See how you can guide the path her cancer takes

Direct access to same-day-results

Fully Automated Molecular Diagnostics

FAST ACCURATE EASY 24/7 ACCESSIBLE

BIOCARTIS

"We at Biocartis aim to provide direct access to personalized medicine for patients worldwide by developing fully integrated and broadly applicable molecular diagnostics. Our platform can be used in a wide variety of healthcare settings to enable rapid and high-quality care close to patients"

Rudi Pauwels, *Founder Biocartis*

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[4,5], 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.[1-3]

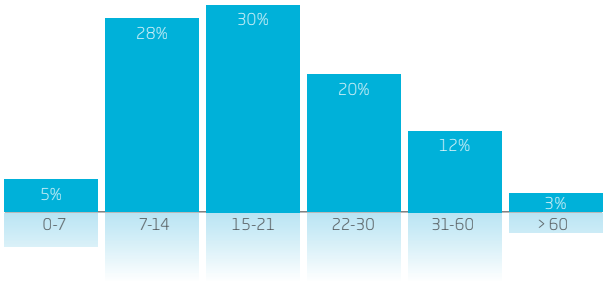
This causes delay to the fast delivery of results, preventing rapid initiation of correct therapy. In the meantime the tumor grows, which is detrimental in case of aggressively growing cancers.

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.[9,10,11,17,22] 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.[6]

Total turnaround time of reference technologies



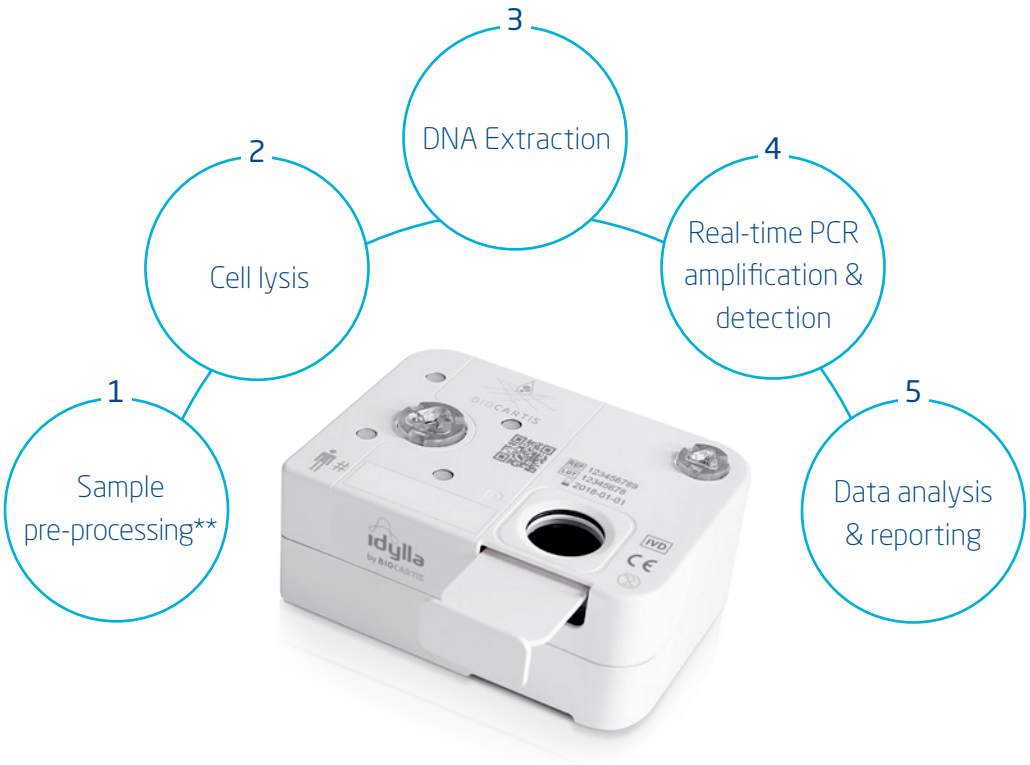
This means that precious time is lost whereas treatment initiation could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.

Idylla™, the next level in disease interception

Idylla™, a **fully automated**, sample-to-result PCR based **molecular diagnostics** system, provides **same-day** results enabling 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 respectively **diagnosis**, and **research** or possibly 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.**



* Liquid biopsy currently available only for research applications
** e.g. deparaffinization for FFPE tissue samples

Idylla™ is the first and only molecular diagnostic system that combines

FAST RESULTS

- Less than 2 minutes hands-on time
- Short turnaround time - 40 to 150 minutes

ACCURATE RESULTS

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

EASE-OF-USE

- Fully automated sample-to-result process
- Walk-away system (no need for any intervention during the automatic process)
- All reagents integrated in a single cartridge
- Only 1 manual step
- Storage and shipment at room temperature

ACCESSIBLE

- Access on demand - no need for pre-processing or batching

SAMPLE VERSATILITY

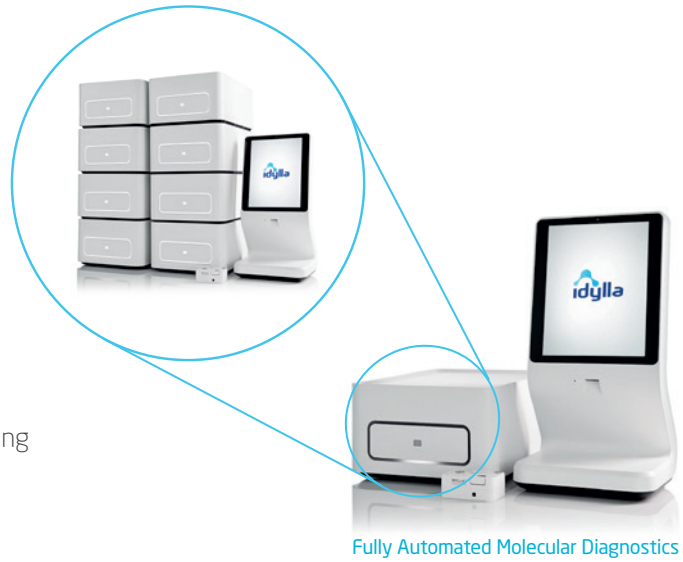
- For solid and liquid biopsy*

MULTIPLEXING CAPABILITY

- Detection of up to 52 relevant mutations in one cartridge
- Multiple genes and loci detection in one cartridge

CONNECTIVITY

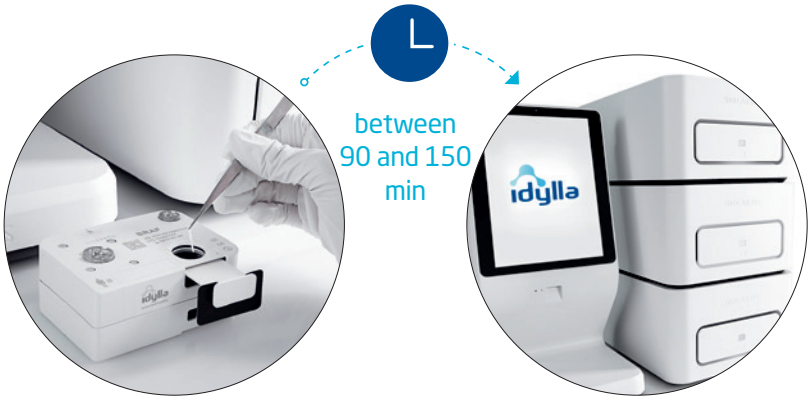
- Remote assistance, monitoring and upgrading
- Bi-directional LIS



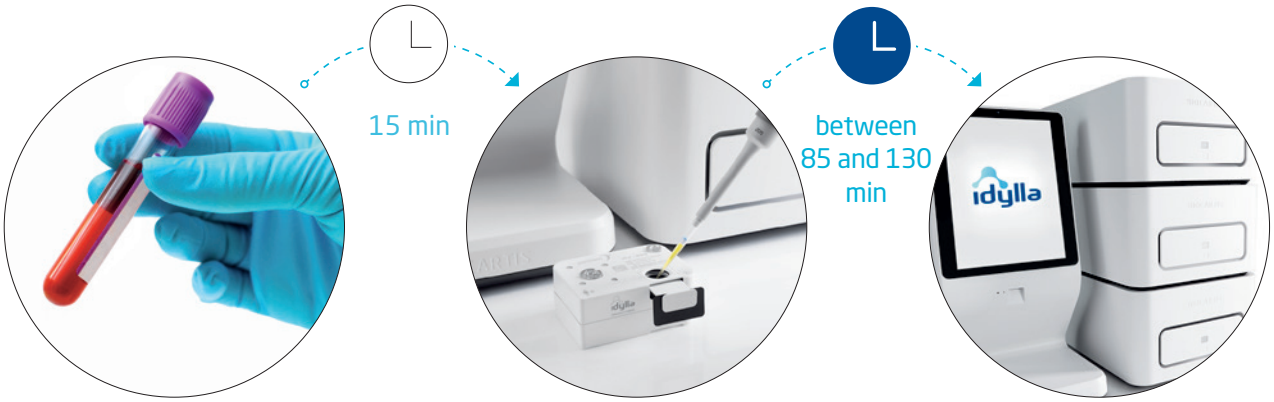
The revolutionary Idylla™ workflow

The Idylla™ system in combination with the Idylla™ Molecular Oncology Assays differs from other technologies in its outstanding **ease-of-use**, leading to an unsurpassed level of **standardization**, and its **short turnaround time**, allowing immediate access to therapy.

FFPE workflow



Liquid biopsy* workflow



Blood draw

Sample loading

Automated processing & analysis

idylla → 85 - 130 min

Conventional PCR → 1 Day

ddPCR → 1 Day

Beaming → 3 Days

NGS → 3-5 Days

* Liquid biopsy currently available only for research applications

Instruments and consumables

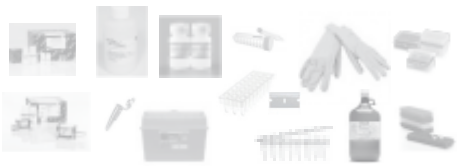
idylla

Instruments	
Consumables	
Lab infrastructure (# of rooms)	1

Other RT-PCR

Instruments	
Consumables	
Lab infrastructure (# of rooms)	3

Pyrosequencing

Instruments	
Consumables	
Lab infrastructure (# of rooms)	4

Next generation sequencing

Instruments	
Consumables	
Lab infrastructure (# of rooms)	4

Current oncology assays

FFPE in - report out

Diagnostic products (CE IVD)

- Idylla™ BRAF Mutation Test
- Idylla™ KRAS Mutation Test
- Idylla™ NRAS-BRAF Mutation Test
- Idylla™ NRAS Mutation Test

Research products (RUO)

- Idylla™ BRAF Mutation Assay
- Idylla™ KRAS Mutation Assay
- Idylla™ EGFR Mutation Assay
- Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay

Plasma in - report out

Research products (RUO)

- Idylla™ ctBRAF Mutation Assay
- Idylla™ ctKRAS Mutation Assay
- Idylla™ ctNRAS-BRAF-EGFR S492R

Future oncology assay targets

FFPE in - report out

- MSI

Plasma in - report out

- ctNRAS-BRAF
- ctEGFR

BRAF ctBRAF

Idylla™ BRAF mutation detection on solid and liquid biopsies

Activating mutations in the *BRAF* gene are observed in about 8% of all cancers[7] 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.[8] 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%.[9]

DIAGNOSTIC PRODUCT

Idylla™ **BRAF** Mutation Test (CE IVD)

BRAF

Diagnostic use

approx. 90 min. Sample-to-result

<2 min. hands-on time

7 mutations in codon 600

FFPE

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

Qualitative genotype call

Mutation detection for **baseline treatment**

RESEARCH PRODUCT

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

ctBRAF

Research Use Only, not for diagnostic use

approx. 85 min. Sample-to-result

<1 min. hands-on time

7 mutations in codon 600

plasma

Directly on 1 ml plasma

Semi-quantitative genotype call + Cq values

Applicable in multiple cancers harboring BRAF mutations

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

"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"

EGFR

Idylla™ EGFR mutation detection on solid biopsy

Activating mutations in the *EGFR* gene have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.[17]

EGFR mutations are mainly observed in lung cancer.

EGFR mutation testing is recommended in all patients with advanced non-small-cell lung cancer (NSCLC) of a non-squamous subtype.

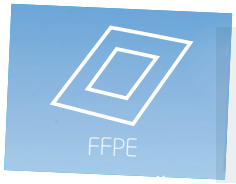
The prevalence of *EGFR* mutations in NSCLC adenocarcinomas is 10-15% of Western and up to 50% of Asian patients. Sensitizing *EGFR* mutations are predictive for response to EGFR tyrosine kinase inhibitors.[11,17,21]

RESEARCH PRODUCT

Idylla™ **EGFR** Mutation Assay (RUO)

EGFR

Research Use Only, not for diagnostic use



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

Qualitative genotype call

Prof Giancarlo Troncone
University of Napoli Federico II, Naples

" 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 assay technology has the potential to change that: it is a cost-effective solution, ensuring reliable and fast detection of all relevant mutations"

KRAS ctKRAS

Idylla™ KRAS mutation detection on solid and liquid biopsies

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.[12] Cancers in which *KRAS* mutations are observed include: colorectal cancer, lung cancer and pancreatic cancer.

According to ESMO[9], NCCN[14], ASCO[16] and CAP/AMP/ASCO guidelines[15], 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[9]. About 46% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *KRAS* gene.[13]

Several studies are ongoing to define the predictive impact of *KRAS* mutations on therapy decision for non-small-cell lung cancer (NSCLC) patients[18,19,20]. 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.[11]

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.

DIAGNOSTIC PRODUCT

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

KRAS

Diagnostic use

approx. 120 min. Sample-to-result

< 2 min. hands-on time

21 mutations in codons 12, 13 59, 61 117 146

FFPE

Directly on FFPE tissue sections (5-10µm) 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

approx. 130 min. Sample-to-result

< 1 min. hands-on time

21 mutations in codons 12, 13 59, 61 117 146

plasma

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 NRAS - BRAF ctNRAS3

Idylla™ NRAS mutation detection on solid and liquid biopsies

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.[12] Cancers in which *NRAS* mutations are observed include colorectal, lung, thyroid cancers and melanoma. According to ESMO[9], NCCN[14], ASCO[16] and the CAP/AMP/ASCO guidelines[15], 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[9]. About 5% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *NRAS* gene.[13]

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[23,24] 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.

DIAGNOSTIC PRODUCT

NRAS - BRAF
NRAS

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

Diagnostic use

approx. 120 min. Sample-to-result

<2 min. hands-on time

5 mutations in BRAF codon 600*
*Only available in Idylla™ NRAS-BRAF Mutation Test

18 mutations in NRAS codons 12, 13 59, 61 117, 146

FFPE

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

Semi-quantitative genotype call + Cq values

Mutation detection **for baseline treatment**

RESEARCH PRODUCT

ctNRAS3

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

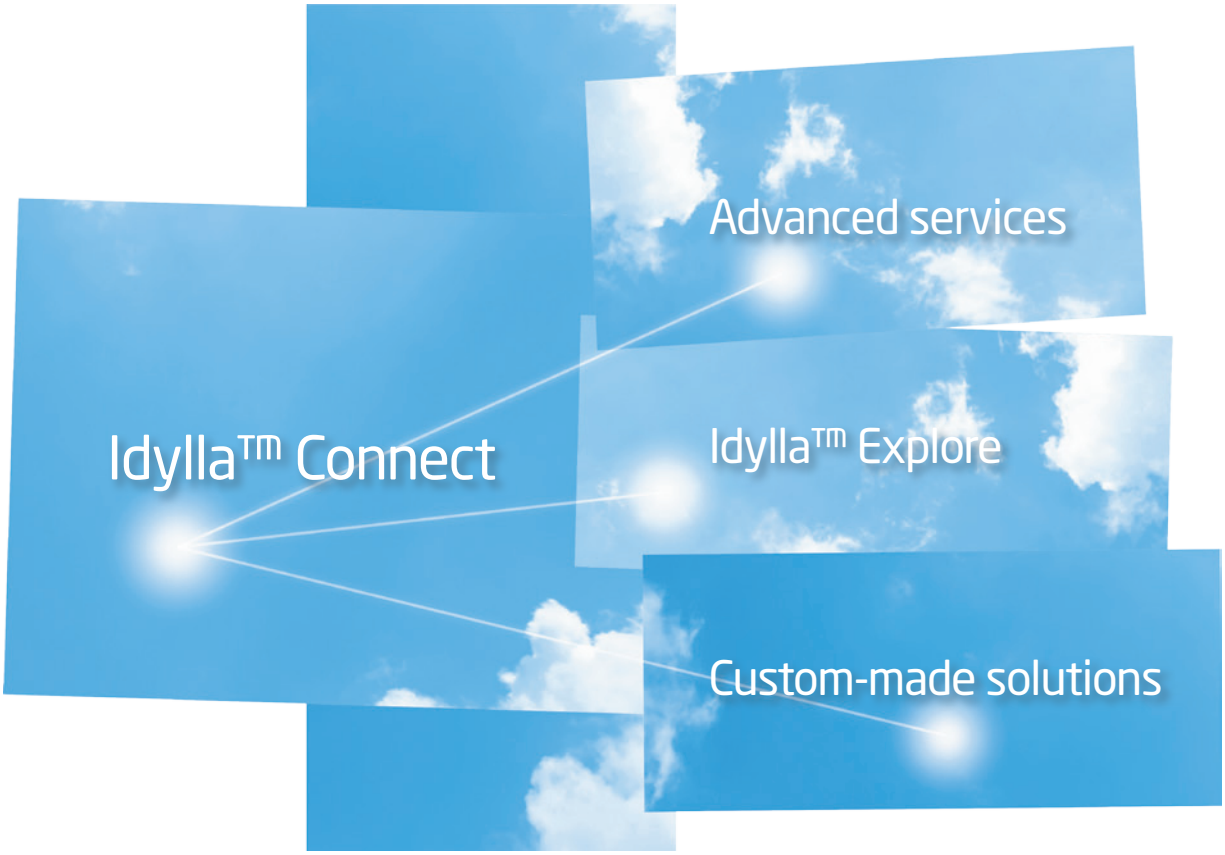
2 mutations in EGFR codon 492

Directly on 1 ml plasma

Semi-quantitative genotype call + Cq values

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

Idylla™ Connect
Engage in the future



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**

Zoom in

Custom-made solutions

Biocartis offers personalized solutions that fit your individual needs

- Create a network between different Idylla™ User sites and share data and knowledge
- Direct access to your data for building your own solution
- Statistical analysis on your obtained data
- Monitoring: Follow-up of your data over time
- Disease surveillance or diagnostic grid: linking of real-time molecular diagnostic test data to geo-location and sample data

Join the investigation

There's a clear need for improved, standardized and fast diagnostics that allow faster initiation of targeted therapy 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™ enables physicians to make timely decisions on patients' therapy.

Idylla™, the next level in disease interception.

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™ NRAS Mutation Test	6 cartridges/box	Catalog# A0040/6

Research Products (RUO)		
Idylla™ BRAF Mutation Assay	6 cartridges/box	Catalog# A0011/6
Idylla™ KRAS Mutation Assay	6 cartridges/box	Catalog# A0021/6
Idylla™ EGFR Mutation Assay	6 cartridges/box	Catalog# A0061/6
Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	Catalog# A0031/6
Idylla™ ctKRAS Mutation Assay	6 cartridges/box	Catalog# A0081/6
Idylla™ ctBRAF Mutation Assay	6 cartridges/box	Catalog# A0071/6
Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	Catalog# A0091/6

Platform (CE-IVD)		
Idylla™ Instrument	1 unit	Catalog# P0010
Idylla™ Console	1 unit	Catalog# P1010

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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.

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Idylla™ BRAF Mutation Assay and Idylla™ ctBRAF Mutation Assay

The MGB Probe contained in the Idylla™ BRAF Mutation Assay and in the Idylla™ ctBRAF 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.

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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 Mutation Test, Idylla™ NRAS-BRAF Mutation Test, Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay and Idylla™ ctNRAS3 Mutation Assay

The Idylla™ NRAS Mutation Test, Idylla™ NRAS-BRAF Mutation Test, Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay and ctNRAS3 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 Mutation Test, 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.

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IMPORTANT INFORMATION

Idylla™ platform, Idylla™ BRAF Mutation Test, Idylla™ KRAS Mutation Test , Idylla™ NRAS Mutation Test and Idylla™ NRAS-BRAF Mutation Test are CE-marked IVDs in Europe. Idylla™ BRAF Mutation Assay, Idylla™ ctBRAF Mutation Assay, Idylla™ KRAS Mutation Assay, Idylla™ ctKRAS Mutation Assay, Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay and Idylla™ EGFR Mutation Assay are available for Research Use Only, not for use in diagnostic procedures. Idylla™ ctBRAF Mutation Test, Idylla™ ctKRAS Mutation Test, Idylla™ EGFR Mutation Test, Idylla™ MSI Assay, Idylla™ ctNRAS-BRAF Mutation Test and Idylla™ ctEGFR Mutation Assay are under development. Idylla™ is not yet for sale in USA.

NOTES

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