

Idylla™





Idylla™, Biocartis' fully automated, real-time PCR based molecular diagnostics system, is designed to offer physicians fast access to clinical molecular diagnostic information, anywhere and anytime. The Idylla™ system works on-demand in virtually any setting, allowing also de-centralized laboratories to rapidly report results. Idylla™ covers the entire process from sample to result in a time frame of 35 to 120 minutes.

This allows laboratories to report same-day results, ensuring physicians have the information needed to make timely decisions. The fully integrated system enables clinical laboratories to perform a broad range of applications, including oncology, infectious diseases and genetic tests.

"The Idylla™ system is so easy to use, we don't have to plan our work. With Idylla™ in our laboratory, we can run samples on-demand."

Mark Kockx,
MD, PhD, Managing Director/
Pathologist
HistoGeneX

Going molecular has never been easier

-  **Ease of use**
Less than 2 minutes hands-on time
-  **Access on-demand**
Run samples on-demand, no need for batching
-  **Speed**
Sample to result in 35 to 120 minutes
-  **Multiplexing**
Detects up to 30 molecular targets in standard mode ⁽¹⁾

⁽¹⁾ Specific assay protocols are under development to enable the detection of more than 30 biomarkers per sample.

Currently, molecular diagnostics involves a series of specialized, labor-intensive and time-consuming steps. To optimize costs and processing times, traditional molecular diagnostics tests are mainly performed on multiple instruments, in batches and operated by highly trained personnel.

With its compact design and unrivaled ease of use, Idylla™ overcomes the traditional barriers of molecular diagnostics, making these types of tests widely accessible to all types of clinical laboratories. Idylla™ is the

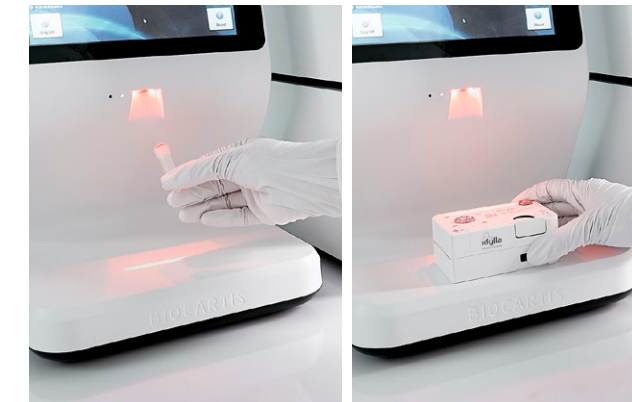
only system that requires less than 2 minutes of operator time to run a sample. The fully integrated sample-to-result solution eliminates the need for manual sample preparation, addition of buffers or master-mix, pre-mixing of reagents or centrifugation.

After the patient sample is inserted, the cartridge is hermetically sealed to prevent the spread of any DNA amplification products which might cause contamination of the laboratory environment or equipment.



Just add the sample, insert the cartridge in the system and walk away.

Unrivaled ease of use



① Scan sample & cartridge
FFPE, swab, blood, urine, stool, sputum, tissue



② Load sample in the cartridge



③ Insert the cartridge in the Idylla™ system

Liquefaction



- Homogenization of solid/ viscous samples by using chemical reagents, enzymes, heat and high-intensity focused ultrasound (HiFU).

Cell Lysis



- Disruption of the cells, containing nucleic acids to be analyzed, by using chemical reagents, enzymes, heat and HiFU.

DNA/RNA Extraction



- Filtration of the lysed sample.
- Silica-based extraction; purification and concentration of nucleic acids.

Real-time PCR Amplification & Detection



- Real-time amplification in up to five individually controlled PCR chambers, each containing 25 µl of eluate.
- Primer/probe mixes and enzyme mixes pre-spotted in every PCR chamber, including primer/probe mix to detect/ amplify a sample processing control (e.g. endogenous control).
- Detection of 6 different fluorophores per PCR chamber, allowing identification of up to 30 different molecular targets in standard mode ⁽¹⁾ in each cartridge.

Data Analysis & Reporting

- Full interpretation of results.
- Automatic creation of Idylla™ test result report.

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All processing steps in one powerful cartridge



System overview



① Independent instruments

- Scalable up to 8 instruments per console
- Fully automated

② Compact console

- Touchscreen user interface
- Built-in barcode scanner
- LIS and remote connectivity capability

③ Fully integrated test cartridge

- Contamination-controlled design
- All reagents on-board
- Applicable for a wide variety of clinical samples

Idylla™ system specifications

Physical dimensions

Console
w: 254 mm / 10 inch
h: 506 mm / 19,92 inch
d: 254 mm / 10 inch

Instrument
w: 305 mm / 12,01 Inch
h: 190 mm / 7,48 Inch
d: 505 mm / 19,88 Inch

Weight
console: 5,2 kg
instrument: 20 kg

Operating conditions

Temperature: 15 ... 30 °C
Humidity: 40 ... 60 %RH
Pressure: 80 ... 106 kPa

Power requirements

Console
Power Supply: 100-240 V; 50/60 Hz
Average Power Consumption: 100 W
Noise Level: Max. 49 dB(A)

Instrument
Power Supply: 100-240 V; 50/60 Hz
Average Power Consumption: 200 W
Noise Level: Max. 54 dB(A)

Cartridges
Single-use disposable cartridges
Polypropylene construction

Contact

Order information

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

Biocartis' trademark and logo are registered in Europe.
Idylla™ is a CE-marked IVD in Europe.
Engineering prototype in United States.

Molecular diagnostics beyond simplicity



Idylla™ Fully-automated molecular diagnostics system