

See how you can
guide the path
her cancer takes



Direct access to
same-day-results



Fully Automated Molecular Diagnostics





"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

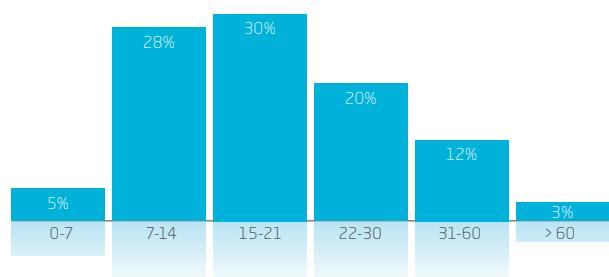
This causes delay to the fast delivery of results, preventing rapid initiation of correct therapy. In the meantime the tumor grows, which is detrimental in case of aggressively growing cancers.

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



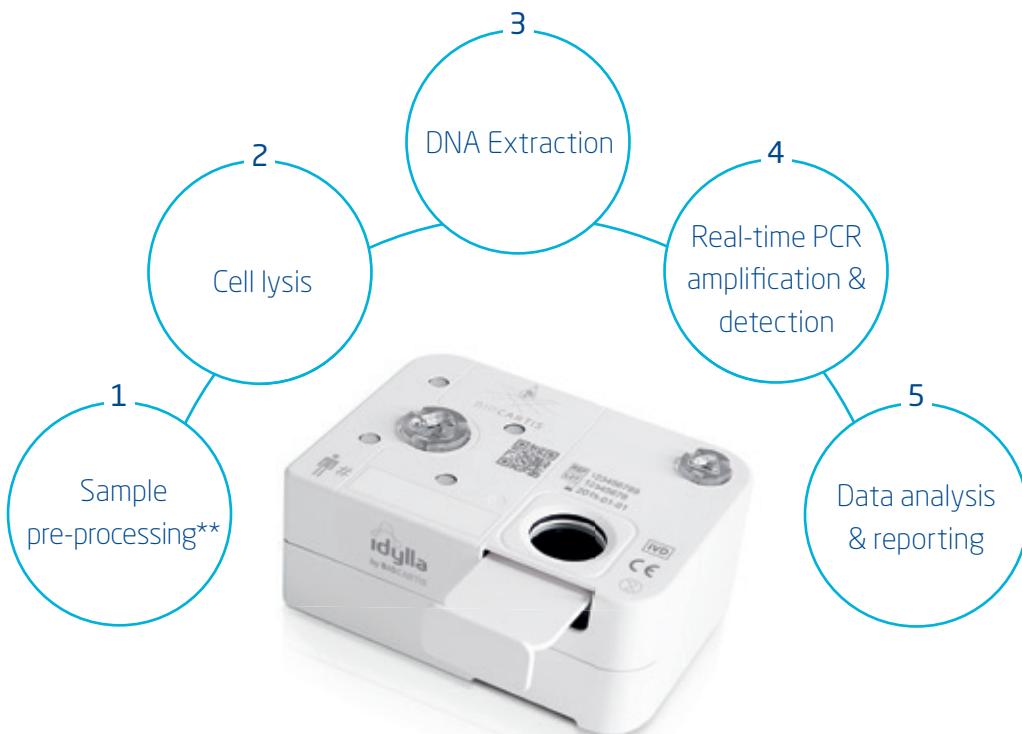
This means that precious time is lost whereas treatment initiation could have been started and unnecessary use of chemotherapy with its side effects could have been avoided.

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



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



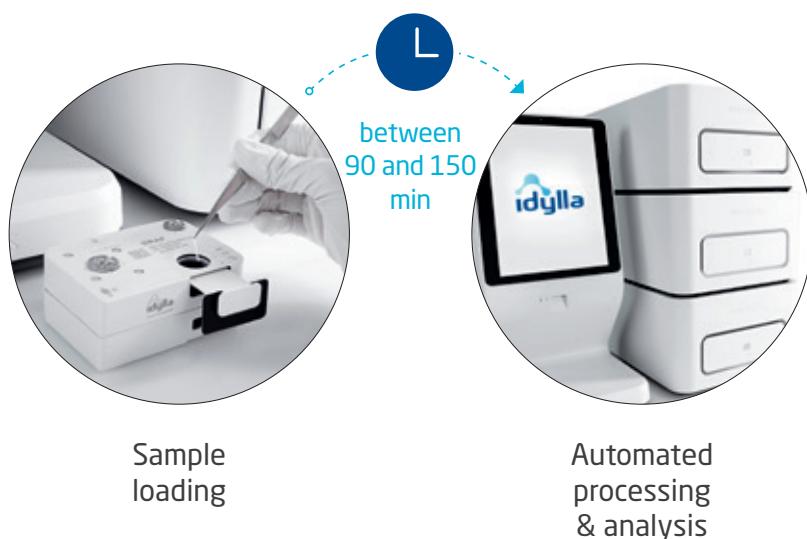
Fully Automated Molecular Diagnostics



The revolutionary Idylla™ workflow

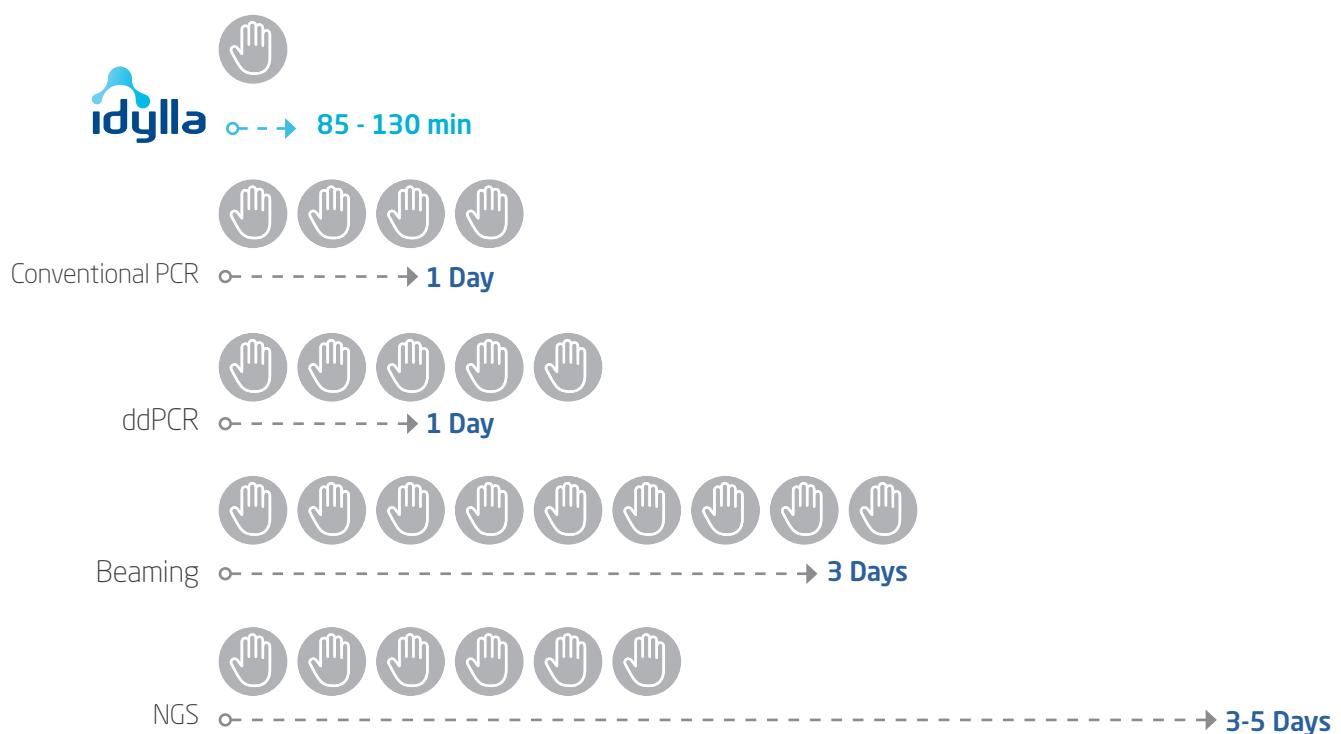
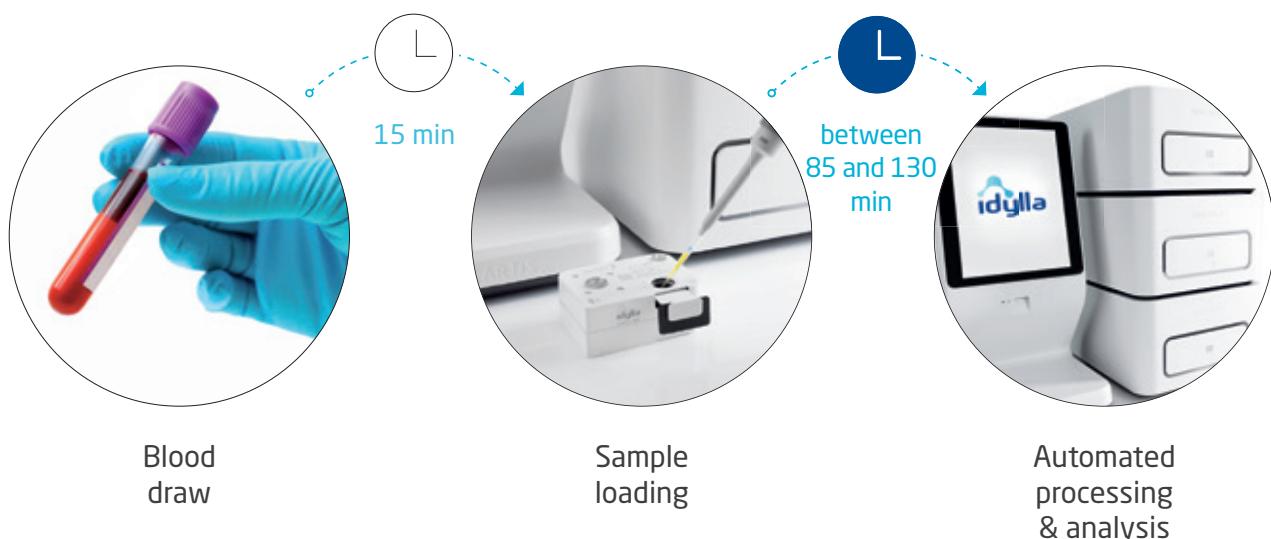
The Idylla™ system in combination with the Idylla™ Molecular Oncology Assays differs from other technologies in its outstanding **ease-of-use**, leading to an unsurpassed level of **standardization**, and its **short turnaround time**, allowing immediate access to therapy.

FFPE workflow





Liquid biopsy* workflow



* Liquid biopsy currently available only for research applications

Instruments and consumables



Instruments



Consumables



Lab infrastructure 1
(# of rooms)

Pyrosequencing

Instruments



Consumables



Lab infrastructure 4
(# of rooms)

Other RT-PCR

Instruments



Consumables



Lab infrastructure 3
(# of rooms)

Next generation sequencing

Instruments



Consumables



Lab infrastructure 4
(# of rooms)



Current oncology assays



FFPE in - report out

Diagnostic products (CE IVD)

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

Future oncology assay targets



FFPE in - report out

- NRAS
- MSI



Plasma in - report out

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

Idylla™ BRAF mutation detection on solid and liquid biopsies



Activating mutations in the BRAF gene are observed in about 8% of all cancers⁷ 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

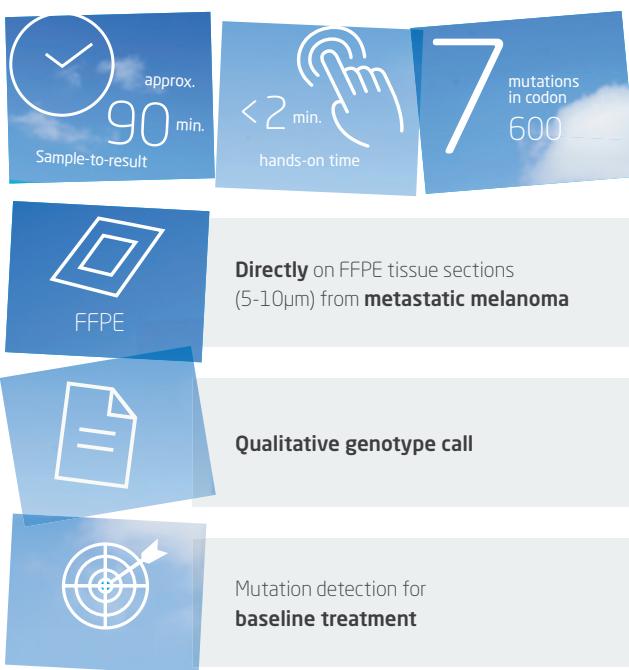
cancer (mCRC). About 50% of all metastatic melanoma patients harbor mutations in the BRAF gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy.⁸ In mCRC, BRAF mutation status should be assessed alongside the assessment of tumor RAS mutational status for prognostic assessment (the presence 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



RESEARCH PRODUCT

Idylla™ ctBRAF Mutation Assay (RUO)

ctBRAF

Research Use Only, not for diagnostic use



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"

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 ESMO⁹, NCCN¹⁴, ASCO¹⁶ and CAP/AMP/ASCO guidelines¹⁵, 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 therapies⁹. 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

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



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



Directly on 1 ml plasma



Qualitative genotype call + Cq values



Useful 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

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 Cancers in which NRAS mutations are observed include: colorectal cancer and melanoma. According to ESMO⁹, NCCN¹⁴, ASCO¹⁶ and the CAP/AMP/ASCO guidelines¹⁵, 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 therapies⁹. About 5% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the NRAS gene.¹³



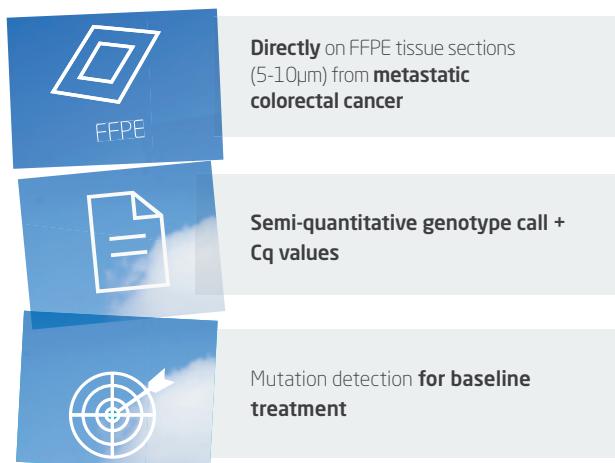
In metastatic colorectal cancer BRAF mutation status should be assessed alongside the assessment of tumor RAS mutational status for prognostic assessment (the presence of a BRAF mutation indicates poor prognosis). The prevalence of BRAF mutations in mCRC is about 8-15%.⁹ The Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay, for Research Use Only, detects 2 additional S492R mutations in the EGFR gene. 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™ NRAS-BRAF-EGFR S492R Mutation Assay can be used for the study of emergence of such mutations.

DIAGNOSTIC PRODUCT

Idylla™ NRAS-BRAF Mutation Test (CE IVD)

NRAS - BRAF

Diagnostic use



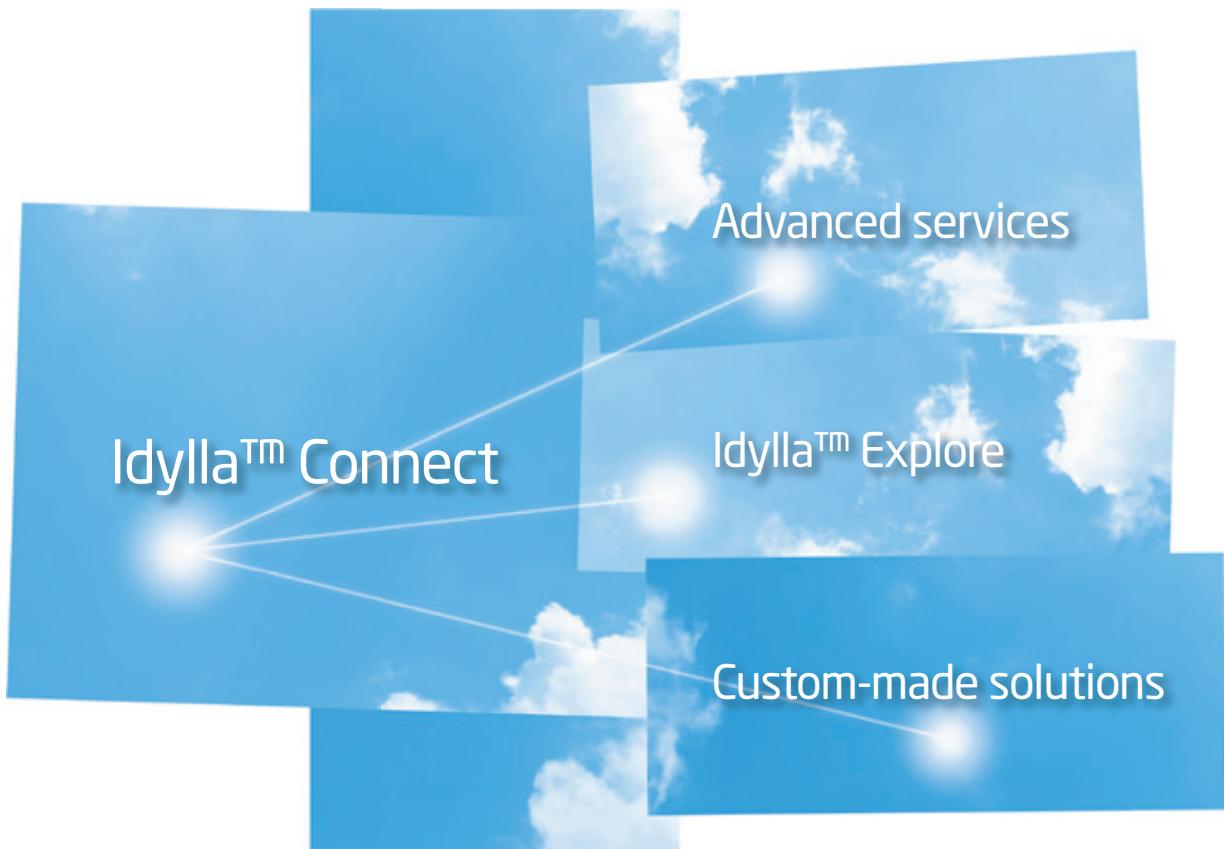
Richard Colling

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

The screenshot displays two main sections of the Idylla™ Explore interface.

Top Section: A table titled "Runs" showing a list of 32,256 total runs. The columns include "State", "Sample ID", "Test type", "Run date", and "Results". The results column shows mutation detection status for each sample. For Sample 1, it indicates "MUTATION DETECTED IN KRAS CODON 12".

State	Sample ID	Test type	Run date	Results
Sample 1	KRAS	15 Jul 2016 08:15:12	MUTATION DETECTED IN KRAS CODON 12	
Sample 2	KRAS	18 Jul 2016 17:24:01	NO MUTATION DETECTED IN KRAS CODON 12, 13, 59, 61, 117, 146	
Sample 3	BRAF	22 Jul 2016 11:02:07	NO MUTATION DETECTED IN BRAF CODON 600	
Sample 4	KRAS	01 Aug 2016 21:07:57	MUTATION DETECTED IN KRAS CODON 146	
Sample 5	cBRAF	04 Aug 2016 14:50:46	MUTATION DETECTED IN BRAF CODON 600	
Sample 6	BRCA1	05 Aug 2016 05:08:01	MUTATION DETECTED IN BRCA1 CODON 1436	

Bottom Section: A detailed view for "Sample 1". It includes a circular diagram of the Idylla cartridge with targets labeled A-E, and a table showing targets G12C and KRAS Total with Cq values of 21.30 and 19.85 respectively. Below this is a "Zoom in" button.

PCR Curve Analysis: Five individual PCR curves (A-E) are shown for Sample 1. Each graph plots fluorescence against cycle number (0-50). Curves A, C, and E show a sharp increase in fluorescence starting around cycle 20, indicating a positive result for KRAS codon 12. Curves B and D show a more gradual increase, indicating a negative result.



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.

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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

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IMPORTANT INFORMATION

Idylla™ platform, Idylla™ BRAF Mutation Test, Idylla™ KRAS 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, and Idylla™ EGFR Mutation Assay are available for Research Use Only, not for use in diagnostic procedures. Idylla™ ctKRAS Mutation Assay, Idylla™ ctKRAS Mutation Test, Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay, Idylla™ EGFR Mutation Test, 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.

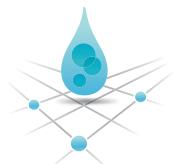
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