See how you can guide the path her cancer takes

Direct access to same-day-results

Fully automated
Molecular Diagnostics

BIOCARTIS

www.biocartis.com

"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, *CEO 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]

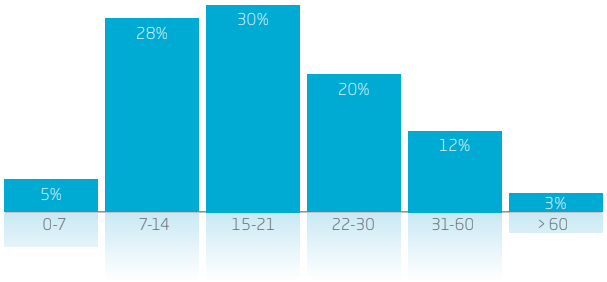
This causes delay to the fast delivery of results, preventing rapid initiation of correct therapy. In the meantime the tumor grows, which is detrimental in case of aggressively growing cancers.

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



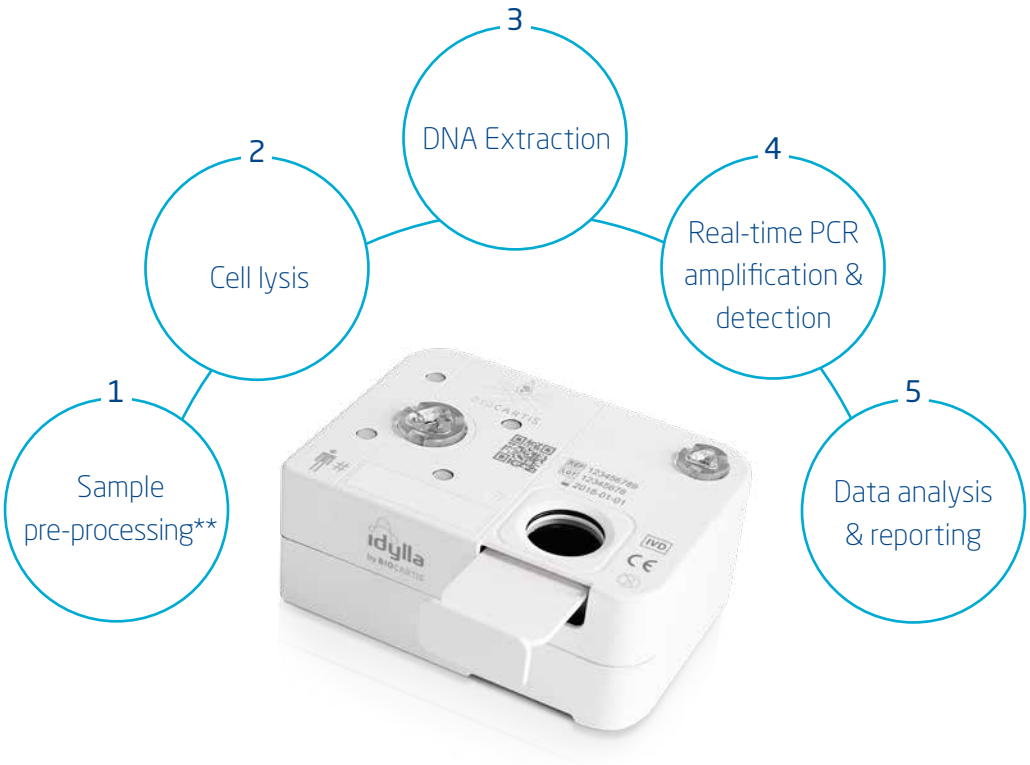
This means that precious time is lost whereas treatment initiation could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.

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:

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

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

FAST RESULTS

- Less than 2 minutes hands-on time
- Short turnaround time - 40 to 150 minutes
- Access on demand - no need for pre-processing or batching

CONNECTIVITY

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

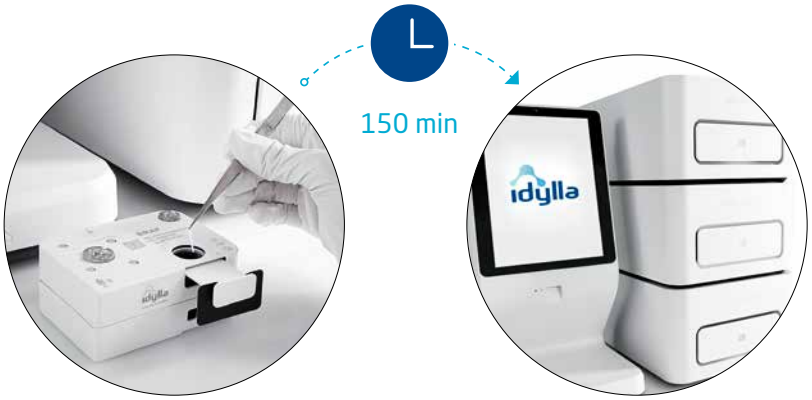
ACCURATE RESULTS

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

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



Sample loading

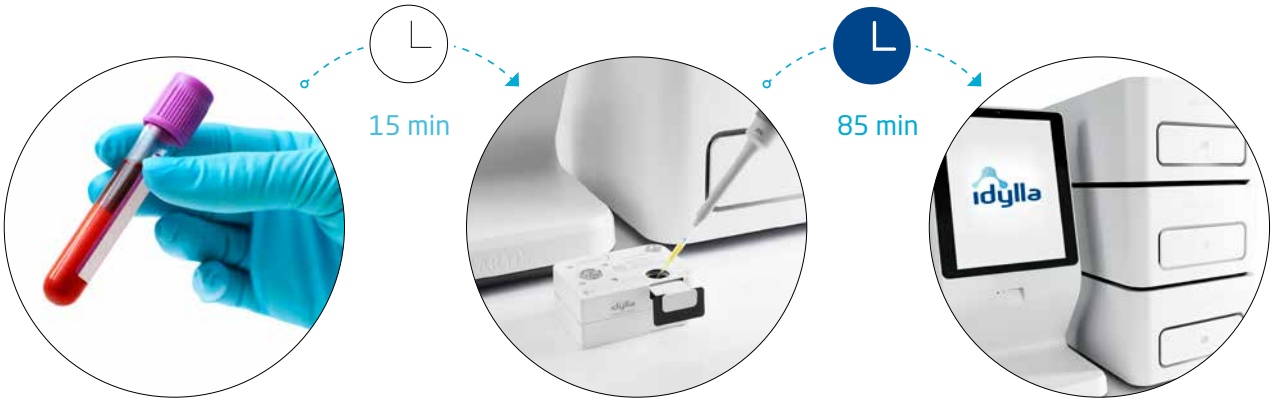
Automated processing & analysis

idylla — **85 - 150 min**

Conventional PCR — **1 Day**

NGS — **3-5 Days**

Liquid biopsy* workflow



Blood draw

Sample loading

Automated processing & analysis

idylla → 85 - 150 min

Conventional PCR → 1 Day

Pyrosequencing → 2 Days

NGS → 3-5 Days

ddPCR → 1 Day

Beaming → 3 Days

* Liquid biopsy currently available only for research applications

Instruments and consumables

idylla

Instruments 

Consumables 

Lab infrastructure (# of rooms) 1

Other RT-PCR

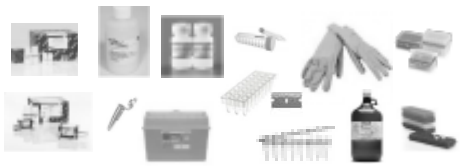
Instruments 

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

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

Future oncology assay targets

FFPE in - report out

- NRAS-BRAF
- NRAS
- EGFR
- MSI

Plasma in - report out

- ctKRAS
- ctNRAS-BRAF-EGFR S492R
- ctNRAS-BRAF
- ctEGFR

Idylla™ BRAF mutation detection on solid and liquid biopsy

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.

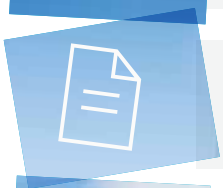
BRAF testing is recommended in all patients with metastatic melanoma and metastatic colorectal cancer (mCRC). About 50% of all metastatic melanoma patients harbor mutations in the BRAF gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy.[8] In mCRC, BRAF mutation status should be assessed 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)

Diagnostic use

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)

Research Use Only, not for diagnostic use

Directly on 1 ml plasma

Semi-quantitative genotype call
+ cq values

Useful 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

FFPE

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

Idylla™ KRAS mutation detection on solid biopsy

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 ESMO9, NCCN14, ASCO16 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 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 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]

DIAGNOSTIC PRODUCT

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

KRAS

Diagnostic use

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

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

Idylla™ NRAS mutation detection on solid biopsy

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]

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 EGFR antibody therapies[9]. About 5% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the NRAS gene.[13]

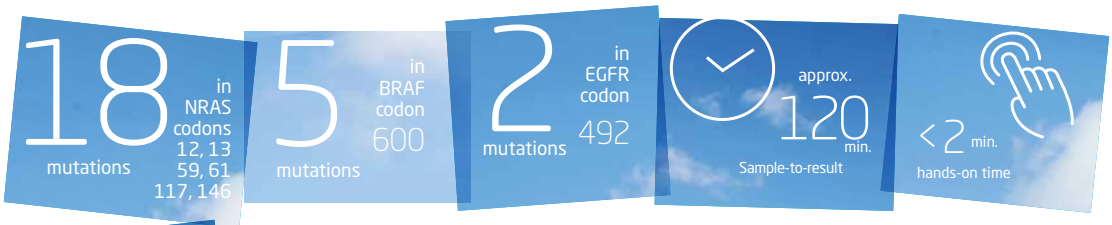
In metastatic colorectal cancer BRAF mutation status should be assessed alongside the assessment of tumor RAS mutational status for prognostic assessment (the presence of a BRAF mutation indicates poor prognosis). The prevalence of BRAF mutations in mCRC is about 8-15%.[9] Recent data suggest that the EGFR S492R mutation may develop as a mechanism of resistance, in about 16% of patients, as a result of certain anti-EGFR antibody therapies such as cetuximab.[23,24] The Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay can be used for the study of emergence of such mutations.

RESEARCH PRODUCT

Idylla™ **NRAS-BRAF-EGFR S492R** Mutation Assay (RUO)

NRAS

Research Use Only, not for diagnostic use



FFPE

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

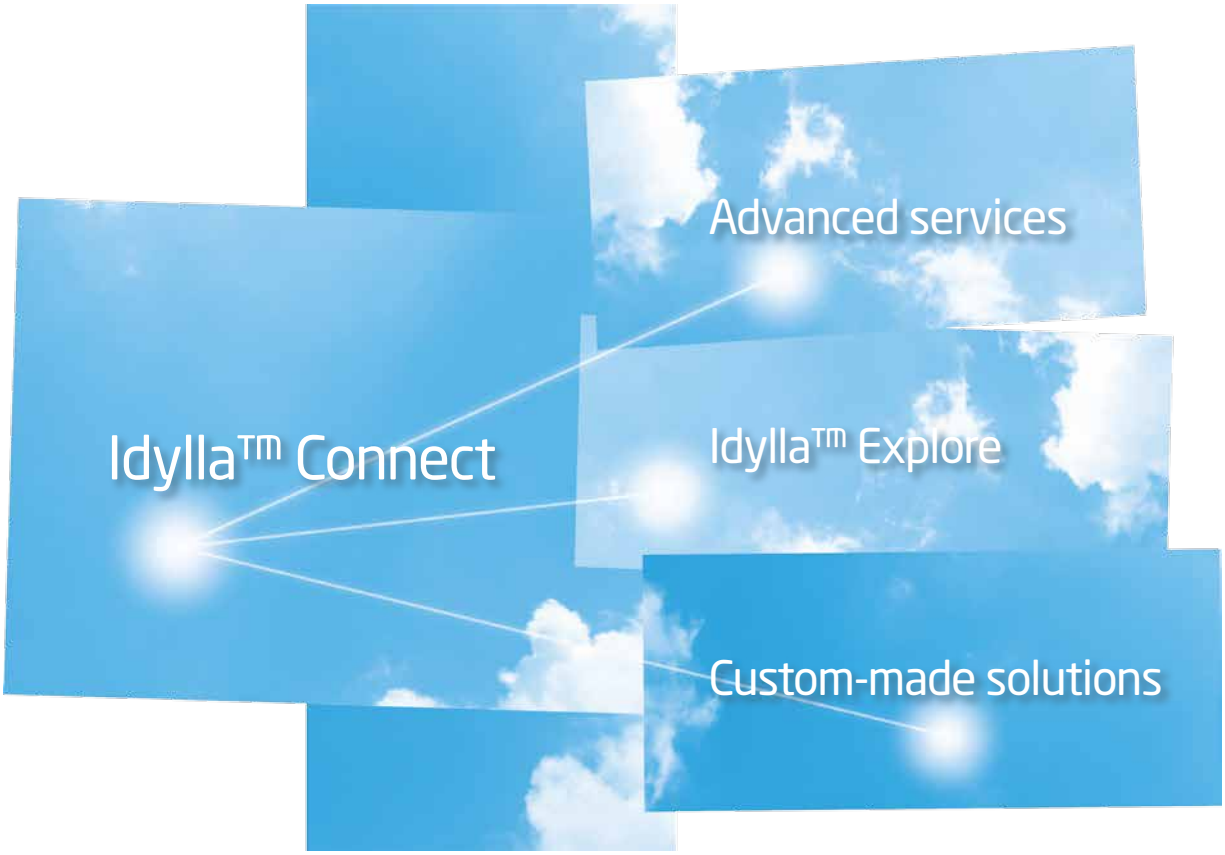
Qualitative genotype call

Applicable in multiple cancers harboring a NRAS, BRAF or EGFR S492R mutation

Richard Colling
University of Oxford, UK

" Idylla™'s unique fully automated and on-demand process has proven to be accurate, reliable and fast"

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.

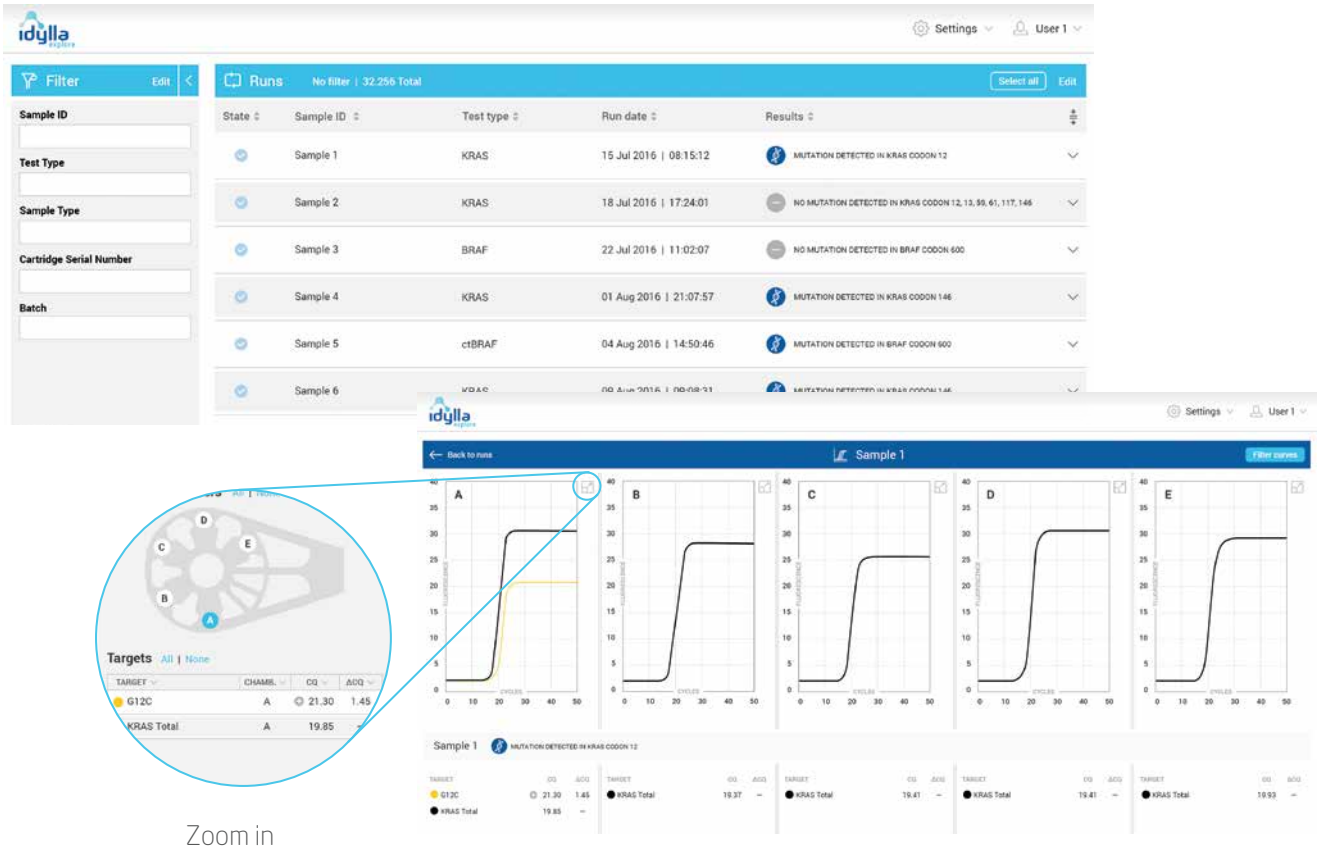
More insight into your data with Idylla™ Explore

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 personalised 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.

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NOTICE

IMPORTANT INFORMATION

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

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