRAS	01 Aug 2016 21:07:57	MUTATION DETECTED IN KRAS CODON 146
Sample 5	✓	Sample 5	ctBRAF	04 Aug 2016 14:50:46	MUTATION DETECTED IN BRAF CODON 600
Sample 6	✓	Sample 6	KRAS	09 Aug 2016 09:08:31	MUTATION DETECTED IN KRAS CODON 146

TARGET	CHAMB.	CQ	ΔCQ
G12C	A	21.30	1.47
KRAS Total	A	19.85	-

ZOOM IN



IDYLLA™ ORDER INFORMATION

DIAGNOSTIC PRODUCTS (CE-IVD)

Idylla™ BRAF Mutation Test	6 cartridges/box	Catalog# A0010/6
Idylla™ KRAS Mutation Test	6 cartridges/box	Catalog# A0020/6
Idylla™ NRAS-BRAF Mutation Test	6 cartridges/box	Catalog# A0030/6
Idylla™ EGFR Mutation Test	6 cartridges/box	Catalog# A0060/6
Idylla™ MSI Test	6 cartridges/box	Catalog# A0100/6
Idylla™ GeneFusion Panel	6 cartridges/box	Catalog# A0120/6

RESEARCH PRODUCTS (RUO)

Idylla™ BRAF Mutation Assay	6 cartridges/box	Catalog# A0011/6
Idylla™ KRAS Mutation Assay	6 cartridges/box	Catalog# A0021/6
Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	Catalog# A0031/6
Idylla™ EGFR Mutation Assay	6 cartridges/box	Catalog# A0061/6
Idylla™ MSI Assay	6 cartridges/box	Catalog# A0101/6
Idylla™ GeneFusion Assay	6 cartridges/box	Catalog# A0121/6
Idylla™ IDH1-2 Mutation Assay (Vial)*	6 vials/box	Catalog# A0181/6
Idylla™ DNA Cartridge*	6 cartridges/box	Catalog# A0191/6

* The Idylla™ IDH1-2 Mutation Assay Kit consists of a Cartridge and a Vial.

Idylla™ PIK3CA-AKT1 Mutation Assay	6 cartridges/box	Catalog# A0171/6
Idylla™ ctKRAS Mutation Assay	6 cartridges/box	Catalog# A0081/6
Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	Catalog# A0091/6
Idylla™ ctEGFR Mutation Assay	6 cartridges/box	Catalog# A0111/6

PLATFORM (CE-IVD)

Idylla™ Instrument	1 unit	Catalog# P0010
Idylla™ Console	1 unit	Catalog# P1010

IDYLLA™ ORDER INFORMATION

CONNECTIVITY

Idylla™ Explore	Catalog# P2041
Connectivity Service	Catalog# S1049

customerservice@biocartis.com

IDYLLA™: NOTHING IS SIMPLE IN ONCOLOGY. NOTHING BUT THIS.



There's a clear need for improved, standardized and fast diagnostics that allow faster treatment initiation for cancer patients.

Idylla™, Biocartis' fully automated molecular diagnostics system, is the first and only molecular diagnostic system that combines unsurpassed ease of use, speed and accuracy on multiple sample types. With its compact, scalable design and outstanding ease of use, Idylla™ overcomes the traditional barriers of molecular diagnostics, allowing it to be used in virtually any laboratory setting.

And by providing same-day-results, Idylla™ supports physicians to make timely decisions on patients' therapy.



REFERENCES

- (1) Bratzman, S. V., et al. (2015). *Expert Rev Mol Diagn.*, 15(6), 715–719.
- (2) Siravegna, G. & Bardelli, A. (2014) *Genome Biol.*, 15(8), 449.
- (3) Janku, F., et al. (2015). *Oncotarget*, 6(29), 26886–26889.
- (4) Sam, S. S., et al. (2015). *Pathol Res Pract*. pii: jclinpath-2015–203345.
- (5) Colling, R., et al. (2015). *J Clin Pathol*. pii: jclinpath-2015–203345.
- (6) ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. *Annals of Oncology* 0: 1–37, 2016.
- (7) NCCN Clinical Practice Guidelines in Oncology – Melanoma - Version 3.2016
- (8) NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 6.2017
- (9) Planchard, D., et al. (2018). Metastatic non-small cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of oncology: official journal of the European Society for Medical Oncology*, 29(Suppl 4), iv192–iv237. <https://doi.org/10.1093/annonc/mdy275>
- (10) AACR 2016: 5-Year Survival Rates for Patients With Metastatic Melanoma Treated With Nivolumab Much Higher Than Historical Rates. <http://www.ascopost.com/News/39500>
- (11) Accès aux tests moléculaires EGFR, RAS et BRAF /Résultats d'une enquête dans 5 régions françaises, appui à la décision, INCa, janvier 2016
- (12) Cooper, W. A., et al. (2013). Molecular Biology of lung cancer. *J Thorac Dis*, 5 (S5), S479-490.
- (13) Stransky, N., et al. (2014). The landscape of kinase fusions in cancer. *Nature communications*, 5, 4846. <https://doi.org/10.1038/ncomms5846>
- (14) Schram, A. M., et al. (2017). Fusions in solid tumours: diagnostic strategies, targeted therapy, and acquired resistance. *Nature reviews. Clinical oncology*, 14(12), 735–748. <https://doi.org/10.1038/nrclinonc.2017.127>
- (15) Mertens, F., et al. (2015). The emerging complexity of gene fusions in cancer. *Nature reviews. Cancer*, 15(6), 371–381. <https://doi.org/10.1038/nrc3947>
- (16) Cox, A. D., et al. (2014). Drugging the undruggable RAS: Mission possible? *Nature reviews. Drug discovery*, 13(11), 828–851. <https://doi.org/10.1038/nrd4389>
- (17) NCCN Clinical Practice Guidelines in Oncology – Colon Cancer – Version 2.2016
- (18) Allegra, C. J., et al. (2016). Extended RAS Gene Mutation Testing in Metastatic Colorectal Carcinoma to Predict Response to Anti-Epidermal Growth Factor Receptor Monoclonal Antibody Therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. *Journal of clinical oncology: official journal of the American Society of Clinical Oncology*, 34(2), 179–185. <https://doi.org/10.1200/JCO.2015.63.9674>
- (19) http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm
- (20) Douillard, J. Y., et al. (2013). Panitumumab-FOLFOX4 treatment and RAS mutations in colorectal cancer. *The New England journal of medicine*, 369(11), 1023–1034. <https://doi.org/10.1056/NEJMoal305275>
- (21) ESMO @ ECC 2015: Response to EGFR Agents in Combination With Chemotherapy Demonstrated in Patients with Metastatic Colorectal Cancer of Rare KRAS Molecular Subtype. <http://www.esmo.org/Conferences/Past-Conferences/European-Cancer-Congress-2015/News/Response-to-EGFR-Agentsin-Combination-With-Chemotherapy-Demonstrated-in-Patients-with-Metastatic-Colorectal-Cancer-of-Rare-KRAS-Molecular-Subtype>. Sept 2015.
- (22) Jänne, P. A., et al. (2015). Impact of KRAS codon subtypes from a randomised phase II trial of selumetinib plus docetaxel in KRAS mutant advanced non-small-cell lung cancer. *British journal of cancer*, 113(2), 199–203. <https://doi.org/10.1038/bjc.2015.215>
- (23) Zer, A., et al. (2016). Pooled Analysis of the Prognostic and Predictive Value of KRAS Mutation Status and Mutation Subtype in Patients with Non-Small Cell Lung Cancer Treated with Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitors. *Journal of thoracic oncology: official publication of the International Association for the Study of Lung Cancer*, 11(3), 312–323. <https://doi.org/10.1016/j.jtho.2015.11.010>
- (24) Montagut, C., et al. (2012). Identification of a mutation in the extracellular domain of the Epidermal Growth Factor Receptor conferring cetuximab resistance in colorectal cancer. *Nature medicine*, 18(2), 221–223. <https://doi.org/10.1038/nm.2609>
- (25) Newhall, K. (2014). Frequency of S492R Mutations in the Epidermal Growth Factor Receptor: Analysis of plasma DNA from Metastatic Colorectal Cancer Patients Treated with Panitumumab or Cetuximab Monotherapy. *16th World Congress on Gastrointestinal Cancer, Barcelona, Spain 2014*.
- (26) Aaltonen, L. A., et al. (1993). Clues to the pathogenesis of familial colorectal cancer. *Science (New York, N.Y.)*, 260(5109), 812–816. <https://doi.org/10.1126/science.8484121>
- (27) Dudley, J. C., et al. (2016). Microsatellite Instability as a Biomarker for PD-1 Blockade. *Clinical cancer research: an official journal of the American Association for Cancer Research*, 22(4), 813–820. <https://doi.org/10.1158/1078-0432.CCR-15-1678>
- (28) Cortes-Ciriano, I., et al. (2017). A molecular portrait of microsatellite instability across multiple cancers. *Nature communications*, 8, 15180. <https://doi.org/10.1038/ncomms15180>
- (29) Haraldsdottir S. (2017). Microsatellite Instability Testing Using Next-Generation Sequencing Data and Therapy Implications. *JCO precision oncology*, 1, 1–4. <https://doi.org/10.1200/PO.17.00189>

- (30) Van Cutsem, E., et al. (2016). ESMO consensus guidelines for the management of patients with metastatic colorectal cancer. *Annals of oncology: official journal of the European Society for Medical Oncology*, 27(8), 1386–1422. <https://doi.org/10.1093/annonc/mdw235>
- (31) NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Colon Cancer V.2.2018. Accessed July 25,2018. To view the most recent and complete version of the guidelines, go online to NCCN.org.
- (32) NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Rectal Cancer V.2.2018. Accessed July 25, 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org.
- (33) NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Uterine Neoplasms V.2.2018. Accessed July 25, 2018. To view the most recent and complete version of the guidelines, go online to NCCN.org.
- (34) Le, D. T., et al. (2015). PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. *The New England journal of medicine*, 372(26), 2509–2520. <https://doi.org/10.1056/NEJMoa1500596>
- (35) Le, D. T., et al. (2017). Mismatch repair deficiency predicts response of solid tumors to PD-1 blockade. *Science (New York, N.Y.)*, 357(6349), 409–413. <https://doi.org/10.1126/science.aan6733>
- (36) <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-alpelisib-metastatic-breast-cancer>
- (37) https://www.ema.europa.eu/en/documents/overview/piqray-epar-medicine-overview_en.pdf
- (38) <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-capivasertib-fulvestrant-breast-cancer>
- (39) Davies, H., et al. (2002). Mutations of the BRAF gene in human cancer. *Nature*, 417(6892), 949–954. <https://doi.org/10.1038/nature00766>
- (40) Clinical Practice Guidelines - Cutaneous melanoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology* 26 (Supplement 5): v126–v132, 2015.

NOTICE

Idylla™ BRAF Mutation Test

The MGB Probe contained in the BRAF Mutation Test is covered by applicable US patents and corresponding patents outside the US and is sold under a license from the ELITech Group. The purchase of this product includes a license to use only this amount of product solely for the purchaser's own use solely in the human in vitro diagnostic field (in accordance with applicable FDA and other regulatory requirements) and may not be used for any other commercial use, including without limitation repackaging or resale in any form (including resale by purchasers who are licensed to make and sell kits for use in the 5' Nuclease Process). No right under any other patent claim or for any other use is conveyed expressly, by implication, or by estoppel. Corresponding products conveying rights for use in all other fields may be obtained from Life Technologies under a separate catalog number. For information on obtaining additional rights, please contact outlicensing@lifetech.com or Out Licensing, Life Technologies Corporation, 5791 Van Allen Way, Carlsbad, California 92008.

Idylla™ BRAF Mutation Assay

The MGB Probe contained in the Idylla™ BRAF Mutation Assay is covered by applicable US patents and corresponding patents outside the US and is sold under a license from the ELITech Group.

The purchase of this product includes a license to use only this amount of product solely for the purchaser's own research use and may not be used for any other commercial use, including without limitation repackaging or resale in any form (including resale by purchasers who are licensed to make and sell kits for use in the 5' Nuclease Process). No right under any other patent claim or for any other use is conveyed expressly, by implication, or by estoppel. Diagnostic use rights for MGB may be obtained under a separate license from ELITech. Corresponding products conveying commercial and diagnostic use rights for MGB may be obtained from LTC only under a separate agreement. For further information contact outlicensing@lifetech.com or Out Licensing, Life Technologies Corporation, 5791 Van Allen Way, Carlsbad, California 92008.

Idylla™ KRAS Mutation Test, Idylla™ KRAS Mutation Assay and Idylla™ ctKRAS Mutation Assay

These assays contain PlexZyme and PlexPrime technology covered by patents granted and pending in certain jurisdictions, which are supplied under licence of SpeedX Pty Ltd. PlexZyme and Plexprime are trademarks of SpeedX Pty Ltd.

Idylla™ NRAS-BRAF Mutation Test, Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay and Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay

The Idylla™ NRAS-BRAF Mutation Test, Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay and ctNRAS-BRAF-EGFR S492R Mutation Assay contain PlexZyme and PlexPrime technology covered by patents granted and pending in certain jurisdictions, which are supplied under licence of SpeedX Pty Ltd. PlexZyme and Plexprime are trademarks of SpeedX Pty Ltd. The Idylla™ NRAS-BRAF Mutation Test and the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay contain Hilyte and QXL probes. QXL and Hilyte are licensed pursuant to an agreement with Eurogentec S.A. and these licensed probes can be used solely for the purchaser's own research use. Hilyte™ is a trademark of Anaspec, Inc. QXL® is a registered trademark of Anaspec, Inc.

Idylla™ EGFR Mutation Test, Idylla™ EGFR Mutation Assay and Idylla™ ctEGFR Mutation Assay

The Idylla™ EGFR Mutation Test contains PlexZyme and PlexPrime technology covered by patents granted and pending in certain jurisdictions, which are supplied under licence of SpeedX Pty Ltd. PlexZyme and Plexprime are trademarks of SpeedX Pty Ltd.

Idylla™ MSI Test

The Idylla™ MSI Test includes MSI biomarkers covered by patents granted and pending in certain jurisdictions, used under license from VIB-KU Leuven.

Idylla™ GeneFusion Panel and Idylla™ GeneFusion Assay

The Idylla™ GeneFusion Panel and Idylla™ GeneFusion Assay contain SuperScript™ III Reverse Transcriptase and is provided subject to a license under patents or patent applications owned by or licensed to Life Technologies Corporation, which license is limited to the human diagnostic field and research field and specifically excludes applications in forensics (including human identity testing). The SuperScript™ III trademark is owned by Life Technologies Corporation.

Patents US 7,700,339, 8,168,383, 8,481,279, 8,486,645, 8,232,060, 8,288,102, 8,377,642, 9,988,688, 9,523,130, 9,096,855, 10,526,661, 9,364,477, 9,539,254, 10,551,383 and pending US applications and all their respective foreign equivalents under license from Cell Signaling Technology, Inc.

Idylla™ PIK3CA-AKT1 Mutation Assay

Idylla™ PIK3CA-AKT1 Mutation Assay has been developed in collaboration with LifeArc.

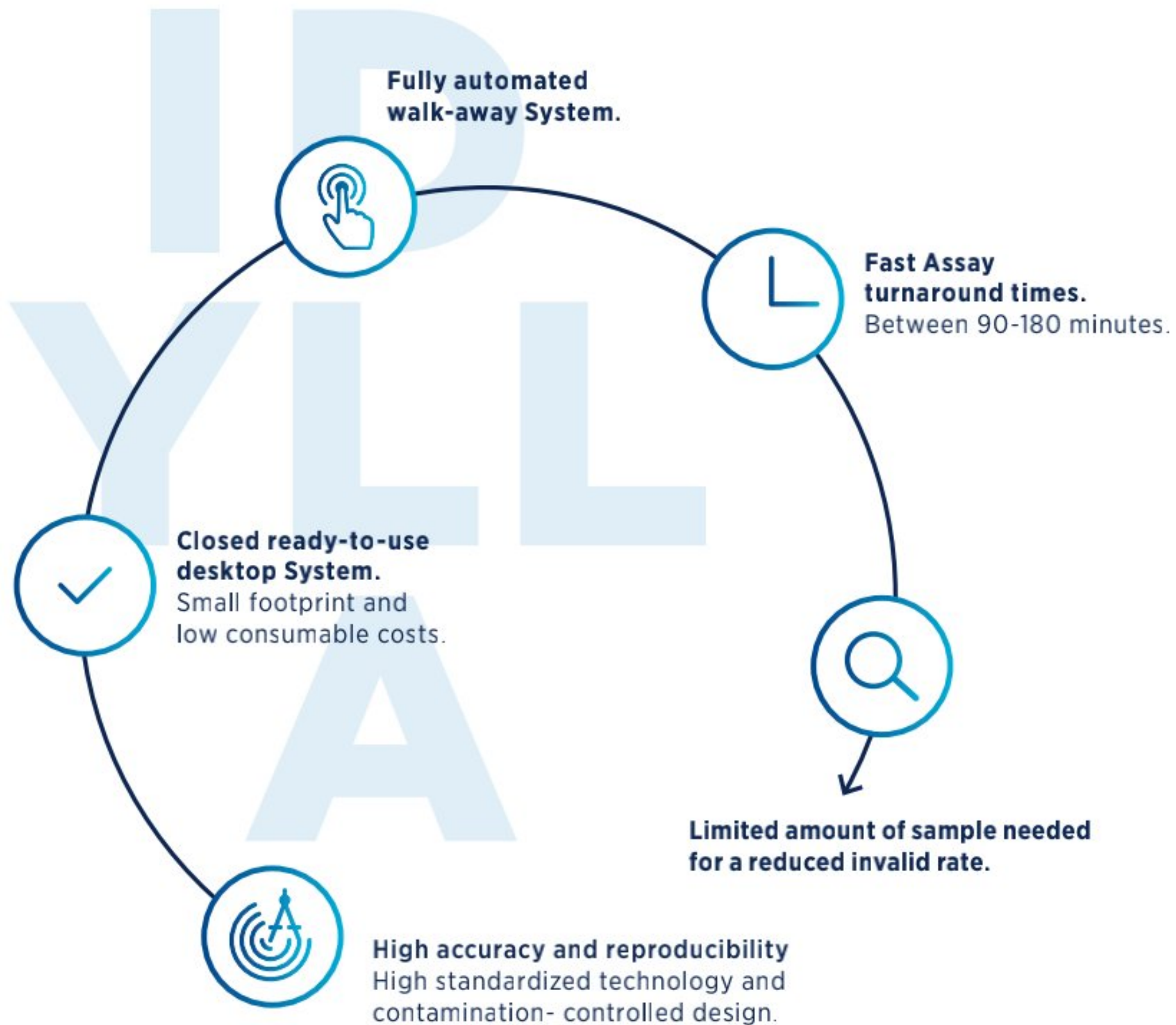
Important information

The Idylla™ Platform; Idylla™ BRAF, KRAS, NRAS-BRAF, EGFR Mutation Tests; Idylla™ MSI Test; and Idylla™ GeneFusion Panel are CE-marked in Europe in compliance with EU IVD Regulation 2017/746. Idylla™ BRAF, KRAS, ctKRAS, NRAS-BRAF-EGFR S492R, ctNRAS-BRAF-EGFR S492R, EGFR, ctEGFR & 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.

Copyright information

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.

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



Biocartis NV
Generaal De Wittelaan 11B
2800 Mechelen - Belgium
T +32 15 632 888

customerservice@biocartis.com
Ref: catalog # B2008
© January 2024, Biocartis NV. All rights reserved.

