Rapid, Molecular Diagnostics Enabling Personalized Medicine for Oncology Patients Worldwide

THINK IDYLLA™

idylla by BIOCARTIS

Idylla™. A revolutionary, fully automated system generating molecular biomarker results in only 3 hours! 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]

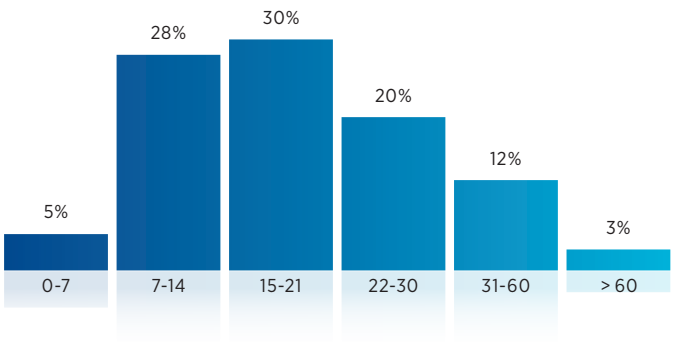
This causes delay to the fast delivery of results, preventing rapid initiation of correct therapy. In the meantime the tumor grows, which is detrimental in case of aggressively growing cancers.

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.[6-9] 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.[10]

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

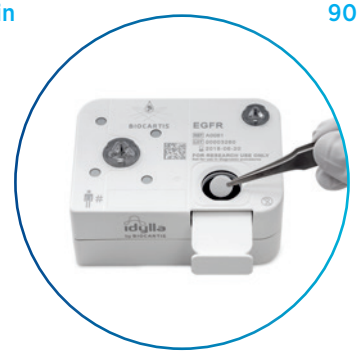
THE REVOLUTIONARY IDYLLA™ WORKFLOW

STANDARD SOLID BIOPSY WORKFLOW

< 3 min

90 - 180 min

SAMPLE PREPARATION



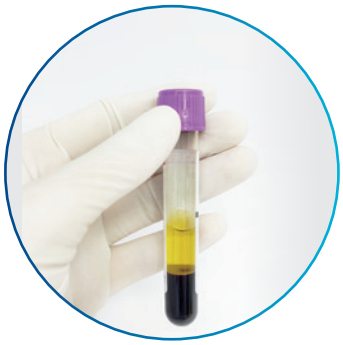
SAMPLE LOADING

AUTOMATED PROCESSING & ANALYSIS

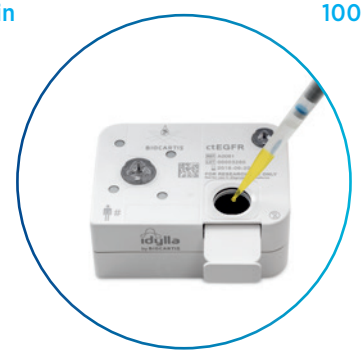
STANDARD LIQUID BIOPSY WORKFLOW

< 1 min

100 - 160 min



PLASMA PREPARATION PROTOCOL ±20 MIN



SAMPLE LOADING

AUTOMATED PROCESSING & ANALYSIS

IDYLLA™ COMPARED TO OTHER TECHNOLOGIES

MINIMAL HANDS-ON AND ASSAY TURNAROUND TIMES

idylla

90 - 180 min

Other RT - PCR

1 day

NGS

3-5 days

REDUCED NUMBER OF INSTRUMENTS AND CONSUMABLES NEEDED

	idylla	OTHER RT-PCR	NEXT GENERATION SEQUENCING
INSTRUMENTS			
CONSUMABLES			
LAB INFRASTRUCTURE (# OF ROOMS)	1	3	4

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 is an important biomarker in lung cancer, particularly in NSCLC. Today, all major clinical guidelines recommend EGFR mutation testing — specifically in exons 18 to 21 — for every patient with advanced NSCLC. Testing is also recommended for patients diagnosed with stage IB to IIIA NSCLC to help guide (neo)adjuvant therapy decisions.

Activating mutations in the *EGFR* gene are linked to how patients respond to targeted therapies. Exon 19 deletions, exon 21 (L858R, L861Q), exon 18 (G719X), and exon 20 (S768I) mutations are associated with increased sensitivity to Tyrosine Kinase Inhibitors (TKIs), while exon 20 insertions predict resistance to TKIs. The prevalence of EGFR mutations in NSCLC is approximately 15% in Western populations and may reach up to 50% in Asian populations.

Determining a patient's EGFR status is key to defining the most effective and personalized treatment.

*Idylla™ EGFR Mutation Test is validated for NSCLC

DIAGNOSTIC PRODUCT

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

EGFR

Diagnostic use

EU-IVDR

approx. 150 min — sample-to-result
< 3 min — hands-on time
44 — in exons 18, 19, 20, 21 — mutations

FFPE

Directly on 2-4 FFPE tissue sections (5-10 µm) from **NSCLC**

Qualitative genotype call + Cq values + Quality status

CDx

Companion diagnostic (CDx): Identifies mutations (exon 19 deletions & L858R) linked to targeted therapy. Other EGFR mutations are analytically validated.

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 — in exons 18, 19, 20, 21 — mutations

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.[12-14]

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

approx. 180 min sample-to-result

< 3 min hands-on time

ALK, ROS1, RET & MET EXON 14 SKIPPING

FFPE

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

approx. 180 min sample-to-result

< 3 min hands-on time

ALK, ROS1, RET, NTRK1/2/3 REARRANGEMENTS & MET EXON 14 SKIPPING

FFPE

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

BRAF

IDYLLA™ BRAF MUTATION DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION*
Activating mutations in the *BRAF* gene are observed in about 8% of all cancers[28] 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.[29] 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

approx. 90 min
sample-to-result

< 2 min
hands-on time

7 in codon 600
mutations

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

ThyroidPrint

IDYLLA™ THYROIDPRINT® GENE EXPRESSION SIGNATURE FOR INDETERMINATE THYROID NODULES ON FINE NEEDLE ASPIRATE BIOPSIES

BACKGROUND INFORMATION

Thyroid nodules are a frequent condition, affecting up to 30-40% of the adult population. Although most thyroid nodules have little clinical significance, in many cases a fine needle aspirate (FNA) biopsy will be performed to determine its nature. In 70% of cases, an FNA will be reported as benign and in 10% of cases as cancer, based on cytological examination. However, in the remaining **20%** of cases, the thyroid nodule will be reported as **indeterminate (Bethesda III/IV)*.**[11]

The Idylla™ ThyroidPrint® Assay assesses the gene expression profile of FNA samples to enable laboratories to conduct further research on risk stratification of indeterminate thyroid nodules. The Assay is a qualitative reverse transcription polymerase chain reaction (RT-PCR)-based assay with real-time detection and reports either a 'HIGH' or 'LOW' Idylla™ ThyroidPrint® result, based on a gene expression classifier score derived from 10 target genes. A **'HIGH'** result is indicative of an **atypical gene expression,** while a **'LOW'** result is indicative of **a normal gene expression.**

The Idylla™ ThyroidPrint® Assay procedure has been optimized for fresh FNA samples collected from an indeterminate thyroid nodule and stored in ThyroidPrint® Collection Buffer.

ThyroidPrint

RESEARCH PRODUCT

Idylla™ **ThyroidPrint®** Assay (RUO)

Research Use Only, not for diagnostic use

approx. 160 min
sample-to-result

< 5 min
hands-on time

10 epithelial and stromal cell target genes combined with a proprietary algorithm

Fresh FNA sample from an indeterminate thyroid nodule (Bethesda III/IV)* collected in ThyroidPrint® Collection Buffer

Idylla™ ThyroidPrint® **Result** reported as either **'HIGH'** or **'LOW'**

Assessment of gene expression profile in FNA for risk stratification of indeterminate thyroid nodules

*Bethesda III and IV (International)/Thy3a and Thy3f (UK)/TIR3A and TIR 3B (Italian)

KRAS ctKRAS

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

According to ESMO[6], NCCN[16], ASCO[17] and CAP/AMP/ASCO guidelines[18], 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 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 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

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 (5-10 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

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-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.[15] Cancers in which *NRAS* mutations are observed include colorectal, lung, thyroid cancers and melanoma.

According to ESMO[6], NCCN[16], ASCO[17] and the CAP/AMP/ASCO guidelines[18], 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.[19] 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.

*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 — in NRAS codons 12, 13, 59 61, 117, 146 — mutations
- 5 — in BRAF codon 600 — mutations
- 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 — in NRAS codons 12, 13, 59 61, 117, 146 — mutations
- 5 — in BRAF codon 600 — mutations
- 2 — in EGFR codon 492 — mutations
- **Directly** on 1 ml plasma
- **Semi-quantitative genotype call + Cq values**
- **Applicable in multiple cancers** harboring NRAS, BRAF or EGFR S492R mutations

MSI-CDx

IDYLLA™ MSI DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION*
Microsatellite instability-high (MSI-H) describes tumors with a high level of variation in microsatellite regions — short, repetitive DNA sequences, often including homopolymers, that are prone to replication errors.

When the DNA mismatch repair (MMR) system is deficient, these errors are no longer corrected and accumulate across the tumor genome. This can lead to the formation of new abnormal proteins (neoantigens) that are recognized by the immune system.

In colorectal cancer, microsatellite status is a critical biomarker used to guide first-line MSI-H mCRC patient stratification and treatment decisions for immunotherapy, such as nivolumab in combination with ipilimumab.

*Idylla™ CDx MSI Test is only validated for mCRC

DIAGNOSTIC PRODUCT

Idylla™ **CDx MSI** Test (CE-IVD)

MSI-CDx

Diagnostic use

EU-IVDR

approx. 150 min
sample-to-result

< 3 min
hands-on time

7 MSI biomarkers**

FFPE

Directly on FFPE tissue sections (4-10 µm) from colorectal cancer. **No need** for **paired normal tissue sections**

Qualitative MSI call

CDx

Companion diagnostic (CDx): Identifies MSI-H mCRC patients who may benefit from treatment with OPDIVO® + YERVOY®

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

POLE-POLD1

IDYLLA™ POLE-POLD1 MUTATION DETECTION ON SOLID BIOPSIES

BACKGROUND INFORMATION
Pathogenic POLE and POLD1 mutations drive an ultramutated phenotype across multiple cancer types, correlating with a favorable prognosis. They are emerging as a predictive biomarker for immunotherapy.[30]

The Idylla™ POLE-POLD1 Mutation Assay (RUO) qualitatively detects 17 mutations in the *POLE* gene (P286H, P286L, P286R, P286S, M295R, S297F, F367S, F367V, D368Y, V411L (c.1231 G>C; G>T), L424I, L424V, P436R, M444K, A456P, S459F). Additionally, the assay detects one mutation in the *POLD1* gene (S478N).

POLE-POLD1

RESEARCH PRODUCT

Idylla™ **POLE-POLD1** Mutation Assay (RUO)

Research Use Only, not for diagnostic use

approx. 95 min
sample-to-result

< 3 min
hands-on time

17 POLE mutations

1 POLD1 mutation

FFPE

Directly on FFPE tissue sections

Qualitative genotype call + Cq values

Applicable in multiple cancers harboring POLE and POLD1 mutations

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

approx. 95 min
sample-to-result

< 5 min
hands-on time

5 mutations in *IDH1* gene (codon 132)

10 mutations in *IDH2* gene (codons 140 & 172)

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

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.[25-27]

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

approx. 150 min
sample-to-result

< 2 min
hands-on time

14 PIK3CA & AKT1
mutations

FFPE

Directly on FFPE tissue sections

Qualitative genotype call
+ Cq values

Applicable in multiple cancers
harboring PIK3CA and AKT1 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**

SAFE & SECURED DATAFLOW

ZOOM IN

IDYLLA™ ORDER INFORMATION

DIAGNOSTIC PRODUCTS (CE-IVD)

			Catalog#
Idylla™ EGFR Mutation Test	IVDR	6 cartridges/box	A0270/6
Idylla™ EGFR Mutation Test	IVDD	6 cartridges/box	A0060/6
Idylla™ GeneFusion Panel	IVDD	6 cartridges/box	A0120/6
Idylla™ BRAF Mutation Test	IVDD	6 cartridges/box	A0010/6
Idylla™ KRAS Mutation Test	IVDD	6 cartridges/box	A0020/6
Idylla™ NRAS-BRAF Mutation Test	IVDD	6 cartridges/box	A0030/6
Idylla™ CDx MSI Test	IVDR	6 cartridges/box	A0220/6
Idylla™ MSI Test	IVDD	6 cartridges/box	A0100/6

RESEARCH PRODUCTS (RUO)

		Catalog#
Idylla™ EGFR Mutation Assay	6 cartridges/box	A0061/6
Idylla™ ctEGFR Mutation Assay	6 cartridges/box	A0111/6
Idylla™ GeneFusion Assay	6 cartridges/box	A0121/6
Idylla™ BRAF Mutation Assay	6 cartridges/box	A0011/6
Idylla™ ThyroidPrint® Assay	6 cartridges/box	TP0011/6
Idylla™ KRAS Mutation Assay	6 cartridges/box	A0021/6
Idylla™ ctKRAS Mutation Assay	6 cartridges/box	A0081/6
Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	A0031/6
Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay	6 cartridges/box	A0091/6
Idylla™ MSI Assay	6 cartridges/box	A0101/6
Idylla™ POLE-POLD1 Mutation Assay	6 cartridges/box	A0281/6
Idylla™ IDH1-2 Mutation Assay (Vial)*	6 vials/box	A0181/6
Idylla™ DNA Cartridge*	6 cartridges/box	A0191/6

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

Idylla™ PIK3CA-AKT1 Mutation Assay	6 cartridges/box	A0171/6

IDYLLA™ ORDER INFORMATION

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

CONNECTIVITY		Catalog#
Idylla™ Explore		P2041
Connectivity Service		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.

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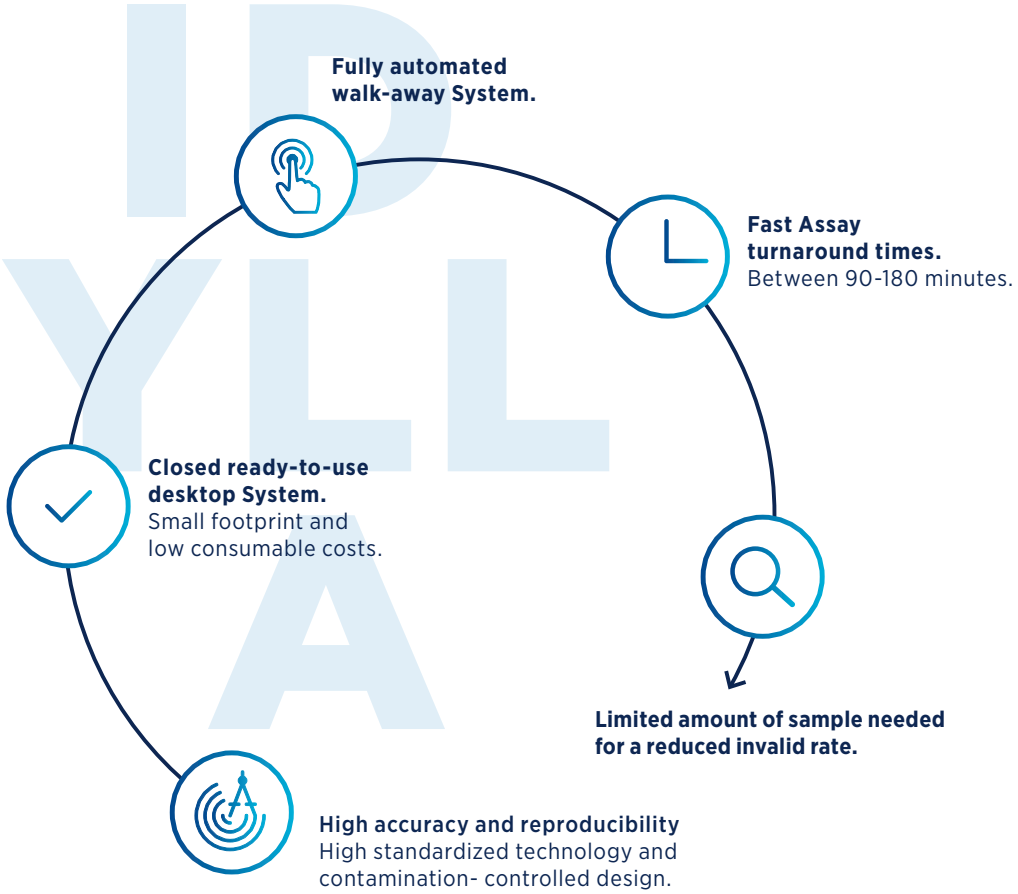

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