Idylla™ A revolutionary, fully automated system that makes molecular testing convenient and exceptionally fast. Suitable for any lab.
BIOCARTIS’ MISSION
IS TO OFFER RAPID & EASY
MOLECULAR DIAGNOSTIC SOLUTIONS
AIMED AT ENABLING
FASTER & MORE ACCURATE
TREATMENT DECISIONS FOR ONCOLOGY
PATIENTS ACROSS THE GLOBE.
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 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.

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.

Fast initiation of immunotherapy or targeted therapy as first-line treatment is crucial for cancer patients, as it increases overall survival rates. 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.

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™, 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 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**

**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
- Storage and shipment at room temperature

**SAMPLE VERSATILITY**
- For solid and liquid biopsy

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

**ACCURATE RESULTS**
- High sensitivity
- Highly standardized technology
- Contamination-controlled design

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

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

**FAST RESULTS**
- ± 2 minutes hands-on time
- Short turnaround time from 85 to ± 160 minutes

**SAMPLE VERSATILITY**
- For solid and liquid biopsy

**ACCESSIBLE**
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- Multiple genes and loci detection in one cartridge

**CONNECTIVITY**
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- Bi-directional LIS
THE REVOLUTIONARY IDYLLA™ WORKFLOW

FFPE WORKFLOW

SAMPLE PREPARATION < 2 min
SAMPLE LOADING 90 - 150 min
AUTOMATED PROCESSING & ANALYSIS

idylla 90 - 150 min

Conventional PCR 1 day
Pyrosequencing 2 days
NGS 3-5 days
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.

**LIQUID BIOPSY WORKFLOW**

- **PLASMA PREPARATION**
  - Protocol: ± 20 min

- **SAMPLE LOADING**
  - ± 2 min

- **AUTOMATED PROCESSING & ANALYSIS**
  - ± 160 min

**Liquid Biopsy Workflow**

- **Conventional PCR**
  - ± 160 min
  - 1 day

- **ddPCR**
  - ± 160 min
  - 1 day

- **Beaming**
  - ± 160 min
  - 3 days

- **NGS**
  - ± 160 min
  - 3-5 days
## Instruments and Consumables

### Other RT-PCR

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### Next Generation Sequencing

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**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™ EGFR Mutation Test
- Idylla™ MSI Test

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

**PLASMA IN - REPORT OUT**
Diagnostic products (CE IVD)
- Idylla™ ctKRAS Mutation Test
- Idylla™ ctNRAS-BRAF Mutation Test

Research products (RUO)
- Idylla™ ctBRAF Mutation Assay
- Idylla™ ctEGFR Mutation Assay
- Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay

**FUTURE ONCOLOGY ASSAY TARGETS**

**FFPE IN - REPORT OUT**
- Idylla™ GeneFusion Assay
BACKGROUND INFORMATION* Activating mutations in the BRAF gene are observed in about 8% of all cancers 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. 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%.

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

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

**Qualitative genotype call**

**Mutation detection for baseline treatment**

**Diagnostic use**

**RESEARCH PRODUCT**

**Directly on 1 ml plasma**

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

**Applicable in multiple cancers harboring BRAF mutations**

“*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
**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.\(^6,9\)

Exon 19 deletion and exon 21 (L858R, L861), exon 18 (G719X), and exon 20 (S768I) mutations are associated with sensitivity to TKI’s. Exon 20 insertion mutation may predict resistance to TKI’s. 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 1\(^{st}\) or 2\(^{nd}\) generation TKI’s.\(^8,9\)

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.\(^8,9,14\)

*Idylla™ EGFR Mutation Test is validated for metastatic NSCLC

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**DIAGNOSTIC PRODUCT**

Idylla™ EGFR Mutation Test (CE IVD)

- Diagnostic use
- **Diagnostic use**
- **Approx. 150 min** sample-to-result
- **< 2 min** hands-on time
- **51mutations**
- Directly on 1 FFPE tissue section (5 \(\mu\)m) from metastatic non-small-cell lung cancer
- Qualitative genotype call + Cq values
- Mutation detection for treatment assessment

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**RESEARCH PRODUCT**

Idylla™ ctEGFR Mutation Assay (RUO)

- Research Use Only, not for diagnostic use
- **Research Use Only, not for diagnostic use**
- **Approx. 160 min** sample-to-result
- **± 2 min** hands-on time
- **49mutations**
- Directly on 2 ml plasma
- Qualitative genotype call + Cq values + Quality status
- Applicable in NSCLC harboring EGFR mutations

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“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
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.15 Cancers in which KRAS mutations are observed include: colorectal cancer, lung cancer and pancreatic cancer.

According to ESMO6, NCCN16, ASCO17 and CAP/AMP/ASCO guidelines18, 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 therapies5. About 46% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the KRAS gene.19 Several studies are ongoing to define the predictive impact of KRAS mutations on therapy decision for non-small-cell lung cancer (NSCLC) patients.20-22 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 can be used as an alternative or complement to tissue testing to determine the RAS mutation status at diagnosis.

*Idylla™ RAS Mutation Tests are validated for use in mCRC

DIAGNOSTIC PRODUCT
Idylla™ KRAS Mutation Test (CE IVD)

Diagnostic use

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

Qualitative genotype call

Mutation detection for baseline treatment

approx. 120 min
< 2 min
21 encoded in codons 12, 13, 59, 61, 117, 146

DIAGNOSTIC PRODUCT
Idylla™ ctKRAS Mutation Test (CE IVD)

Diagnostic use

Directly on 1 ml plasma from mCRC patients

Qualitative genotype call + Cq values

Mutation detection for baseline treatment

approx. 130 min
< 1 min
21 encoded in codons 12, 13, 59, 61, 117, 146

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

“Idylla™ allows very quick results with little hands-on time”
NRAS-BRAF ctNRAS-BRAF

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. Cancers in which NRAS mutations are observed include colorectal, lung, thyroid cancers and melanoma. According to ESMO, NCCN, ASCO and the CAP/AMP/ASCO guidelines, 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. About 5% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the NRAS gene. 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-BRAF testing is minimally invasive, fast and easy to perform and can be used as an alternative or complement to tissue testing to determine the RAS mutation status at diagnosis.

*Idylla™ RAS Mutation Tests are validated for use in mCRC

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

Diagnostic use

- Qualitative genotype call + Cq values
- Mutation detection for baseline treatment

ctNRAS-BRAF DIAGNOSTIC PRODUCT
Idylla™ ctNRAS-BRAF Mutation Test (CE IVD)

Diagnostic use

- Qualitative genotype call + Cq values
- Mutation detection for baseline treatment

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

Directly on 1 ml plasma from mCRC patients

In BRAF codon 600

In BRAF codon 600
**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.\(^{23}\)

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.\(^{24}\)

Clinical trials and pathophysiological studies indicate a wide distribution of MSI-H across tumor types.\(^{25}\)

In addition to CRC, high incidences are observed in endometrial cancer (20-30%), and gastric cancer (15-20%).\(^{26}\)

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.\(^{27,30}\)

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.\(^{31,32}\)

*Idylla™ MSI Test is only validated for CRC

**DIAGNOSTIC PRODUCT**

**Idylla™ MSI Test (CE IVD)**

**Diagnostic use**

- **aprox. 150 min** sample-to-result
- **< 2 min** hands-on time
- 7 novel MSI Bio-markers*  

- 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

**“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

*ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2
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
IDYLLA™: NOTHING IS SIMPLE IN ONCOLOGY. NOTHING BUT THIS.

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™ ORDER INFORMATION

## Diagnostic Products (CE-IVD)

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customerservice@biocartis.com
REFERENCES

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(8) NCCN Clinical Practice Guidelines in Oncology – NSCLC – Version 6.2017
(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
(18) http://www.amp.org/committees/clinical_practice/CRCOpenComment.cfm
(26) Sigurdis Haraldsdottir (2017) Microsatellite instability testing using next-generation sequencing data and therapy implications. JCO Precision Oncology 1, 1-4.
(27) Van Cutsem et al. (2016) ESMO Consensus Guidelines for the management of patients with mCRC. Annals of Oncology 27, 1386.
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 and Idylla™ ctBRAF Mutation Assay
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Idylla™ KRAS Mutation Test, Idylla™ KRAS Mutation Assay, Idylla™ ctKRAS Mutation Test and Idylla™ ctKRAS Mutation Assay
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Idylla™ NRAS-BRAF Mutation Test, Idylla™ ctNRAS-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, ctNRAS-BRAF-EGFR S492R Mutation Assay and Idylla™ 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
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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.

Important information
Idylla™ platform and Idylla™ BRAF, KRAS, NRAS-BRAF, EGFR, ctKRAS & ctNRAS-BRAF Mutation Tests and Idylla™ MSI Test are CE-marked IVD’s in Europe. Idylla™ BRAF, KRAS, EGFR, NRAS-BRAF-EGFR S492R, ctBRAF, ctKRAS, ctNRAS-BRAF-EGFR S492R & ctEGFR Mutation Assays and Idylla™ MSI Assay are available for Research Use Only (RUO), not for use in diagnostic procedures. Idylla™ GeneFusion Assay is under development. Idylla™ is available for sale in EU, USA and some other countries. Please check availability with the local Biocartis sales representative.

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