GeneXpert®

Cepheid®

GeneXpert® System

Improving healthcare through on-demand molecular diagnostics

Improving Healthcare

"GeneXpert outperforms what I expected. Most companies promise the sun and deliver the moon. It promised the moon and delivered the sun. If you have a device that can save you money in terms of patient time in the hospital, supplies in the hospital, and the health of the patient, its value isn't measureable."

Gail Woosley, Lab Director — Wooster Community Hospital

Our goal is patient safety. We want to decrease our nosocomial and MRSA infection rates. This tool will enable us to decrease them. It lets us put patients on contact precaution on a quicker time basis than if we cultured and waited two or three days and then put them on contact precaution. It's an early warning system. The staff loves it, especially for patient placement.

Beverly Sturgill, IC Control Officer — Carilion Clinic

Cepheid®


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The GeneXpert® System

A

paradigm shift

in the accessibility and utility of molecular diagnostics.

Cepheid is bringing fast, accurate and simplified molecular testing to the front lines of the clinical market —giving healthcare professionals the immediate answers they need to improve patient care.

Cepheid's GeneXpert® System represents a major paradigm shift in the accessibility and utility of molecular diagnostics. Until now, slow, labor-intensive methods have confined molecular testing to large and expensive specialty laboratories run by highly trained technologists. And, traditional batch testing protocols have limited the timely availability of important test results to healthcare professionals.

The GeneXpert System delivers actionable results on-demand, when they matter most. The system requires no specialized skills to operate, enabling round-the-clock testing 24 hours a day, 365 days a year. Each of up to 16 sites are operated independently, so samples can be processed immediately, delivering rapid, actionable test results that will enable health care professionals to make the most informed decisions possible. With a level of performance that may be greater than any other real-time PCR system, the GeneXpert can be used to detect any genetic element in the genome—including DNA, RNA, chromosomal trans-locations, gene amplification and suppression.

The GeneXpert® System

fully integrates and automates the three processes required for real-time PCR-based molecular testing: sample preparation, amplification, and detection, all in one cartridge.

On-demand. Just load a biological sample and the system does the rest.

GeneXpert Cartridge

The cornerstone of the GeneXpert testing process is Cepheid's patented, self-contained, single use cartridges. Sample processing, amplification and detection are all carried out within this self-contained device.

Sample preparation and extraction of nucleic acids.

The GeneXpert® System completely automates sample preparation, performing all the complex steps of DNA extraction in its advanced “microfluidic” cartridges. The GeneXpert cartridges are designed to handle a variety of sample volumes, enabling them to obtain higher concentrations of starting target materials. Concentration and purification of the target in the cartridge further increases the sensitivity of the resulting test. Once the sample nucleic acid is extracted, it is moved from the sample processing chamber in the cartridge into the cartridge reaction tube where amplification and detection take place.

Amplification of extracted nucleic acids.

The GeneXpert System modules perform the extremely rapid heating and cooling cycles required for highly reliable, real-time PCR in the reaction tube of the cartridge. The modules continuously monitor the chemical reactions in each cartridge in order to quickly create enough copies of the sample nucleic acid for reliable measurement. Each of the modules works independently and can be used to conduct different tests simultaneously.

Detection of a target gene sequence.

The GeneXpert System’s optics detect the presence of multiple target nucleic acids in the same cartridge. Continuous optical monitoring allows the software to automatically stop the reaction as soon as the target(s) is detected, further accelerating time to results. The GeneXpert software also contains the unique feature of Advance to Subsequent Stage which allows for automated reflex or confirmation testing with a second reaction based on the results of the first reaction — **all in the same cartridge with no human intervention.**

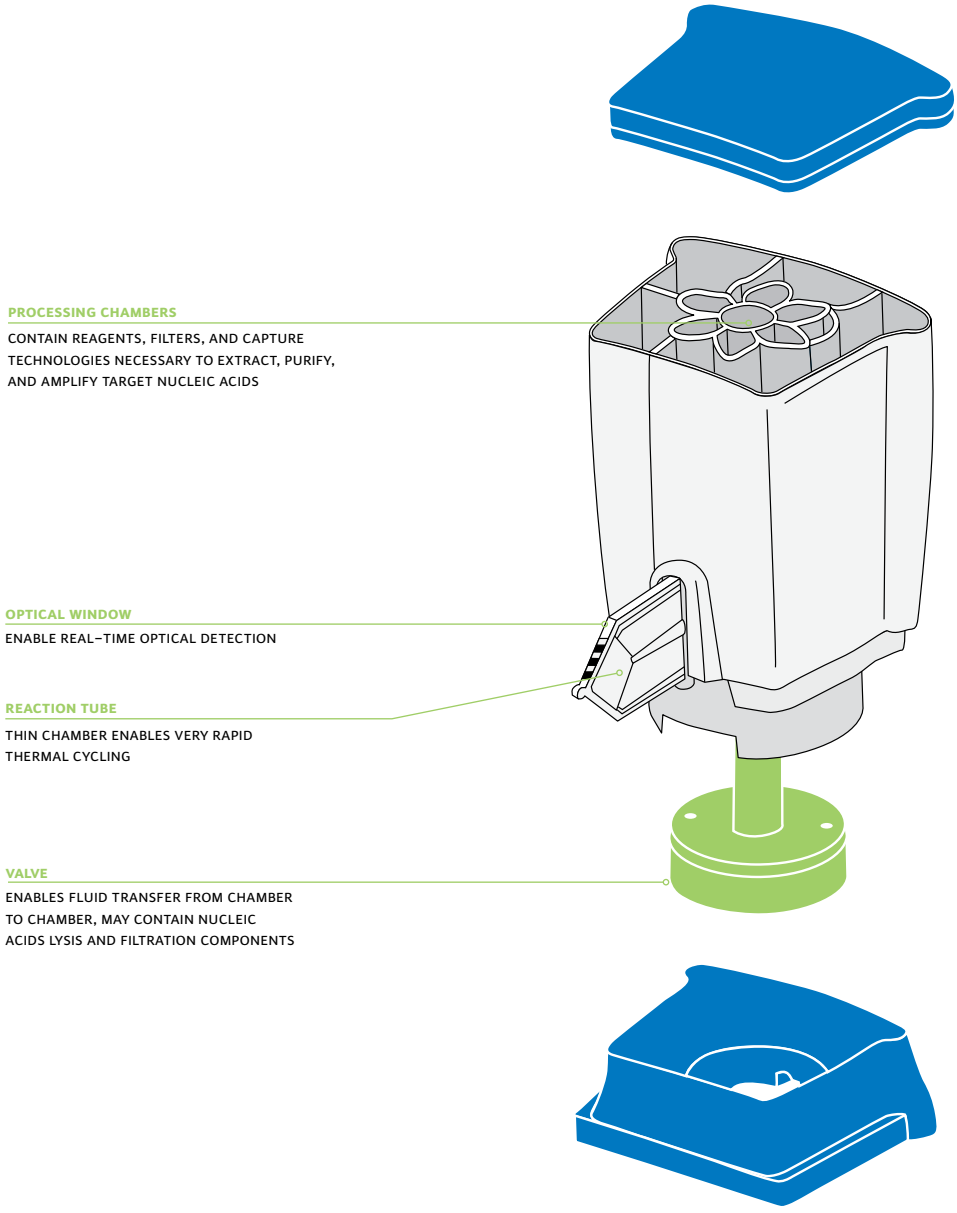
GeneXpert Module

Each module can detect six targets in a single reaction cycle with up to twelve results per assay

Processing Unit

A four-site GeneXpert System can be configured with 1, 2, 3 or 4 modules. For higher throughput applications, a 16-site system can be configured with 4, 8, 12, or 16 modules. Systems can be easily upgraded with additional modules.

The cornerstone of the GeneXpert® System is Cepheid's patented, self-contained, single-use cartridges.



The GeneXpert® System

The GeneXpert Cartridge

The GeneXpert® System is the world's first and only real-time PCR instrument which combines fully integrated sample preparation with the amplification and detection process. The cornerstone of the GeneXpert testing processes are Cepheid's patented, self-contained, single-use cartridges. This ground-breaking technology allows laboratory and non-laboratory personnel to conduct sophisticated molecular-based testing in a wide range of environments—including hospitals, research laboratories, public health clinics or a physician's office.

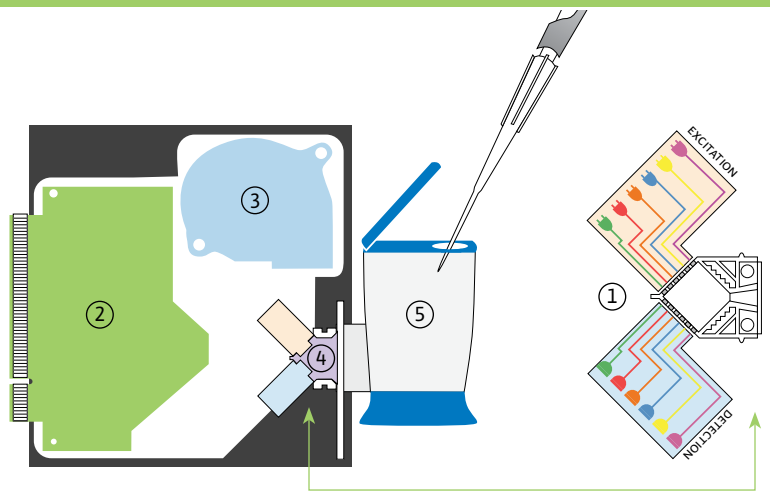
Most DNA analysis and detection procedures start with DNA that has been extracted or removed from the sample. In many cases, samples are complex in composition (whole blood, human cells or tissue, swabs) and the associated sample preparation protocols are complex and time-consuming. In addition, many real world applications involve detection of a very small number of pathogens or target genes in a large volume of sample. Cepheid's cartridges are designed to handle a variety of starting sample materials and volumes, which provides the ability to obtain higher concentrations of starting target materials in the cartridge.

The GeneXpert Module

GeneXpert module is a complete, independent, temperature-controlled fluorimeter for performing and continuously monitoring chemical reactions such as real-time PCR. The temperature of the sample can be controlled rapidly and precisely, allowing faster reactions and more accurate results. Cepheid's technology allows sample analysis to be performed using much less power than traditional methods. This permits our systems to be truly portable, giving our customers the capability to obtain bioanalytical results when and where they are needed.

Each module includes a six-channel optics system capable of exciting and detecting multiple fluorescent dyes in the same reaction tube. Continuous optical monitoring during amplification also allows the software to automatically stop the reaction as soon as the target is detected, shortening the time to results.

Each unit is operated and controlled independently. In contrast to traditional thermal cycling systems, in which all samples are subjected to the same time/temperature/optical protocol, each sample in a GeneXpert System can be subjected to a different protocol.



THE GENEXPERT MODULE

1 **OPTICAL BLOCKS**
OPTICAL ANALYSIS, DETECT AND QUANTIFY UP TO SIX DIFFERENT NUCLEIC ACID TARGETS PER REACTION

2 **CIRCUITRY**
PASSES OPTICAL INFORMATION TO COMPUTER FOR ANALYSIS AND DISPLAY

3 **FAN**
COOLING CYCLE

4 **HEATING PLATES**
HEATING CYCLE

5 **GENEXPERT CARTRIDGE**
SAMPLE PREPARATION SIMULTANEOUSLY

Representing a major paradigm shift in the accessibility and utility of molecular testing, the GeneXpert® System ushers in a new era of simplified, fully-automated testing—delivering rapid answers 24 hours a day, 365 days a year.

What does all this mean?

Better healthcare decisions

Improved patient outcomes

XPERT: **BY DESIGN**

easy to use:
Combines sample prep, amplification and real-time detection. The GeneXpert System requires little operator handling or specialized knowledge. Users simply insert the biological sample for testing into a self-contained cartridge, and the GeneXpert System does the rest.

comprehensive:
Works with many types of raw specimens. GeneXpert cartridges accept virtually any kind of airborne, liquid or solid sample. Human specimens can be drawn from whole blood, urine, vaginal, anal, and nasal swabs, bone marrow, sputum, serum, plasma and cerebral-spinal fluid. Advanced ultrasonic techniques enable rapid lysing of all cell types.

small footprint:
Compact and self contained, GeneXpert can be installed in non-laboratory settings. The GeneXpert System's space-saving design and low-power requirements make it possible for the system to be installed and operated in virtually any indoor setting.

XPERT: **FOR ON-DEMAND RESULTS**

fast:
Built to give you the answers you need now. Batch testing is no longer your only option. The GeneXpert System can process samples as they come in, 24 hours a day, seven days a week, delivering the power of true on-demand molecular testing.

flexible:
Configurable up to 16 modules, GeneXpert® enables you to perform multiple diagnostic tests simultaneously. Each of the GeneXpert System's modules can be individually and independently operated. This unique capability enables users to conduct up to 16 different tests concurrently. And because runs can be started at different times, multiple operators can easily use the GeneXpert System at the same time.

intelligent:
Automated diagnostic software eliminates interpretation.
The system software comes pre-installed on a desktop or laptop computer and displays results for each module in real time as soon as the PCR is complete. Time to results is available by checking the status indicator screen. Whether you need to run one or multiple tests simultaneously, the GeneXpert System's fully automated software delivers.

XPERT: **IN ACTION**

safe:
Self-contained, disposable cartridges increase safety. The single use test cartridges come pre-loaded with the chemical reagents required for sample preparation. They are designed to eliminate the possibility of amplicon contamination or accidental environmental discharge. The sample and reagents do not come into contact with the working parts of the instrument

accurate:
Six-channel optics gives you reliable and consistent PCR results. The GeneXpert System enables the detection of multiple unique targets within a single cartridge (multiplex assays) with the use of six-channel optics for fluorescent detection. This enables highly reliable and consistent results.

sensitive:
Integrated sample preparation and testing eliminates carry-over contamination and increases sensitivity. By eliminating major sources of external contamination, the GeneXpert System is potentially more specific than any other system on the market today.

integrated:
The GeneXpert System now includes a new standardized HL7 and ASTM interface which enables bi-directional connectivity with your Laboratory Information System. This provides optimized order/result management that empowers healthcare providers with truly actionable results. By automating cumbersome paper-based data flows and manual sample test order/results entries, transcription error will be reduced, efficiencies gained, and patient care optimized while reducing costs.

GeneXpert® Specifications

Optics

Dye detection limit < 1 nM

Optical channel characterization:

Channel	Excitation	Emission	Calibrated reporter dyes
1	375–405	420–480	CF 1
2	450–495	510–535	FAM
3	500–550	565–590	Alexa Fluor® 532
4	555–590	606–650	Texas Red®
5	630–650	665–685	Alexa Fluor® 647
6	630–650	>700	CF 6

Reaction site thermal controls

- Solid state heater and forced-air cooling at each site
- Reaction chamber thermistors calibrated to ± 1.0 °C using National Institute of Standards and Technology (NIST)-traceable standards
- Up to 16 independently-controlled reaction sites

Cartridges

Single-use disposable cartridges
Polypropylene construction

Performance parameters

Heating ramp rates (max.):
10 °C/sec from 50 °C to 95 °C

Cooling ramp rates (max.):
2.5 °C/sec from 95 °C to 50 °C

Temperature duration accuracy:
± 1.0 sec from programmed time

Temperature accuracy:
± 1.0 °C from 60 °C to 95 °C

Melt curve programmable ramp rates:
0.1 °C/sec to 1.0 °C/sec

Physical dimensions

GX-I Processing Unit: 4.3" W x 13.5" H x 13.25" D
GX-IV Processing Unit: 11.5" W x 14" H x 12.25" D
GX-XVI Processing Unit: 21" W x 29.5" H x 18" D

Power requirements

Rated Voltage: 100-240 V~, 50-60 Hz
Rated Current GX-I 1.5A @ 100V~, 0.75 A @ 200V~
Rated Current GX-IV: 1.9 A @ 100 V~, 0.95 A @ 200 V~
Rated Current GX-XVI: 8.24 A @ 100 V~, 4.12 A @ 200 V~

GeneXpert® Diagnostic System	U.S. Part Numbers*
GeneXpert Model GX-I Single Module Instrument with Laptop	GXI-N3-6
GeneXpert Model GX-IV 4 Module Instrument with Desktop	GXIV-4N1-6
GeneXpert Model GX-XVI 16 Module Instrument with Desktop	GXXVI-16N1-6

*For a full listing of the instrument configurations available to meet your needs visit www.cepheid.com

WWW.CEPHEID.COM

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Bring answers to life.