[tech] guide

Molecular Diagnostic Instruments

	Cepheid Sunnyvale, Calif (888) 336-2743; www.cepheid.com	Great Basin Scientific Inc Salt Lake City (801) 990-1055; www.gbscience.com	Hologic Inc Marlborough, Mass (781) 999-7453; www.hologic.com
1. What is the brand name of your company's molecular diagnostic instrument?	GeneXpert system	Great Basin PA500.	Panther system
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2006; TUV CE mark, 2006.	CE mark, 2012, 2015, 2016; FDA 510(k), 2012, 2015, 2016.	Years vary, as each assay was independently approved/cleared/ CE-marked.
3. What is the intended use or primary function of the product?	GeneXpert Dx systems automate and integrate sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time polymerase chain reaction (PCR); GeneXpert Infinity systems are fully automated, high-throughput, on-demand, random-access closed systems that fully integrate the process required for real-time PCR-based molecular diagnostic testing.	Definitive diagnosis of infectious disease and hospital-acquired infections.	Diagnosis.
4. What type of specimen/sample does the product employ?	Specimen type dependent on assay.	Positive blood culture, preserved stool, raw stool, and vaginal swab.	Pap (ThinPrep test), plasma, serum, swab (cervical, endocervical, vaginal), and urine.
5. What types of diseases, conditions, or analytes does the system detect?	Proprietary Xpert test cartridges span critical infectious disease, healthcare-associated infections, genetics, oncology, sexual health, and virology.	Group B Strep, toxigenic *C. difficile*, Shiga toxin direct, Shiga toxin-producing *E. coli* and *E. coli* 0157, Staph ID/R blood culture panel, methicillin-resistant *Staphylococcus aureus*, *Staphylococcus aureus, Staphylococcus spp, Staphylococcus lugdunensis.*	*Chlamydia trachomatis*, hepatitis B virus, hepatitis C virus, human immunodeficiency virus 1, human papillomavirus, *Mycoplasma genitalium, Neisseria gonorrhoeae,* and *Trichomonas vaginalis*.
6. What platform technologies does the product employ?	Automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time polymerase chain reaction.	Chip-based detection, helicase dependent amplification, and polymerase chain reaction.	Transcription-mediated amplification (TMA) uses biochemical reactions to drive amplification; real-time TMA (RT-TMA) is utilized for certain assays.
7. Under ideal conditions, what is the time to first result; how are the test results made available?	30 to 90 minutes per sample on average; summarized and detailed test results data are provided in tabular and graphic formats.	90 to 120 minutes time to result; definitive results are reported electronically.	For TMA-based assays, results are ready 3.5 hours after sample is pipetted (2.5 hours for RT-TMA assays); results are available in sets of five, every 5 minutes after first results are completed.
8. What are the product's maximum capacity and throughput under ideal conditions?	GeneXpert systems have the capacity to perform 1–80 tests at the same time; Infinity 48s: 1,300 tests in 24 hours; Infinity 80: 2,300 tests in 24 hours.	Random access, on-demand stat testing; one sample per run.	120 samples on board, 1,000 test reagent capacity, 750 specimens processed in 14–16 hours.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	Laboratory information system connectivity; system monitoring and disease surveillance capabilities; Xpert tests have internal quality control and autocalibration; Infinity systems are fully automated for on-demand processing and 24/7 robotic sample handling.	Automated self-checks with every run; internal control with each test cartridge that monitors all stages of the assay; error code reporting for any system failures; analyzers are wi-fi enabled; support can connect remotely for additional troubleshooting.	Reagent dispensing verification and liquid level sensing on all samples and reagents; positive sample ID with automated sample barcode scanning.
10. What types of technical support are available?	Global service and product support capabilities include 24/7 phone support, onsite field service, remote system monitoring, onsite implementation and training, and eight global repair centers.	We provide customers with technical support at no cost, with no service contracts; toll-free phone and e-mail support are available; analyzer swapouts are completed at no charge.	Field application specialists and technical support hotline.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Produces accurate results with minimal risk of contamination; Xpert tests require <2 minutes of hands-on time; results are available in approximately 1 hour in any workflow environment; random access to batch testing.	Unique business model with no-cost analyzer, no contracts, and low-cost assays; Shiga toxin direct test is the only FDA-cleared standalone molecular test detecting Shiga toxin-producing *E. coli* and *E. coli* 0157; Staph ID/R blood culture panel provides species information, including the pathogenic *S. Lugdunensis*, ruling out CoNS infections.	Integrated platform with sample-in, result-out capacity; random access allows user to access assay reagents and samples during processing and sampling with multiple assays; scheduled and automated daily maintenance activities.

Qiagen Inc **Germantown, Md** **(800) 362-7737;** **www.qiagen.com**	Qiagen Inc **Germantown, Md** **(800) 362-7737;** **www.qiagen.com**	Qiagen Inc **Germantown, Md** **(800) 362-7737;** **www.qiagen.com**
EZ1 Advanced XL	QiaSymphony RGQ MDx	Rotor-Gene Q MDx
CE mark, 2009; FDA PMA, 2014.	FDA 510(k), 2014.	FDA 510(k), 2010; FDA PMA, 2012.
Intended for automated purification of nucleic acids from up to 14 human molecular diagnostics samples.	Intended for in vitro diagnostic (IVD) use in performing FDA-cleared or -approved nucleic acid testing in clinical laboratories.	Real-time nucleic acid amplification and detection system that measures signals from amplified DNA using fluorescent detection; intended for in vitro diagnostic use with FDA-cleared or -approved nucleic acid tests in clinical laboratories.
Viral DNA and RNA and bacterial DNA from cerebrospinal fluid, dried swab samples, plasma, respiratory samples, serum, stool, transport media, urine, and whole blood; genomic DNA from human whole blood.	Direct qualitative detection of herpes simplex virus (HSV) 1/2 requires human oral or genital lesion swabs collected in M4RT or universal transport media; detection of *Clostridium difficile* requires human liquid or soft stool.	Sample types vary and depend on the assay being performed.
Viral nucleic acids purified using the EZ1 DSP virus kit and genomic DNA purified using the EZ1 DSP DNA blood kit are ready to use in downstream diagnostic assays based on enzymatic amplification.	HSV 1/2; *C. difficile* toxin genes A and B.	Cytomegalovirus (CMV) viral load quantitation; *C. difficile* and herpes simplex virus (HSV) 1/2 qualitative detection; EGFR and KRAS mutation detection.
Fully automated nucleic acid purification using magnetic particles.	Integrated automated nucleic acid purification and assay setup with manual transfer for real-time polymerase chain reaction amplification and detection; automated result analysis and interpretation.	Real-time polymerase chain reaction (PCR) amplifying specific pathogen or mutation-associated sequence, as well as a heterologous amplification control system.
EZ1 DSP virus, 40 minutes for 14-sample run; EZ1 DSP DNA, 15–20 minutes for 14-sample run.	HSV 1/2 and *C. difficile*, 380 min for 72 results, including full process controls; Rotor-Gene AssayManager analysis interpretation for both applications.	Real-time PCR run times are assay-specific; *C. difficile* and HSV 1/2, 110 minutes; CMV, 109 minutes; EGFR and KRAS, 117 minutes.
14 samples per instrument; up to four instruments can be connected to an external computer to simplify data input/output for a total of 56 samples.	As many as 72 samples, including full process controls.	As many as 72 samples, including controls.
All processing steps are performed by the instrument, from piercing reagent cartridges to nucleic acid elution; foil-sealed reagent cartridges remain sealed until instrument door is closed and protocol run starts, reducing the risk of contamination.	Fully automated sample purification and assay setup; Rotor-Gene AssayManager for automated analysis and data interpretation; optional QiaLink for automated data transfer between QiaSymphony RGQ MDx and laboratory information management system.	Data security with audit trails, digital signatures, and user management; Rotor-Gene Q software or Rotor-Gene AssayManager software for automated analysis and data interpretation (assay-dependent).
Technical services for remote support, and field service and field application specialists for onsite support.	Technical services for remote support, and field service and field application specialists for onsite support.	Technical services for remote support, and field service and field application specialists for onsite support.
Optimal ease of use and walkaway automation; separate computer not required for operation; operation via simple display and keypad; handheld barcode scanner for reading reagent and sample information; uses preprogrammed protocols on EZ1 Advanced XL DSP cards and EZ1 DSP kits for sample processing.	Sample-to-result IVD workflow solution for performing FDA-cleared or -approved nucleic acid testing; flexible sample batching and efficient processing optimize IVD workflows; reduces hands-on time; automates data handling; allows lab-developed tests (when using open mode).	Up to six excitation sources and six detection filters (red and HRM channels are not intended for use with FDA-cleared or -approved nucleic acid tests), combined with a short, fixed optical path; allows use for multiplex reactions; ensures minimum fluorescence variability between samples and eliminates the need for calibration.

Upcoming Tech Guides

Each month, *CLP* invites leading IVD manufacturers and clinical laboratory suppliers to complete a standarized topic-specific questionnaire highlighting their products.

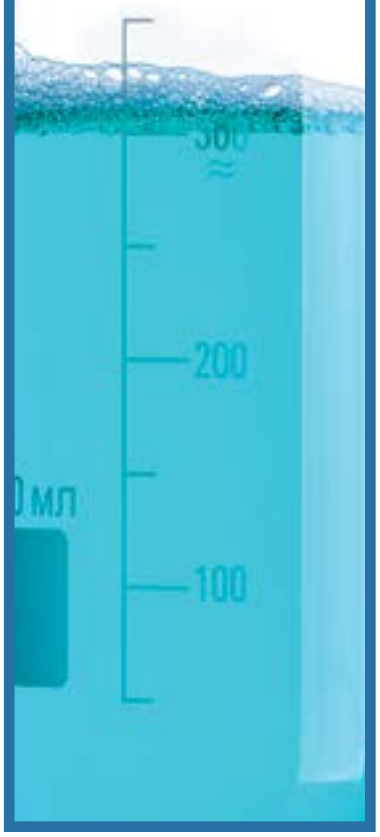
Below is a preview of topics that will appear in future issues of *CLP:*

OCTOBER
Hematology Analyzers

NOVEMBER
Lab and Patient Safety Products

DECEMBER
Buyer's Guide

To be considered for inclusion, contact associate editor Elaine Sanchez Wilson at ewilson@allied360.com



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	Qiagen Inc Germantown, Md (800) 362-7737; www.qiagen.com	Randox Biosciences Crumlin, UK (866) 472-6369; www.randox.com	Vela Diagnostics USA Inc Singapore (877) 593-7528; www.veladx.com
1. What is the brand name of your company's molecular diagnostic instrument?	GeneReader NGS system	Evidence Investigator	Sentosa SQ301 (120 V) with Sentosa SQ reporter software
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	N/A	CE mark, 2009.	FDA 510(k), 2014; assays are for research use only.
3. What is the intended use or primary function of the product?	For research use only; target enrichment panels designed with the cancer research lab in mind.	A semiautomated, benchtop biochip analyzer that offers complete patient profiling.	Combines simple chemistry and semiconductor technology to translate chemical signals into digital information.
4. What type of specimen/sample does the product employ?	For use with formalin-fixed, paraffin-embedded and liquid biopsy sample types.	Bronchoalveolar lavage fluid, formalin-fixed paraffin-embedded tissue, fresh and frozen tissues, nasopharyngeal swab, serum, urine, urogenital swab, whole blood.	Formalin-fixed, paraffin-embedded tissue; plasma; serum.
5. What types of diseases, conditions, or analytes does the system detect?	Designed for the identification of single nucleotide variants (SNVs) and indels associated with breast, colorectal, lung, melanoma, and ovarian cancers; by the end of the year detection of copy number variants (CNVs) will also be possible, along with additional targeted gene panels focusing on lung cancer and BRCA-associated variants.	KRAS, BRAF, PIK3CA array (research use only); cardiac array; familial hypercholesterolemia arrays; respiratory multiplex array; STI multiplex array.	Oncology: colorectal cancer, melanoma, non-small cell lung cancer, thyroid cancer; virology: hepatitis C virus genotyping, human immunodeficiency virus genotyping.
6. What platform technologies does the product employ?	Next-generation sequencing (NGS).	Biochip microarray coupled with multiplex polymerase chain reaction (PCR) priming technology; uses chemiluminescence as detection signal.	Next-generation sequencing (NGS).
7. Under ideal conditions, what is the time to first result; how are the test results made available?	From sample preparation to final report takes 5 days (<8 hours hands-on time); the report is presented in an interactive graphical and tabular format.	One full batch can be run in less than 3.5 hours, generating 1,080 test results (KRAS/BRAF/Plk3CA array).	Sample to report in about 2 days, requiring about 2.5 hours of hands-on time; results provide a summary of variants in an automatically generated report.
8. What are the product's maximum capacity and throughput under ideal conditions?	The system is capable of processing between 10 and 40 samples in either a parallel or a staggered manner, depending on the number of flow cells loaded.	Generates 1,080 test results in 210 minutes using the familial hypercholesterolaemia array, which equates to 2,160 tests per day (two full batch runs) or 10,800 test results per week.	Oncology: up to 7 samples per run; virology: up to 15 samples per run.
9. Briefly describe any automation or connectivity features or options that pertain to the product.	All steps of the workflow offer either complete or partial automation; integrated software enables sample tracking and connection to a laboratory information management system; automated data analysis and interpretation is performed with a customized informatics pipeline.	Barcode scanning of samples; unidirectional laboratory information management enabled; semiautomated testing; full Levy-Jennings capabilities; troubleshooting guide.	IT connectivity to laboratory information system; sample traceability throughout the workflow; one system control and one extraction control with each run; NGS-specific QC metrics.
10. What types of technical support are available?	24/7 phone support and service agreements; different support levels are available.	Software-generated support; technical support helpline; regional technical support offered globally; regular system checks to assure the operator of optimal system performance.	Local service and support team approachable by e-mail and telephone; instrument certification services include all functional tests and calibrations required for installation, operational, and performance qualification of the instrument.
11. What capabilities, features, or accessories distinguish this product from others on the market?	The complete NGS workflow is designed to take the user from sample preparation to generation of a comprehensive report; the inventive turntable design of the GeneReader platform makes it possible to sequence multiple samples in a parallel or staggered manner.	Allows consolidation of immunoassay and molecular diagnostics with protein and DNA-based biochips; broad CE marked multiplex array for sexually transmitted infections; offers comprehensive bacterial and viral respiratory infection testing in a single multiplex PCR reaction; high sensitivity, by combining PCR priming technology and biochip hybridization of amplified product to spatially tethered probes.	Enables increased accuracy in variant calling with minimal sample input for targeted sequencing; reports are easy to read, without the need for a bioinformatician; complete end-to-end workflow from sample extraction and NGS library prep to automated reporting; LIS connectivity for traceabiity of sample identification.