Automated molecular platforms

Part 1 of 8	Abbott Laboratories, Abbott Molecular Division Francisco Cline francisco.cline@abbott.com 1300 E. Touhy Ave., Des Plaines, IL 60018 224-361-7000 www.abbottmolecular.com
Name of instrument	*m*2000 RealTime System comprised of the *m*2000sp and *m*2000rt
Country where designed/manufactured/reagents manufactured	U.S./Switzerland, Singapore/U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical
First year sold in U.S./sold internationally/installed	2007/2005/2005
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	*m*2000sp: 66.2 × 69.5 × 31.3; *m*2000rt: 19.3 × 13.4 × 17.8/15; 1.6/—; <85 (1m)
Supplied with UPS/BTU/Space modification requirements	yes/*m*2000sp: 4,100 BTU (1,200 Wh); *m*2000rt: 3,241.5 BTU per hour (950 W)/—
Instrument requires floor drain/separate room for contamination control	no/no
Physical contamination control features	instrument hood; extraction platform process flow design; 50-µL aspiration airgap in each pipette tip; aerosol barrier pipette tips; others
List price/Price for sample extraction and amplification detection modules	$199,900/sample extraction: $149,900; amplification detection: $69,000
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/none
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/*m*2000sp: 100–240 VAC at 50–60 Hz; *m*2000rt: 100–240 VAC at 50–60 Hz
Labor and parts warranties/Training with purchase/Advanced operator training	labor and parts: 1 year/yes/yes
Delivery time/Delivery charges/Installer/Time to install on site	1–4 weeks/$1,500 (destination)/Abbott Molecular/sp: 3 days; rt: 1 day
Training location/No. of techs that can receive initial training/Length of training	on site and off site/2/3 days
Additional on-site training/Retraining at company facility	yes/yes
Test menu	HIV VL, HIV Qual, HCV VL, HCV GT, HBV VL, CT/NG, CT, CMV, EBV, HPV, ms9, KIF6
No. of tests for which analyzer has FDA-cleared applications/CE-mark	3/11
Tests available in U.S./outside the U.S.	HIV VL*, HIV Qual****, HCV VL***, HBV VL*, CT/NG*, CMV***, EBV***, HCV GT****/ HIV VL**, HIV Qual****, HCV VL**, HCV GT**, HBV VL**, CT/NG**, CT**, CMV**, EBV**, HPV**, ms9**, KIF6**
Tests not available in U.S. but submitted to FDA/available in other countries only	HCV VL***/CT**, HPV**, ms9**, KIF6**
Research-use-only assays/Tests in development	HCV GT****, HIV Qual****/RT CMV, HIV Qual****
Open-channel capabilities/Start-up and preparation time	yes/15 minutes for batch of 24 samples
Model type of sample handling system/Maximum sample load capacity	*m*2000sp/96 samples
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	0.4 mL/yes (FDA protocols include: 0.2, 0.4, 0.5, 0.6, and 1.0 mL)/0.05–4.0 mL
Min. dead volume/Pediatric sample volume/Primary tube sampling	0.2 mL/0.2 mL/yes
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	11.5 mm–16 mm diameter/yes/no
Sample bar-code languages/Sample types available in open mode	codes 39, 128, and 93, UPCA, Codabar, Interleaved 2 of 5/plasma, serum, urine, whole blood, swabs, dry blood spots, CSF, breast milk, semen, leucocytes, biopsy, surgical fluids, punction fluids, liquid based cytology, others
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/plasma, serum, urine, whole blood, swabs, dry blood spots, others
Amplification reagents or methods supported	real-time polymerase chain reaction
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	chaotropic lysis w/nucleic acid isolation via magnetic separation/yes/yes/yes
No. of different assays onboard at once/Programmed or calibrated at once	one w/standard operation, two w/MaxCycle†, 12 w/open mode
Tests per container set/Multiple reagent configurations supported	24–96/nucleic acid: DNA, RNA, total nucleic acid; master mix: up to 4 reagents
Reagent container placed directly on system/Onboard test auto inventory	yes/no
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	yes/yes/yes
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	yes/yes/yes
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/not required
Onboard test auto inventory/Capacity for inventory monitoring by bar code	yes/no
System is open to homebrew/General-purpose reagents allowed	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes
Closed-vial stability for amplification reagents/extraction reagents	18 months at -10°C/18 months at 15°–30°C
Storage temp. requirement for amplification reagents/extraction reagents	-10°C/15°–30°C
Shipment temp. requirement for amplification reagents/extraction reagents	frozen on dry ice/15°–30°C
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	U.S./3 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes
Assay calibrations required by end-user/Calibrants can be stored onboard	yes/yes
Multiple calibrant lots stored for same assay/Required calibration frequency	yes/every 6 months, after any reagent lot changes, or any major service event
Length of assay calibration/Typical calibration frequency	up to 6 months/every 6 months
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/sample extraction: none; amplification detection: 15 minutes/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	Only three controls needed regardless of batch size (24, 42, 72, and 96)
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	up to 3.5 hours/<1 hour
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/864
Time between start and initial result/Instrument automatic shutdown	for a CT/NG batch of 48 samples: 4 hours, 41 minutes/yes
Startup programmable/Remote system monitoring/Waste req. for disposables	no/yes/plastic and liquid; waste containers on-board
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes
Service contracts available/Mean time between failures/to repair failures	phone, on-site service/samp. extract.: 30 wks; ampli. detect.: 162 wks/4hours
Turnaround time for problem solving: by phone/e-mail/field service	1 minute–4 hours/10 minutes–24 hours/30 hours within tech arriving on site
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	7/within 48 hours/M-F, 8 AM–5 PM all time zones
Guaranteed response time/Modem servicing available	yes (when requested)/yes
System can diagnose own malfunctions	yes
Order parts via modem/Onboard error codes/Maintenance training demo module	varies/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: <10 minutes; weekly: 60 minutes; monthly: 15 minutes/yes
Preventive maintenance per year for sample extraction/amplification detection	2/1
Downtime for preventive maintenance/Spare parts on site	4–8 hours/yes
Patient demographics and insurance data available via rules-based architecture	no
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/yes
Online real-time help, QC, stats and management reports/Evaluates results validity	yes/yes
Priority processing/Random-access specimen movement	no/—
Supports accession No. redundancy/Specimen carrier and level identification	no/yes
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	no/no
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/—
Sample storage and retrieval software supports CLSI standards	no
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—
QC results auto transferred to LIS/Data management capability	yes/yes
Interfaces operational in active user sites	yes
Rules-based control subsystem/Process control via control subsystem	yes/yes
LIS operates simultaneously with assays running	yes
Auto transfer QC results to LIS/Onboard capability to review QC	yes/—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	yes/no
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	yes/yes/yes/yes
Software upgrades since system launch/Can print, archive, transmit data	8/yes
Distinguishing features (supplied by company)	enables consolidation of many NAAT tests & a broad range of sample types onto a single system while providing bar-coded primary tube sampling, contamination control and maxRatio (a proprietary built-in PCR curve validation software)

**for calibration and controls*
Note: a dash in lieu of an answer means company did not answer question or question is not applicable
** FDA, ** CE Mark, *** ASR, **** RUO, †program enables cocycing of HIV and HCV in same batch*

Tabulation does not represent an endorsement by the College of American Pathologists.

Automated molecular platforms

Part 2 of 8	AutoGenomics Anand Vairavan avairavan@autogenomics.com 2980 Scott St., Vista, CA 92081 760-477-2248 www.autogenomics.com
Name of instrument	INFINITI
Country where designed/manufactured/reagents manufactured	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/analytical
First year sold in U.S./sold internationally/installed	2007/2007/2007
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	26 × 44 × 24/7.3/—
Supplied with UPS/BTU/Space modification requirements	no/—/—
Instrument requires floor drain/separate room for contamination control	—/no/no
Physical contamination control features	no aspiration tubing, disposable tips
List price/Price for sample extraction and amplification detection modules	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/1 sample
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/100–240 volts
Labor and parts warranties/Training with purchase/Advanced operator training	labor: 1 year; parts: 1 year/yes/no
Delivery time/Delivery charges/Installer/Time to install on site	1 week/—/AGI/1–2 days
Training location/No. of techs that can receive initial training/Length of training	on site and off site/1/2.5 days
Additional on-site training/Retraining at company facility	yes/yes
Test menu	—
No. of tests for which analyzer has FDA-cleared applications/CE-mark	5/15
Tests available in U.S./outside the U.S.	42/42
Tests not available in U.S. but submitted to FDA/available in other countries only	—
Research-use-only assays/Tests in development	37/10
Open-channel capabilities/Start-up and preparation time	yes/20
Model type of sample handling system/Maximum sample load capacity	—/24
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	2 µL/no/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	—/—/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	—yes/—
Sample bar-code languages/Sample types available in open mode	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/yes/—
Amplification reagents or methods supported	—
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	—
No. of different assays onboard at once/Programmed or calibrated at once	4/42
Tests per container set/Multiple reagent configurations supported	48/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	yes/yes/yes
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	yes/yes/yes
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/—
Onboard test auto inventory/Capacity for inventory monitoring by bar code	yes/yes
System is open to homebrew/General-purpose reagents allowed	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/—
Closed-vial stability for amplification reagents/extraction reagents	—
Storage temp. requirement for amplification reagents/extraction reagents	amplification: -20°C
Shipment temp. requirement for amplification reagents/extraction reagents	amplification: -20°C
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	U.S./minimum: 12 months; maximum: 24 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes
Assay calibrations required by end-user/Calibrants can be stored onboard	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	—
Length of assay calibration/Typical calibration frequency	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/—
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	5 hours/15 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/—
Time between start and initial result/Instrument automatic shutdown	3 hours/no
Startup programmable/Remote system monitoring/Waste req. for disposables	no/no/built-in waste tray
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes
Service contracts available/Mean time between failures/to repair failures	annual/—/—
Turnaround time for problem solving: by phone/e-mail/field service	24 hours/24 hours/48 hours
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	—/24–48 hours/6 AM–6 PM (PDT)
Guaranteed response time/Modem servicing available	yes (within 24 hours)/no
System can diagnose own malfunctions	yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 min.; weekly: 10 min.; monthly: 20 min.; yearly: 45 min./no
Preventive maintenance per year for sample extraction/amplification detection	amplification detection: 1
Downtime for preventive maintenance/Spare parts on site	1 day/no
Patient demographics and insurance data available via rules-based architecture	no
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/yes
Online real-time help, QC, stats and management reports/Evaluates results validity	no/yes
Priority processing/Random-access specimen movement	yes/—
Supports accession No. redundancy/Specimen carrier and level identification	—
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	yes/no
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/no/—
Sample storage and retrieval software supports CLSI standards	no
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/—
QC results auto transferred to LIS/Data management capability	—/yes
Interfaces operational in active user sites	yes
Rules-based control subsystem/Process control via control subsystem	yes/yes
LIS operates simultaneously with assays running	yes
Auto transfer QC results to LIS/Onboard capability to review QC	—/—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/no
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	yes/—
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	—/yes/yes/no
Software upgrades since system launch/Can print, archive, transmit data	—/yes
Distinguishing features (supplied by company)	true load and go automation increases lab productivity by freeing up personnel; replicate testing on each BioFilmChip microarray ensures assay integrity; broad spectrum of more than 40 tests available on same instrument

**for calibration and controls*
Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Tabulation does not represent an endorsement by the College of American Pathologists.

Automated molecular platforms

Part 3 of 8	**Becton Dickinson and Company** bdgeneohmcustomerservice@bd.com **11085 N. Torrey Pines Rd., La Jolla, CA 92037** **888-436-3646** www.bd.com/geneohm	**bioMérieux** **Steve Shumoski** steve.shumoski@biomerieux.com **100 Rodolphe St., Durham, NC 27712** **800-654-0331** www.biomerieux-usa.com
Name of instrument	**BD MAX**	**NucliSENS EasyMAG**
Country where designed/manufactured/reagents manufactured	U.S./U.S./U.S. and Canada	Netherlands and Australia/Italy/France
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/preanalytical
First year sold in U.S./sold internationally/installed	2010 (launched with FDA clearance on BD MAX GBS assay)/2010/2010	2005/2005/2005
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	28.5 × 37 × 29.7/5/64 dB at 48 dB background	20.9 × 39.4 × 25.6/3.7/between 67 and 75
Supplied with UPS/BTU/Space modification requirements	yes/—/bench must accommodate 250 lbs.	no/341 BTU per hour max. (less in standby)/none
Instrument requires floor drain/separate room for contamination control	—/no/no	no/no
Physical contamination control features	unitized reagent strip; dedicated pipette tips, microfluidic PCR cartridge with microvalves; pipettor flight path avoids crossing strips/tubes	single-well processing; onboard extraction buffers in closed containers; separation of buffer dispense and aspiration functions; others
List price/Price for sample extraction and amplification detection modules	$124,500/—	$79,500/sample extraction: $79,500
Purchase options/Minimum test volume requirements	straight purchase, reagent rental/specimen dependent (low as 10 to 15 µL)	straight purchase, reagent rental, lease/1
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/100–240 VAC ~50–60 Hz, 10A	yes/110V
Labor and parts warranties/Training with purchase/Advanced operator training	labor and parts: 1 year (1–3 year contracts optional)/yes/yes	labor and parts: 1 year/yes/yes
Delivery time/Delivery charges/Installer/Time to install on site	~4 weeks from order acceptance/—/BD/one-half day	30 days/destination and origin, price varies/field service engineer/5 hours
Training location/No. of techs that can receive initial training/Length of training	on site/flexible/1 day	on site/1 or more/1.5 days
Additional on-site training/Retraining at company facility	yes/yes	yes/no
Test menu	BD MAX GBS (IVD), DNA and RNA extraction kits and generic DNA master mix with and without process control for open system use w/user-defined protocols	universal set of reagents for total nucleic acid extraction; claims for use in front of specific assays
No. of tests for which analyzer has FDA-cleared applications/CE-mark	1/1 plus extraction and master mix reagents	7/8
Tests available in U.S./outside the U.S.	BD MAX GBS/BD MAX GBS	xTAG respiratory viral panel (Luminex); ProFlu, Pro hMPV, ProParaflu, ProGastro Cd, ProFAST (Gen-Probe); influenza panel (CDC)/HIV-1, HPV (bioMérieux)
Tests not available in U.S. but submitted to FDA/available in other countries only	—	—
Research-use-only assays/Tests in development	—/MRSA, Cdiff, others	U.S.: HIV-1 RUO, HPV RUO; outside U.S.: influenza A/B RUO, hMPV RUO/KPC
Open-channel capabilities/Start-up and preparation time	yes/ready 24 hours, 7 days	yes/10–15 minutes
Model type of sample handling system/Maximum sample load capacity	performs preanalytical and analytical functions/24	EasyMAG/24
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	specimen dependent (low as 10 to 15 µL)/yes/volumes range up to 750 µL	10 µL/yes (intra-run/batch range of 10–1,000 µL)/up to 1,000 µL
Min. dead volume/Pediatric sample volume/Primary tube sampling	50–200 µL/specimen dependent/no	10 µL/same sample volume range, dependent on downstream application/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	uses standard 4 mL tube format/yes/—	—/yes/no
Sample bar-code languages/Sample types available in open mode	Codabar, codes 39, Interleave 2 of 5, EAN/UCC code 128/swab, swab in transport medium, whole blood, urine, plasma	code 128 for reagents and disposables, EAN 8/EAN, 13 / UPC A/UPC E, Interleaved 2 of 5, Standard Code 39, others/various
Clot detection/Open extraction platform/Sample types (open extraction)	no/yes/swab, swab in transport medium, whole blood, urine, plasma	yes/yes/various types of samples
Amplification reagents or methods supported	real-time PCR methods	— (extraction instrument)
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	yes/yes/in development	yes/yes/yes
No. of different assays onboard at once/Programmed or calibrated at once	designed for multiple assays up to 24 samples/significant number	24 positions each can extract for a distinct assay/—
Tests per container set/Multiple reagent configurations supported	unitized reagent strips; one test per strip; 24 strips per kit/yes	main components: 384 extractions/universal reagent set
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	—/yes/yes	yes/yes/yes
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	yes/yes/yes	yes/yes/no
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	yes/liquid and dry	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/No. system has a closed unit test format disposable	no/—
Onboard test auto inventory/Capacity for inventory monitoring by bar code	yes/no	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/—	no/no
Closed-vial stability for amplification reagents/extraction reagents	amplification and extraction: 12-month shelf life	extraction: up to 30 days onboard the system
Storage temp. requirement for amplification reagents/extraction reagents	room temperature/room temperature	extraction: mostly room temperature with 2 components at 2°–8°C
Shipment temp. requirement for amplification reagents/extraction reagents	room temperature/room temperature	extraction: RTI
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	Baltimore, MD/minimum: 3 months; maximum: 12–24 months	U.S./min.: 60 days; max: 15–24 months, varies by individual reagent component
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	no/no
Assay calibrations required by end-user/Calibrants can be stored onboard	—/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	yes/determined and validated by user	no/—
Length of assay calibration/Typical calibration frequency	determined and validated by user/determined and validated by user	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/no	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/—	no/extraction module: 0 minutes/no
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	each test contains internal process control for extraction and amplification	24 tests: downstream assay dependent/—/—/—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	24 specimens per run in 2.5 hours/approx. 1 minute per sample	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/self-contained in unitized reagent strip	no/—
Time between start and initial result/Instrument automatic shutdown	1–4 samples: 1 hour, 15 minutes; 24 samples: 2.5 hours	45 minutes/no
Startup programmable/Remote system monitoring/Waste req. for disposables	no/no/biohazard waste	no/no/normal biohazardous waste
Windows technology/Mouse or touchscreen/Modular add-on capability	no/mouse/no	yes/mouse and touchscreen/yes
Service contracts available/Mean time between failures/to repair failures	5 and 7 days per week/180 days/<24 hours from field service visit	7 days full service, preventive maintenance/extraction: 328 days/3.5 hours
Turnaround time for problem solving: by phone/e-mail/field service	immediate (<1 hr. after hours)/same day (next day after hours)/next bus. day	immediate (30 min. after hours)/<24 hours/within 2 hrs. after scheduling
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	—/next business day/24 hours, 7 days	32/within 24 hours/24–7 phone support; 12–7 on-site support
Guaranteed response time/Modem servicing available	—/no	yes/no
System can diagnose own malfunctions	yes	no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	weekly: 10 minutes/—	daily: 5 minutes; weekly: 10 minutes; yearly: performed by FSE/no
Preventive maintenance per year for sample extraction/amplification detection	1/1 (for total system)	extraction: 2
Downtime for preventive maintenance/Spare parts on site	5 hours/no	3 hours/no
Patient demographics and insurance data available via rules-based architecture	no	no
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/—	yes/yes to data retrieval
Online real-time help, QC, stats and management reports/Evaluates results validity	no/yes	no/no
Priority processing/Random-access specimen movement	—	no/—
Supports accession No. redundancy/Specimen carrier and level identification	yes/—	no/no
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	yes/—	yes/no
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	—	yes/no/—
Sample storage and retrieval software supports CLSI standards	—	no
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	—	yes/XML file transfer
QC results auto transferred to LIS/Data management capability	—	yes/yes
Interfaces operational in active user sites	—	yes
Rules-based control subsystem/Process control via control subsystem	—	no/yes
LIS operates simultaneously with assays running	—	yes
Auto transfer QC results to LIS/Onboard capability to review QC	—	yes/—
Uses LOINC to transmit orders and results/Unidirectional interface capability	—	no/yes
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	—	yes/no
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	yes/yes/yes/yes	no/yes/yes/no
Software upgrades since system launch/Can print, archive, transmit data	1/yes	1/yes
Distinguishing features (supplied by company)	fully automated from sample analysis through extraction, amplification, and result detection for PCR-based molecular testing	extreme flexibility: ability to vary sample and elution volumes from sample to sample in the same run; entire extraction process takes place in a single sample compartment, which minimizes potential sample loss and cross contamination; doesn't use multiple racks of pipette tips or processing plates, thus reducing plastics waste

**for calibration and controls*
Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Automated molecular platforms

Part 4 of 8	**bioMérieux** **Steve Shumoski** steve.shumoski@biomerieux.com **100 Rodolphe St., Durham, NC 27712** **919-620-2528 www.biomerieux-usa.com**	**Cepheid** **David Freestone** MarCommGroup@cepheid.com **904 Carribean Ave., Sunnyvale, CA 94079** www.cepheid.com
Name of instrument	**NucliSENS EasyQ**	**GeneXpert 1, GeneXpert 4, GeneXpert 16**
Country where designed/manufactured/reagents manufactured	Finland/Finland/France	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/preanalytical and analytical
First year sold in U.S./sold internationally/installed	2002/2002/2002	2006/2006/2006
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	8.7 × 16.5 × 16.5/1.9/—	GeneXpert 16: 29.5 × 21 × 18/2.625/—
Supplied with UPS/BTU/Space modification requirements	no/~340 BTU per hour/none	yes/—/none
Instrument requires floor drain/separate room for contamination control	no/no	no/no
Physical contamination control features	closed reaction tubes	closed cartridge technology
List price/Price for sample extraction and amplification detection modules	$55,000/amplification detection: $55,000	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/1	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/110V	yes/100–120 VAC, 50–60 Hz
Labor and parts warranties/Training with purchase/Advanced operator training	labor and parts: 1 year/yes/yes	labor and parts: 1 year/yes/yes
Delivery time/Delivery charges/Installer/Time to install on site	30 days/destination and origin: price varies/field service engineer/6 hours	less than 1 week/FOB origin/company/<1 day
Training location/No. of techs that can receive initial training/Length of training	on site and off site/1 or more/2 days	on site/1/<1 day
Additional on-site training/Retraining at company facility	yes/yes	yes/no
Test menu	basic NASBA reagents for laboratory-developed tests plus specific company-developed assays	MRSA, SA nasal Complete, MRSA/SA BC, MRSA/SA SSTI, C. difficile, vanA, EV, GBS, HemosIL FII & FV
No. of tests for which analyzer has FDA-cleared applications/CE-mark	1/5	9/10
Tests available in U.S./outside the U.S.	enterovirus (FDA-cleared bioMérieux)/HIV-1, HPV, enterovirus, HSV, RSV (bioMérieux)	—
Tests not available in U.S. but submitted to FDA/available in other countries only	MRSA/HIV-1, HPV, enterovirus, HSV, RSV	—
Research-use-only assays/Tests in development	U.S.: HIV-1 RUO, HPV RUO; outside U.S.: influenza A/B RUO, hMPV RUO/KPC	—
Open-channel capabilities/Start-up and preparation time	yes/30–40 minutes	yes/<1 minute
Model type of sample handling system/Maximum sample load capacity	—/48	cartridge-based/up to 16, based on number of installed modules
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	—	—/yes (sample type dependant: whole blood, swab, sputum fluids, others)/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	—/function of extraction platform/no	—/yes/yes
Sample bar-code languages/Sample types available in open mode	—	all common/no restrictions
Clot detection/Open extraction platform/Sample types (open extraction)	—	no/no/no restrictions
Amplification reagents or methods supported	real-time NASBA applications	—
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	analytical instrument	yes/yes/yes
No. of different assays onboard at once/Programmed or calibrated at once	one	full menu/full menu
Tests per container set/Multiple reagent configurations supported	48/basic NASBA reagent kits and specific assay kits	single-use cartridges/reagents contained in cartridge
Reagent container placed directly on system/Onboard test auto inventory	no/no	yes/yes
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	no/no/no	yes/yes/yes
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	no/no/no	yes/yes/yes
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	no/liquid and dry	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	yes/—	no/closed cartridge technology
Onboard test auto inventory/Capacity for inventory monitoring by bar code	no/no	yes/yes
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/no	no/no
Closed-vial stability for amplification reagents/extraction reagents	—	up to 2 years/up to 2 years
Storage temp. requirement for amplification reagents/extraction reagents	2°–8°C with some at –20°C/—	amplification and extraction: room temperature (2°–8°C depending on test)
Shipment temp. requirement for amplification reagents/extraction reagents	amplification: refrigerate (some with dry ice)/—	room temperature/room temperature
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	U.S./min.: 30 days; max.: 24 months (basic kit); 18 months (specific assay kits)	Sunnyvale, CA/minimum: 3 months; maximum: varies
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/no	yes/yes
Assay calibrations required by end-user/Calibrants can be stored onboard	no/no	no/—
Multiple calibrant lots stored for same assay/Required calibration frequency	no/assay dependent	—/2,000 tests or 1 year
Length of assay calibration/Typical calibration frequency	assay dependent/assay dependent	2,000 tests or 1 year/once per year
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/yes	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/amplification module: 15 minutes/yes	no/none/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	24 and 42 tests: assay dependent, but typically 2	0/0/0/0
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	—	random access/random access
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	assay dependent (as early as 1 hour)/no	35 minutes to 2 hours, depending on test/no
Startup programmable/Remote system monitoring/Waste req. for disposables	no/no/normal biohazardous waste	—/—disposable cartridges
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/mouse/yes
Service contracts available/Mean time between failures/to repair failures	7 days full service, preventive maintenance/amplification: 1,322 days/3.5 hrs.	full service, labor and parts/—/24–48 hours
Turnaround time for problem solving: by phone/e-mail/field service	immediate (30 min. after hours)/<24 hours/within 2 hours after scheduling	M-F, 5 am–5 pm: 5 min. to 2 hrs; limited on weekend/same as phone/—
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	32/within 24 hours/24–7 phone support; 12–7 on site support	10/within 24 hours/24-7 or M-F, 5 am–5 pm
Guaranteed response time/Modem servicing available	yes/no	yes (M-F, 5 am–5 pm)/no
System can diagnose own malfunctions	no	no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 minutes; weekly: 10 minutes/no	monthly: up to 30 minutes for a fully populated system (GeneXpert 16)/no
Preventive maintenance per year for sample extraction/amplification detection	amplification: 1	—
Downtime for preventive maintenance/Spare parts on site	4 hours/no	1–2 hours/no
Patient demographics and insurance data available via rules-based architecture	no	yes
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/yes to data retrieval	yes/yes
Online real-time help, QC, stats and management reports/Evaluates results validity	no/no	yes/yes
Priority processing/Random-access specimen movement	no/—	yes/—
Supports accession No. redundancy/Specimen carrier and level identification	no/no	yes/yes
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	yes/no	yes/yes
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/no/—	yes/yes/—
Sample storage and retrieval software supports CLSI standards	no	yes
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/XML file transfer	yes/TCP-IP
QC results auto transferred to LIS/Data management capability	yes/yes	yes/yes
Interfaces operational in active user sites	yes	yes
Rules-based control subsystem/Process control via control subsystem	no/yes	yes/yes
LIS operates simultaneously with assays running	yes	yes
Auto transfer QC results to LIS/Onboard capability to review QC	yes/—	yes/—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	yes/yes
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	yes/no	yes/yes
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	no/yes/yes/yes	yes/yes/yes/yes
Software upgrades since system launch/Can print, archive, transmit data	3/yes	GeneXpert Dx 4.0/yes
Distinguishing features (supplied by company)	specifically designed to analyze real-time NASBA applications: isothermal amplification using fluorophore-labeled molecular beacons for detection; intuitive and flexible assay-analysis software; compact footprint for 48-test capacity instrument	fully integrated real-time PCR system; simplifies hands-on preparation; provides PCR test results from a raw sample in ~1 hour, which enables time-critical DNA tests at the point of need; modular design offers a variety of configurations to meet broad range of testing demands

**for calibration and controls*
Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Automated Molecular Platforms

Part 5 of 8	Cepheid **David Freestone** MarCommGroup@cepheid.com 904 Carribean Ave., Sunnyvale, CA 94079 888-336-2743 www.cepheid.com	GenMark Diagnostics **Courtney Tate** courtney.tate@genmarkdx.com 5964 La Place Court, Carlsbad, CA 92008 800-eSensor (373-6767) www.genmarkdx.com
Name of instrument	**GeneXpert Infinity-48**	**eSensor XT-8**
Country where designed/manufactured/reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/analytical
First year sold in U.S./sold internationally/installed	2009/2009/2009	2007/—/2007
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	79.1 × 105.2 × 34.6/25.25/—	18 × 18 × 15/2.25/—
Supplied with UPS/BTU/Space modification requirements	yes/—/none	yes/—/none
Instrument requires floor drain/separate room for contamination control	no/no	no/no
Physical contamination control features	closed cartridge technology	closed cartridge technology
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/1+
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/100–120 VAC, 50–60 Hz	yes/100–230 VAC
Labor and parts warranties/Training with purchase/Advanced operator training	labor and parts: 1 year/yes/yes	labor and parts: standard 1 year, additional years available/yes/yes
Delivery time/Delivery charges/Installer/Time to install on site	2–4 weeks/FOB origin/Cepheid/1 day	3 days/variable/GenMark Dx/<1 hour
Training location/No. of techs that can receive initial training/Length of training	on site/1/1–3 days	on site/up to 3/1–3 days
Additional on-site training/Retraining at company facility	yes/no	yes/yes
Test menu	MRSA, SA nasal Complete, MRSA/SA BC, MRSA/SA SSTI, C. difficile, vanA, EV, GBS, HemosIL FII & FV	eSensor warfarin sensitivity test, eSensor cystic fibrosis genotyping test, eSensor thrombophilia risk test
No. of tests for which analyzer has FDA-cleared applications/CE-mark	9/10	3/—
Tests available in U.S./outside the U.S.	—	3/—
Tests not available in U.S. but submitted to FDA/available in other countries only	—	—
Research-use-only assays/Tests in development	—	—
Open-channel capabilities/Start-up and preparation time	yes/<1 minute	no/<5 minutes
Model type of sample handling system/Maximum sample load capacity	cartridge-based/1,300 in 24 hours	cartridge-based/96 samples in 8-hour shift
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	—/yes (sample type dependant: whole blood, swab, sputum fluids, others)/—	varies by test/yes/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	—/yes/yes	—/yes/no
Sample bar-code languages/Sample types available in open mode	all common/no restrictions	bar-code scanner shipped with system (Symbol LS 2208)/—
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/no restrictions	—/yes/—
Amplification reagents or methods supported	—	PCR
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	yes/yes/yes	no/yes/yes
No. of different assays onboard at once/Programmed or calibrated at once	full menu/full menu	multiple (random access)/multiple (random access)
Tests per container set/Multiple reagent configurations supported	single-use cartridges/reagents contained in cartridge	48 tests per kit/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	no/no
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	yes/yes/yes	no/yes/yes
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	yes/yes/yes	yes/yes/yes
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	yes/liquid and dry	no/liquid
Reagent reconstitution required/Chemical contamination control	no/closed cartridge technology	no/—
Onboard test auto inventory/Capacity for inventory monitoring by bar code	yes/yes	no/—
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/no	no/yes
Closed-vial stability for amplification reagents/extraction reagents	up to 2 years/up to 2 years	up to 12 months/—
Storage temp. requirement for amplification reagents/extraction reagents	amplification and extraction: room temperature (2°–8°C depending on test)	-20°C/-20°C
Shipment temp. requirement for amplification reagents/extraction reagents	room temperature/room temperature	frozen/frozen
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	Sunnyvale, CA/minimum: 3 months; maximum: varies	California/minimum: up to 60 days; maximum: up to 12 months
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	—
Assay calibrations required by end-user/Calibrants can be stored onboard	no/—	—
Multiple calibrant lots stored for same assay/Required calibration frequency	—/2,000 tests or 1 year per module	—
Length of assay calibration/Typical calibration frequency	2,000 tests or 1 year per module/1 year	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/—	—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	—
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	0/0/0/0	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	~130: random access/<2 minutes per sample: random access	30 minutes, 24 samples/90 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	yes/—
Time between start and initial result/Instrument automatic shutdown	35 minutes to 2 hours, depending on test/no	30 minutes/no
Startup programmable/Remote system monitoring/Waste req. for disposables	yes/no/disposable cartridges	no/no/laboratory standards; disposable cartridges
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/yes	yes/touchscreen/yes
Service contracts available/Mean time between failures/to repair failures	full service, labor and parts/—/24–48 hours	field and depo service/—/within 48 hours
Turnaround time for problem solving: by phone/e-mail/field service	M-F, 5 AM–5 PM: 5 min. to 2 hours limited on weekend/same as phone/—	yes/yes/yes
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	10/within 24 hours/24-7 or M-F, 5 AM–5 PM	4/within 48 hours/7 AM–6 PM PT
Guaranteed response time/Modem servicing available	yes (M-F, 5 AM–5 PM)/no	yes (within 48 hours)/no
System can diagnose own malfunctions	no	yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: <1 minute; weekly: <5 minutes; monthly: <30 minutes/no	yearly: 60 minutes/yes
Preventive maintenance per year for sample extraction/amplification detection	—	amplification: 1
Downtime for preventive maintenance/Spare parts on site	1–2 hours/no	60 minutes/no
Patient demographics and insurance data available via rules-based architecture	yes	no
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/yes	yes/no
Online real-time help, QC, stats and management reports/Evaluates results validity	yes/yes	no/yes
Priority processing/Random-access specimen movement	yes/—	yes/—
Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	no/no
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	yes/yes	yes/no
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/yes/—	no/no/—
Sample storage and retrieval software supports CLSI standards	yes	yes
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/TCP-IP	no/—
QC results auto transferred to LIS/Data management capability	yes/yes	no/yes
Interfaces operational in active user sites	yes	yes
Rules-based control subsystem/Process control via control subsystem	yes/yes	no/yes
LIS operates simultaneously with assays running	yes	no
Auto transfer QC results to LIS/Onboard capability to review QC	yes/—	no/—
Uses LOINC to transmit orders and results/Unidirectional interface capability	yes/yes	no/yes
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	yes/yes	no/no
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	yes/yes/yes/yes	no/yes/yes/no
Software upgrades since system launch/Can print, archive, transmit data	yes/yes	yes/yes
Distinguishing features (supplied by company)	fully automated, robotic, real-time PCR system integrates all the steps required for PCR-based DNA testing, for example, sample preparation, DNA amplification and detection; cartridge handling; fluid master scheduler prioritizes test runs that meet workflow needs	multiplex capability; small footprint; no maintenance

**for calibration and controls*

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Tabulation does not represent an endorsement by the College of American Pathologists.

Automated Molecular Platforms

Part 6 of 8

Gen-Probe
Julie Cole julie.cole@gen-probe.com
10210 Genetic Center Dr., San Diego, CA 92121
858-410-8000 www.gen-probe.com

Idaho Technology
Wade Stevenson wade_stevenson@idahotech.com
390 Wakara Way, Salt Lake City, UT 84108
801-736-6354 www.idahotech.com

Name of instrument	TIGRIS DTS Analyzer	FilmArray
Country where designed/manufactured/reagents manufactured	U.S./U.S./U.S and UK	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	no/preanalytical and analytical
First year sold in U.S./sold internationally/installed	2004/2005/2004	2009/—/2009
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	72 × 69 × 36/17.25/compliant with EN 61010-1	6.5 × 10 × 15.5/1.08/74 dB at 3 feet
Supplied with UPS/BTU/Space modification requirements	yes/2,637/24 in. surrounding instrument	—/—/none
Instrument requires floor drain/separate room for contamination control	no/no	no/no
Physical contamination control features	closed system	closed system
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/variable	straight purchase, reagent rental/none
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/220V	yes/90–264 VAC, 10A
Labor and parts warranties/Training with purchase/Advanced operator training	labor and parts: 1 year/yes/yes	labor and parts: 5 years/yes/no
Delivery time/Delivery charges/Installer/Time to install on site	<1 week/variable at origin and destination/Gen-Probe/2–3 days	—/origin/Idaho Technology/1 hour
Training location/No. of techs that can receive initial training/Length of training	on and off site/2/4 day	on site/up to 5/1 hour per tech
Additional on-site training/Retraining at company facility	yes/yes	yes/yes
Test menu	CT-GC, CT, GC, HPV, *Trichomonas*	respiratory panel: adenovirus, bocavirus, coronavirus 229E, HKU1, OC43, NL63; influenza A, A H1, A H1 2009, A H3, B; metapneumovirus, parainfluenza 1, 2, 3, 4; respiratory syncytial virus; rhinovirus/enterovirus; bordetella pertussis; *Chlamydophila pneumoniae*; *Mycoplasma pneumoniae*
No. of tests for which analyzer has FDA-cleared applications/CE-mark	3/5	none/none
Tests available in U.S./outside the U.S.	CT-GC, CT, GC/CT-GC, CT, GC, HPV, *Trichomonas*	—
Tests not available in U.S. but submitted to FDA/available in other countries only	—/HPV, *Trichomonas*	—
Research-use-only assays/Tests in development	—/HPV, HPV genotyping, *Trichomonas*	—/GI track panel, STD panel, sepsis panel
Open-channel capabilities/Start-up and preparation time	no/<45 minutes	no/2 minutes
Model type of sample handling system/Maximum sample load capacity	onboard automated pipettor/180	—/1
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	400 µL/yes/—	300 µL/no/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	800 µL/—/yes	—/—/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	various/yes (automated onboard scanner to maintain positive sample ID)/no	—/yes/—
Sample bar-code languages/Sample types available in open mode	2 of 5 interleaved, Codabar, codes 39 and 128/—	—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/—	—/no/—
Amplification reagents or methods supported	transcription mediated amplification	PCR
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	yes/no/no	yes/yes/yes
No. of different assays onboard at once/Programmed or calibrated at once	4/5	21/21
Tests per container set/Multiple reagent configurations supported	250/yes	1/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	yes/yes/yes	—/yes/yes
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	yes/yes/yes	yes/yes/yes
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	yes/liquid	no/dry
Reagent reconstitution required/Chemical contamination control	yes/onboard addition of sodium hypochlorite solution	yes/—
Onboard test auto inventory/Capacity for inventory monitoring by bar code	yes/yes	—/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/yes	no/no
Closed-vial stability for amplification reagents/extraction reagents	assay dependent	6 months/6 months
Storage temp. requirement for amplification reagents/extraction reagents	refrigerate	room temperature/room temperature
Shipment temp. requirement for amplification reagents/extraction reagents	room temperature	room temperature/room temperature
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	U.S. and UK/up to 1.5 years after manufacture date	Salt Lake City, UT/up to 6 months
Autocalibration or autocalibration alert/Multipoint calibration supported	—/yes	yes/—
Assay calibrations required by end-user/Calibrants can be stored onboard	—/no	no/—
Multiple calibrant lots stored for same assay/Required calibration frequency	no/assay dependent (done per worklist)	—
Length of assay calibration/Typical calibration frequency	—/assay dependent (done per worklist)	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	—/—	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/—	—/1 minute/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	4/4/4/4 (4 controls for up to 250 tests)	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	—	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/480	no/—
Time between start and initial result/Instrument automatic shutdown	3.5 hours/no	1 hour/—
Startup programmable/Remote system monitoring/Waste req. for disposables	no/yes/plastics and cardboard	—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/no	yes/mouse/no
Service contracts available/Mean time between failures/to repair failures	premiere and standard/—/—	parts and labor/—/—
Turnaround time for problem solving: by phone/e-mail/field service	—	—
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	—/—/premiere: 24-7; standard: M-F 8–5 PM PST	—/—/24 hours, 7 days
Guaranteed response time/Modem servicing available	<24 hours/Internet	—
System can diagnose own malfunctions	no	—
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	—
Average maintenance time for lab personnel/Onboard maintenance records	daily: 15 minutes; weekly: 5 minutes; monthly: 3 hours/yes	—
Preventive maintenance per year for sample extraction/amplification detection	2/2	—
Downtime for preventive maintenance/Spare parts on site	1 day/yes	—
Patient demographics and insurance data available via rules-based architecture	no	—
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/yes	yes/yes
Online real-time help, QC, stats and management reports/Evaluates results validity	no/yes	no/—
Priority processing/Random-access specimen movement	no/—	—
Supports accession No. redundancy/Specimen carrier and level identification	no/yes	—
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	yes/no	—
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/—	—
Sample storage and retrieval software supports CLSI standards	no	—
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/LIS1-A and LIS2-A2 (ASTM), custom flat file LIS formats	—
QC results auto transferred to LIS/Data management capability	yes/yes	—
Interfaces operational in active user sites	yes	—
Rules-based control subsystem/Process control via control subsystem	yes/yes	—
LIS operates simultaneously with assays running	yes	—
Auto transfer QC results to LIS/Onboard capability to review QC	yes/—	—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	—
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	yes/no	—
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	yes/yes/yes/no	—/—/—/yes
Software upgrades since system launch/Can print, archive, transmit data	numerous/yes	—/yes
Distinguishing features (supplied by company)	totally integrated platform; high-throughput CT/GC platform; flexible worklist size from 1–246 patient samples; sample pos-ID for confidence in results; scalable for menu expansion and lab growth; built-in process controls to minimize crossover contamination	user-friendly multiplex PCR; fully automated; sample preparation to results in one hour; requires two minutes of hands-on time

**for calibration and controls*
Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Tabulation does not represent an endorsement by the College of American Pathologists.

Automated Molecular Platforms

Part 7 of 8	Nanosphere **Zack Crowther** zcrowther@nanosphere.us **4088 Commercial Ave., Northbrook, IL 60062** **888-VERIGENE (837-4436)** www.nanosphere.us	Nanosphere **Zack Crowther** zcrowther@nanosphere.us **4088 Commercial Ave., Northbrook, IL 60062** **888-VERIGENE (837-4436)** www.nanosphere.us
Name of instrument	**Verigene Processor SP with Verigene Reader**	**Verigene Processor with Verigene Reader**
Country where designed/manufactured/reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/analytical
First year sold in U.S./sold internationally/installed	2009/2010/2009	2007/—/2007
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	18.7 × 19.3 × 22.9/3.1/—	12.4 × 37.1 × 20.5/5.3/—
Supplied with UPS/BTU/Space modification requirements	—/—/none	—/—/none
Instrument requires floor drain/separate room for contamination control	no/no	no/no
Physical contamination control features	—	—
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical req.	—/standard	—/standard
Labor and parts warranties/Training with purchase/Advanced operator training	—/yes/no	—/yes/no
Delivery time/Delivery charges/Installer/Time to install on site	varies/varies/Nanosphere technician/1–2 days	varies/varies/Nanosphere technician/1–2 days
Training location/No. of techs that can receive initial training/Length of training	on site/1 or more/varies	on site/1 or more/varies
Additional on-site training/Retraining at company facility	yes/—	yes/—
Test menu	Verigene respiratory virus nucleic acid test SP	Verigene warfarin metabolism nucleic acid test; Verigene F5/F2/MTHFR nucleic acid test
No. of tests for which analyzer has FDA-cleared applications/CE-mark	1/—	4/—
Tests available in U.S./outside the U.S.	Verigene respiratory virus nucleic acid test SP/—	Verigene warfarin metabolism nucleic acid test; Verigene F5-F2-MTHFR nucleic acid test/—
Tests not available in U.S. but submitted to FDA/available in other countries only	Verigene clopidogrel metabolism (2C19) nucleic acid test/—	Verigene hemochromatosis (HFE) nucleic acid test, cardiac troponin I/—
Research-use-only assays/Tests in development	—/multiplex blood culture ID test; expanded respiratory virus panels; F5-F2-MTHFR (hypercoagulation) nucleic acid test (migration from semiautomated platform); warfarin metabolism nucleic acid test (migration from semiautomated platform); hemochromatosis (HFE) nucleic acid test; more	—/—
Open-channel capabilities/Start-up and preparation time	no/5 minutes	no/10 minutes
Model type of sample handling system/Maximum sample load capacity	—/1 mL	—/4
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	200 µL/—/1 mL	25 µL/—/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	—/—/yes	—
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	—/yes/—	—
Sample bar-code languages/Sample types available in open mode	—	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/—/—	no/—/—
Amplification reagents or methods supported	proprietary	no target amplification required
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	—	—
No. of different assays onboard at once/Programmed or calibrated at once	1/—	4/—
Tests per container set/Multiple reagent configurations supported	—	—
Reagent container placed directly on system/Onboard test auto inventory	yes/—	—
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	—/yes/yes	—/yes/yes
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	yes/—/no	yes/—/no
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	no/liquid	no/liquid
Reagent reconstitution required/Chemical contamination control	no/—	no/—
Onboard test auto inventory/Capacity for inventory monitoring by bar code	—	—
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/—	no/—
Closed-vial stability for amplification reagents/extraction reagents	—	no target amplification required/—
Storage temp. requirement for amplification reagents/extraction reagents	-20°C/refrigerate	no target amplification required/—
Shipment temp. requirement for amplification reagents/extraction reagents	-20°C/refrigerate	no target amplification required/refrigerate
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	Northbrook, IL/—	Northbrook, IL/varies by test
Autocalibration or autocalibration alert/Multipoint calibration supported	—	—
Assay calibrations required by end-user/Calibrants can be stored onboard	no/—	no/—
Multiple calibrant lots stored for same assay/Required calibration frequency	—	—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	—	—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	—/sample extraction: ~2 minutes/—	—
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	—	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	random access system/random access system	4 samples per processor/random access system
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/—	—
Time between start and initial result/Instrument automatic shutdown	2.5–3.5 hours/—	1.5–2 hours/—
Startup programmable/Remote system monitoring/Waste req. for disposables	—	—
Windows technology/Mouse or touchscreen/Modular add-on capability	no/touchscreen/yes	no/touchscreen/yes
Service contracts available/Mean time between failures/to repair failures	—	—
Turnaround time for problem solving: by phone/e-mail/field service	—	—
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	—	—
Guaranteed response time/Modem servicing available	—	—
System can diagnose own malfunctions	—	—
Order parts via modem/Onboard error codes/Maintenance training demo module	—/yes/—	—/yes/—
Average maintenance time for lab personnel/Onboard maintenance records	daily: 1 minute/—	daily: 1 minute/—
Preventive maintenance per year for sample extraction/amplification detection	—	—
Downtime for preventive maintenance/Spare parts on site	—	—
Patient demographics and insurance data available via rules-based architecture	—	—
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/yes	yes/yes
Online real-time help, QC, stats and management reports/Evaluates results validity	—	—
Priority processing/Random-access specimen movement	—	—
Supports accession No. redundancy/Specimen carrier and level identification	—	—
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	—	—
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	—	—
Sample storage and retrieval software supports CLSI standards	—	—
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	—	—
QC results auto transferred to LIS/Data management capability	—	—
Interfaces operational in active user sites	yes	yes
Rules-based control subsystem/Process control via control subsystem	—	—
LIS operates simultaneously with assays running	—	—
Auto transfer QC results to LIS/Onboard capability to review QC	—	—
Uses LOINC to transmit orders and results/Unidirectional interface capability	—	—
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	—	—
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	—	—
Software upgrades since system launch/Can print, archive, transmit data	—	—
Distinguishing features (supplied by company)	FDA-cleared tests; processor SP designed as CLIA moderate complexity; scalable, random access platform; on-demand, automated, multiplex testing for respiratory viruses; only one user pipetting step	FDA-cleared tests; scalable, random access platform; on-demand, semiautomated, multiplex testing

**for calibration and controls*
Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Tabulation does not represent an endorsement by the College of American Pathologists.

Automated molecular platforms

Part 8 of 8	**QIAGEN** **Tracy Gambrell** tracy.gambrell@qiagen.com **19300 Germantown Rd., Germantown, MD 20874** **240-686-7430** www.qiagen.com	**Siemens Healthcare Diagnostics** **Kevin Culver** kevin.culver@siemens.com www.usa.siemens.com/diagnostics
Name of instrument	**QIAsymphony RGQ**	**VERSANT 440 Molecular System**
Country where designed/manufactured/reagents manufactured	Switzerland/Switzerland/Germany	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	no/preanalytical and analytical	yes/analytical
First year sold in U.S./sold internationally/installed	2011/2010/2010	2007/2005/2005
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	107 × 150 × 50/27/—	24.2 × 59.7 × 31/—/78
Supplied with UPS/BTU/Space modification requirements	no/—/placement on benchtop or cabinets available	yes/1,700 per hour/—
Instrument requires floor drain/separate room for contamination control	no/no	—/no/no
Physical contamination control features	UV decontamination, built-in tip drop-catchers	—
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/8	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/110 volts	yes/100 to 120 VAC plus 10%, 50/60 Hz, 600 VA maximum 1,700 BTU per hour
Labor and parts warranties/Training with purchase/Advanced operator training	labor and parts: 1 year/yes/yes	—/yes/yes
Delivery time/Delivery charges/Installer/Time to install on site	2–4 weeks/destination/Qiagen Service Solutions/2 days	—/—/Siemens/6–8 hours
Training location/No. of techs that can receive initial training/Length of training	on site/2–4/3 days	on site/—/—
Additional on-site training/Retraining at company facility	yes/yes	yes/yes
Test menu	open system	HIV, HCV, HBV viral load
No. of tests for which analyzer has FDA-cleared applications/CE-mark	0/9	2/—
Tests available in U.S./outside the U.S.	3/—	HIV, HCV, HBV viral load/—
Tests not available in U.S. but submitted to FDA/available in other countries only	—/CMV, EBV, BKV, HSV, VZV, HIV, HCV, HBV	—/—
Research-use-only assays/Tests in development	BKV/9	HVB/—
Open-channel capabilities/Start-up and preparation time	yes/30 minutes	no/—
Model type of sample handling system/Maximum sample load capacity	QIAsymphony SP/96 (continuous load)	—/192
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	200 µL/yes (varies per sample type)/400 µL, 500 µL, 800 µL, 1,000 µL	—/no/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	100 µL/200 µL/yes	—/—/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	1.5–15 mL/yes/no	—/yes/—
Sample bar-code languages/Sample types available in open mode	codes 39 & 128, Codabar/plasma, serum, blood, respiratory, stool, urine, tissue, CSF, investigator, swabs, cytology, transport media	—/—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/plasma, serum, blood, respiratory, stool, urine, tissue, CSF, others	yes/no/—
Amplification reagents or methods supported	open system	Signal
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	yes/yes/yes	—
No. of different assays onboard at once/Programmed or calibrated at once	4/—	1/1
Tests per container set/Multiple reagent configurations supported	—/yes	96/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent container vol./Reagent bar-code reading/Reagents bar coded	yes/yes/yes	yes/no/no
Info. in bar code/Monitors expiration date/Auto lot recognition or calibration	yes/yes/yes	no/yes/no
Auto detection of adequate reagent or specimen/Reagents avail. liquid or dry	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	yes/—	no/—
Onboard test auto inventory/Capacity for inventory monitoring by bar code	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes	no/yes
Closed-vial stability for amplification reagents/extraction reagents	1 year/1year	—
Storage temp. requirement for amplification reagents/extraction reagents	room temperature/room temperature	—
Shipment temp. requirement for amplification reagents/extraction reagents	room temperature/room temperature	—
Location from which reagents shipped/Min. and max. reagent shelf-life guarantee	U.S./6 months/1 year	—
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	—/yes
Assay calibrations required by end-user/Calibrants can be stored onboard	no/yes	—/no
Multiple calibrant lots stored for same assay/Required calibration frequency	yes/—	no/—
Length of assay calibration/Typical calibration frequency	—/—	—/—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	—/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	—/—/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	assay dependent	12/12/12/12
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	4 hours/1 hour	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/sufficient for 96 samples	no/—
Time between start and initial result/Instrument automatic shutdown	6.5 hours for 96/no	—
Startup programmable/Remote system monitoring/Waste req. for disposables	no/yes/liquid, plastic	—/no/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/yes	yes/mouse and touchscreen/no
Service contracts available/Mean time between failures/to repair failures	24 hours, 48 hour, and 5 days/—/—	—
Turnaround time for problem solving: by phone/e-mail/field service	24 hours, 6 days/24 hrs., 6 days/based on contract type and working day	—
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	56/contract dependent/ M-F 8–5 PM	—/—/8 AM–8 PM
Guaranteed response time/Modem servicing available	yes (response time depends on contract purchased)/yes	—/no
System can diagnose own malfunctions	yes	no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 30 min.; weekly: 30 min.; monthly: 30 min./no	—/yes
Preventive maintenance per year for sample extraction/amplification detection	1/1 (both could increase depending on usage)	—
Downtime for preventive maintenance/Spare parts on site	half day for QIAsymphony; 2–3 hrs. for Rotor-Gene Q/no	6 hours/yes
Patient demographics and insurance data available via rules-based architecture	no	yes
Sample ID tracked from sample input to result/Data retrieval or Internet connectivity	yes/no	—/no
Online real-time help, QC, stats and management reports/Evaluates results validity	yes/no	no/—
Priority processing/Random-access specimen movement	yes/—	—
Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	—
Unique bar code per container req./Multistop routing (1 tube to mult. workstations)	yes/no	—
Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/—	—
Sample storage and retrieval software supports CLSI standards	no	—
LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/XML interface	yes/—
QC results auto transferred to LIS/Data management capability	no/yes	yes/—
Interfaces operational in active user sites	yes	yes
Rules-based control subsystem/Process control via control subsystem	no/no	—
LIS operates simultaneously with assays running	yes	yes
Auto transfer QC results to LIS/Onboard capability to review QC	—	—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	yes/yes	yes/no
Stores QC lot files/Worklist edit capability/Security/Viewable PCR graphs	yes/yes/yes/yes	no/yes/yes/no
Software upgrades since system launch/Can print, archive, transmit data	—/yes	—/yes
Distinguishing features (supplied by company)	flexible, convenient product solutions; open assay platform; limited hands-on processing from sample to result for standardized and reliable processing	

*for calibration and controls
Note: a dash in lieu of an answer means company did not answer question or question is not applicable