

GeneXpert®



GeneXpert® System

Improving healthcare through on-demand molecular diagnostics



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 medicine —giving healthcare professionals the immediate answers they need to improve patient management.

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.

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.

The GeneXpert® System 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 measurable.

Gail Woosley, Lab Director —
Wooster Community Hospital



The GeneXpert® System

fully integrates and automates sample preparation, amplification, and detection — all in one cartridge.

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

PROCESSING CHAMBERS

CONTAINS REAGENTS, FILTERS, AND CAPTURE TECHNOLOGIES NECESSARY TO EXTRACT, PURIFY, AND AMPLIFY TARGET NUCLEIC ACIDS

OPTICAL WINDOW

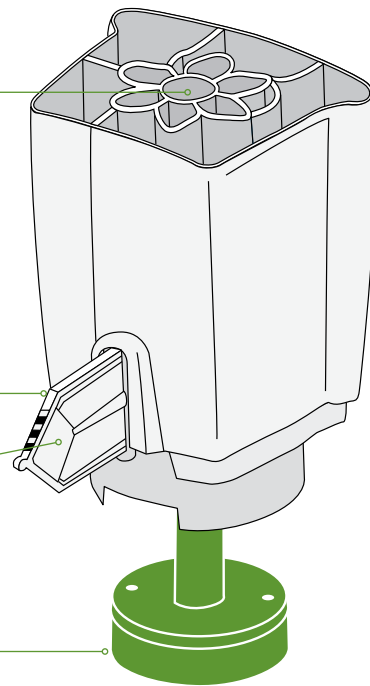
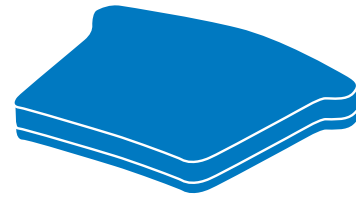
ENABLES REAL-TIME OPTICAL DETECTION

REACTION TUBE

THIN CHAMBER ENABLES VERY RAPID THERMAL CYCLING

VALVE

ENABLES FLUID TRANSFER FROM CHAMBER TO CHAMBER, MAY CONTAIN NUCLEIC ACIDS LYSIS AND FILTRATION COMPONENTS



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 or RNA 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.

Amplification of extracted nucleic acids.

The GeneXpert System modules perform rapid heating and cooling cycles required for highly reliable, real-time PCR in the reaction tube of the cartridge. 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 multiple optics detect the presence of multiple target nucleic acids in the same cartridge. With the Advance to Subsequent Stage feature, the system can 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, Decision Command, which enables automated reflex, or confirmation, testing with a second reaction based on the results of the first reaction.



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. A 16-site system can be configured with 4, 8, 12, or 16 modules. For the highest throughput applications, a GeneXpert Infinity System can scale to 48 modules. Systems can be easily upgraded with additional modules.



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.

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, the GeneXpert System can be installed in non-laboratory settings. 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, The GeneXpert System enables you to perform multiple diagnostic tests simultaneously. Each module can be individually and independently operated, enabling 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.

integrated:

A new standardized HL7 and ASTM interface enables bi-directional connectivity with your Laboratory Information System. This provides optimized order/result management that empowers healthcare providers with truly actionable results. Automation of cumbersome paper-based data flows and manual entries reduces transcription errors and improves patient management.

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:
0.01 °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

Practice of the patented polymerase chain reaction (PCR) process requires a license. The GeneXpert® System is an authorized thermal cycler and may be used with PCR licenses available from Applied Biosystems. Its use with authorized reagents also provides a limited PCR license in accordance with the label rights accompanying such reagents. Purchase of this instrument does not convey any right to practice the 5' nuclease assay or any of the other real-time methods covered by patents owned or controlled by Roche or Applied Biosystems. Cepheid's GeneXpert® System is a licensed real-time thermal cycler under Applera's European Patent No. EP 0 872 562, Japanese Patent No. JP 3136129 and patents pending, for all fields including human in vitro diagnostics except for diagnosis and monitoring of HIV and HCV infections.

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