Automated molecular platforms

Part 1 of 10	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	AutoGenomics **Anand Vairavan** avairavan@autogenomics.com 2980 Scott St., Vista, CA 92081 760-477-2248 www.autogenomics.com
Name of instrument	***m*2000 RealTime System comprised of the *m*2000sp and *m*2000rt**	**INFINITI Analyzer**
Country where designed/Manufactured/Reagents manufactured	U.S./Switzerland, Singapore/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	2007/2005/2005	2007/2007/2007
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)	26 × 44 × 24/7.3/—
Supplied with UPS/BTU	yes/*m*2000sp: 4,100 BTU (1,200 Wh); *m*2000rt: 3,241.5 BTU per hour (950 W)	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	no aspiration tubing, disposable tips
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	straight purchase, reagent rental, lease/1 µL
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	yes/110V and 220V, 50–60 Hz
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	1–4 weeks/$1,500 (destination)/Abbott Molecular/sp: 3 days; rt: 1 day	1 week/—/AGI/1–2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site and off site/2/3 days/yes	on site and off site/1/2.5 days/yes
Test menu	HIV VL, HIV Qual, HCV VL, HCV GT, HBV VL, CT/NG, CT, CMV, EBV, HPV, ms9, KIF6	CYP2C19 (IVD), CYP450 2D6, warfarin assay (IVD), KRAS-BRAF, HPV genotyping, HPV-HR, STD-6 panel, bacterial vaginosis, candida vaginitis, and more
No. of tests for which analyzer has FDA-cleared applications/CE-mark	4/11	6/18
Tests available on instrument in U.S./Outside U.S.	HIV VL*, HIV Qual****, HCV VL*, HBV VL*, CT/NG*, HCV GT****/HIV VL**, HIV Qual****, HCV VL**, HCV GT**, HBV VL**, CT/NG**, CT**, CMV**, EBV**, HPV**, ms9**, KIF6**	CYP2C19 (IVD), CYP450 2D6, warfarin assay (IVD), KRAS-BRAF, HPV genotyping, HPV-HR, STD-6 panel, bacterial vaginosis, candida vaginitis, factor II-V leiden panel (IVD), RVP plus, MDR-TB, ApoE, CFTR-31, FMF panel, 5-FU, UGT1A1
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/CT**, HPV**, ms9**, KIF6**	—
Research-use-only assays/Tests in development	HCV GT****, HIV Qual****/CMV, VRE, C. Diff	factor II plus, factor V genotyping, MTHFR, many others/—
Open-channel capabilities/Start-up and preparation time	yes/15 minutes for batch of 24 samples	yes/20 minutes
Model type of sample-handling system/Maximum sample load capacity	*m*2000sp/96 samples	—/24
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	1 µL/no/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	0.2 mL/0.2 mL/yes	—/—/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	11.5 mm–16 mm diameter/yes/no	—/yes/—
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, others	—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/plasma, serum, urine, whole blood, swabs, dry blood spots, others	—/yes/—
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	4/47
Tests per container set/Multiple reagent configurations supported	24–96/nucleic acid: DNA, RNA, total nucleic acid; master mix: up to 4 reagents	48/—
Reagent container placed directly on system/Onboard test auto inventory	yes/no	yes/yes
Determines reagent volume in container	yes	yes
Reagent bar-code reading/Reagents bar coded	yes/yes	yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/—	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/not required	no/—
Onboard test auto inventory/Capable of inventory monitoring by bar code	yes/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/yes	no/no
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	-20°C/—
Shipment temp. requirement for amplification reagents/Extraction reagents	frozen on dry ice/15°–30°C	-20°C/—
Minimum/maximum reagent shelf-life guarantee	3 months/18 months	12 months/24 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	no/yes
Assay calibrations required by end-user/Calibrants can be stored onboard	yes/yes	no/no
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	yes/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/sample extraction: none; amplification detection: 15 minutes/yes	no/—/—
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	5 hours/15 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/864	yes/504
Time between start and initial result/Instrument automatic shutdown	for a CT/NG batch of 48 samples: 4 hours, 41 minutes/yes	3 hours/no
Startup programmable/Remote system monitoring/Waste req. for disposables	no/yes/plastic and liquid; waste containers on-board	no/no/built-in waste tray; solid state waste products
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	phone, on-site service/samp. extract.: 30 wks; ampli. detect.: 162 wks/4 hours	annual/—/—
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	24 hours/24 hours/48 hours
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	—/24–48 hours/6 AM–6 PM (PDT)
Guaranteed response time/Modem servicing available	yes (when requested)/yes	yes, within 24 hours/no
System can diagnose own malfunctions	yes	yes
Order parts via modem/Onboard error codes/Maintenance training demo module	varies/yes/yes	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: <10 minutes; weekly: 60 minutes; monthly: 15 minutes/yes	daily: 5 min.; weekly: 10 min.; monthly: 20 min.; yearly: 45 min./no
Preventive maintenance per year for sample extraction/amplification detection	2/1	—/1
Downtime for preventive maintenance/Spare parts on site	4–8 hours/yes	1 day/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/yes
• Priority processing	no	yes
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	—
• Unique bar code per container/Multistop routing (1 tube to many workstations)	no/no	yes/no
• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions	no/—/—	yes/no/—
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—	yes/—
• QC results transferred automatically to LIS/Data management capability	yes/yes	—/yes
Interfaces operational in active user sites	yes	yes
Rules-based control subsystem/Process control via control subsystem	yes/yes	yes/yes
LIS operates simultaneously with assays running	yes	yes
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/no
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	yes/no	yes/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	—/yes/no
Can print, archive, transmit data	yes	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)	load-and-go automation increases lab productivity by freeing up personnel; built-in replicate testing on each BioFilmChip microarray ensures assay result integrity; broad spectrum of more than 45 applications 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

** 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.

Survey editor: Raymond Aller, MD

Automated molecular platforms

Part 2 of 10	**Becton Dickinson and Company** bdgeneohmcustomerservice@bd.com **11085 N. Torrey Pines Rd., La Jolla, CA 92037** **888-436-3646** www.bd.com/geneohm	**BD Diagnostic Systems** **John S. Favara** john_favara@bd.com **7 Loveton Circle, Sparks, MD 21512** **410-316-3597** www.bdx.com
Name of instrument	**BD MAX**	**Affirm VPIII Microprocessor**
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S. and Canada	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	2010/2010/2010	1996/1996/1996
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	6 × 10 × 9/.63/quiet
Supplied with UPS/BTU	yes/—	no/—
Physical contamination control features	unitized reagent strip; dedicated pipette tips, microfluidic PCR cartridge with microvalves; pipettor flight path avoids crossing strips/tubes	—
List price/Price for sample extraction and amplification detection modules	$150,500/—	$12,990/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/specimen dependent (low as 10–15 µL)	straight purchase, reagent rental/three tests per day
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/100–240 VAC ~50–60 Hz, 10A	no/120V
Labor and parts warranties/Advanced operator training	1 year (1–3 year contracts optional)/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	~6 weeks from order acceptance/—/BD/one-half day	2 weeks/none for instrumentation/BD field applications/4 hours
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/flexible/1 day/yes	on site/6/4 hours/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	Candida sp. (six different), Gardnerella vaginalis, Trichomonas vaginalis
No. of tests for which analyzer has FDA-cleared applications/CE-mark	1/1 plus extraction and master mix reagents	3/3
Tests available on instrument in U.S./Outside U.S.	BD MAX GBS/BD MAX GBS	3/3
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	—
Open-channel capabilities/Start-up and preparation time	yes/ready 24 hours, 7 days	no/immediate
Model type of sample-handling system/Maximum sample load capacity	performs preanalytical and analytical functions/24	swab, tube, and cap/6
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	—/no/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	50–200 µL/specimen dependent/no	—/—/yes
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	uses standard 4 mL tube format/yes/—	5 mL/no/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	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/yes/swab, swab in transport medium, urine, plasma, CSF	no/no/—
Amplification reagents or methods supported	real-time PCR methods	—
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	yes/yes/in development	—
No. of different assays onboard at once/Programmed or calibrated at once	designed for multiple assays up to 24 samples/significant number	3/3
Tests per container set/Multiple reagent configurations supported	unitized reagent strips; one test per strip; 24 strips per kit/yes	24 or 120/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container	—	no
Reagent bar-code reading/Reagents bar coded	yes/yes	no/no
Monitors expiration date/Auto lot recognition or calibration	yes/yes	no/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	no/dry
Reagent reconstitution required/Chemical contamination control	no/No. system has a closed unit test format disposable	no/—
Onboard test auto inventory/Capable of inventory monitoring by bar code	yes/no	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/—	no/no
Closed-vial stability for amplification reagents/Extraction reagents	12 months/12 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Minimum/maximum reagent shelf-life guarantee	3 months/12–24 months	6 months/14 months
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/factory calibrated only
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/—/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	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	24 specimens per run in 2.5 hours/approximately 1 minute per sample	6/5 minutes
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/bio-waste
Windows technology/Mouse or touchscreen/Modular add-on capability	no/mouse/no	no/—/no
Service contracts available/Mean time between failures/To repair failures	5 and 7 days per week/180 days/<24 hours from field service visit	repair by replacement (normally ships same day of call to tech service)/—/single swap option within 24 hours
Turnaround time for problem solving by phone/e-mail/field service	immediate (<1 hour after hours)/same day (next day after hours)/next business day	immediate during business hours; one hour nonbusiness/immediately/as needed
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	—/next business day/24 hours, 7 days	10–12 reps/repair by replacement
Guaranteed response time/Modem servicing available	—/no	no/no
System can diagnose own malfunctions	yes	yes
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	weekly: 10 minutes/—	daily: <5 minutes/no
Preventive maintenance per year for sample extraction/amplification detection	1/1 (for total system)	—
Downtime for preventive maintenance/Spare parts on site	4 hours/no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	—	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/—	no/no
• Unique bar code per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions	no/no/no	no/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/no
• QC results transferred automatically to LIS/Data management capability	—	no/no
Interfaces operational in active user sites	—	no
Rules-based control subsystem/Process control via control subsystem	—	no/no
LIS operates simultaneously with assays running	—	no
Uses LOINC to transmit orders and results/Unidirectional interface capability	—	no/no
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	—	no/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	no/no/no
Can print, archive, transmit data	yes	no
Distinguishing features (supplied by company)	fully automated from sample analysis through extraction, amplification, and result detection for PCR-based molecular testing	simultaneous detection/differentiation of the three organisms that cause up to 90 percent of vaginal infections; one sample with three results; quick turnaround time (45 minutes for six samples or 18 results); simultaneously detects mixed infections caused by three organisms

**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 3 of 10	BD Diagnostics **Germán Núñez** german_nunez@bd.com 54 Loceton Circle, Sparks, MD 21152 410-316-3568 www/bd.com/ds	bioMérieux **Steve Shumoski** steve.shumoski@biomerieux.com 100 Rodolphe St., Durham, NC 27712 800-654-0331 www.biomerieux-usa.com
Name of instrument	**BD Viper System with XTR Technology**	**NucliSENS EasyMAG**
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	Netherlands and Australia/Italy/France
Instrument FDA cleared or approved/Platform	yes/analytical	yes/preanalytical
First year sold in U.S./Sold internationally/Installed	2009/2008/2009	2005/2005/2005
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	83 × 75 × 42/262/<65	20.9 × 39.4 × 25.6/3.7/between 67 and 75
Supplied with UPS/BTU	yes/2048 BTU per hour	no/341 BTU per hour maximum (less in standby)
Physical contamination control features	closed solid barrier amplification	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	$345,000/—	$79,500/sample extraction: $79,500
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/12,000 specimens per year	straight purchase, reagent rental, lease/1
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/208–240 VAC	yes/110V
Labor and parts warranties/Advanced operator training	1 year/yes	labor and parts: 1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	30 days/FOB (origin)/field service engineer/3 days	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/Retraining at company facility	on site and off site/1/3 days/yes	on site/1 or more/1.5 days/no
Test menu	Chlamydia, gonorrhea, HSV 1, HSV 2	universal set of IVD-labeled reagents for total nucleic acid extraction; on label for use with specific FDA-cleared assays
No. of tests for which analyzer has FDA-cleared applications/CE-mark	4/4	9/8
Tests available on instrument in U.S./Outside U.S.	Chlamydia, gonorrhea, HSV 1, HSV 2/Chlamydia, gonorrhea, HSV 1, HSV 2	xTAG RVP (Luminex); ProFLu+, Pro hMPV+, ProParaflu+, ProGastro Cd, ProFAST+, ProAdeno+ (Gen-Probe); influenza H1N1 (CDC); Simplexa flu A/B and RSV (Focus Dx) / HIV-1, HPV (bioMerieux)
Tests not available in U.S. but submitted to FDA/available in other countries only	—	—
Research-use-only assays/Tests in development	—	U.S.: HIV-1 RUO, HPV RUO, KPC RUO; outside U.S.: hMPV RUO/KPC RUO
Open-channel capabilities/Start-up and preparation time	no/10 minutes	yes/10–15 minutes
Model type of sample-handling system/Maximum sample load capacity	sample rack/96 samples	EasyMAG/24
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	2.5 mL/no/—	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	800 µL/—/yes	10 µL/same sample volume range, dependent on downstream application/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	2.5 mL/yes/no	—/yes/no
Sample bar-code languages/Sample types available in open mode	2 of 5, code 39, code 128, Codabar/vaginal and endocervical swabs, urethral swabs, urine, liquid-base cytology (SurePath, ThinPrep)	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)	yes/no/vaginal and endocervical swabs, urethral swabs, urine, and more	yes/yes/various types of samples
Amplification reagents or methods supported	strand displacement amplification (SDA)	— (extraction instrument)
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	yes/yes/yes	yes/yes/yes
No. of different assays onboard at once/Programmed or calibrated at once	4/4	24 positions each can extract for a distinct assay/—
Tests per container set/Multiple reagent configurations supported	CT: 1,152; GC: 1,152; HSV1 and 2: 96/no	main components: 384 extractions/universal reagent set
Reagent container placed directly on system/Onboard test auto inventory	yes/no	yes/yes
Determines reagent volume in container	no	yes
Reagent bar-code reading/Reagents bar coded	yes/yes	yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/no	yes/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/—	no/—
Onboard test auto inventory/Capable of inventory monitoring by bar code	no/no	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	yes/no
Same capabilities when third-party reagent used/Lot sequestering available	no/yes	no/no
Closed-vial stability for amplification reagents/Extraction reagents	18 months/18 months	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
Minimum/maximum reagent shelf-life guarantee	3 months/24 months	60 days/15–24 months, varies by individual reagent component
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	no/no
Assay calibrations required by end-user/Calibrants can be stored onboard	no/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	no/—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/yes	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/no	no/extraction module: 0 minutes/no
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	2/2/4/4	24 tests: downstream assay dependent/—/—/—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	3 hours, 5 minutes/10 minutes	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/768	no/—
Time between start and initial result/Instrument automatic shutdown	3 hours, 15 minutes/no	45 minutes/no
Startup programmable/Remote system monitoring/Waste req. for disposables	yes/yes/solid (disposable tips) and neutralized liquid waste	no/no/normal biohazardous waste
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/no	yes/mouse and touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	5 days, 8:00 AM–5 PM, 7 days, 24 hours/280 days/24 hours	7 days full service, preventive maintenance/extraction: 328 days/3.5 hours
Turnaround time for problem solving by phone/e-mail/field service	real time/—/24 hours	immediate (30 min. after hours)/<24 hours/within 2 hours after scheduling
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	>30/24 hours/24-7	32/within 24 hours/24–7 phone support; 12–7 on-site support
Guaranteed response time/Modem servicing available	—/yes	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	daily, weekly, and monthly: 15 minutes/no	daily: 5 minutes; weekly: 10 minutes; yearly: performed by FSE/no
Preventive maintenance per year for sample extraction/amplification detection	1/1	extraction: 2
Downtime for preventive maintenance/Spare parts on site	1 days/no	3 hours/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes to data retrieval
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	no/no
• Unique bar code per container/Multistop routing (1 tube to many workstations)	no/no	yes/no
• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions	no/no/no	yes/no/—
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/LIS-RS-232 serial ASTM 1381/1394	yes/XML file transfer
• QC results transferred automatically to LIS/Data management capability	yes/no	yes/yes
Interfaces operational in active user sites	yes	yes
Rules-based control subsystem/Process control via control subsystem	no/no	no/yes
LIS operates simultaneously with assays running	no	yes
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/Viewable PCR graphs	yes/yes/no	no/yes/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	reduced hands-on time requirement for set up and maintenance; fully automated specimen processing with high walkaway time; FDA cleared for two common liquid-base cytology specimens and fully automated for FDA-cleared HSV 1 and 2 assays	extreme flexibility: varies sample and elution volumes from sample to sample in the same run; entire extraction process in a single sample compartment, minimizing 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

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

Automated molecular platforms

Part 4 of 10	**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 2, 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 (2011 for GX 2)/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 1: 4 × 12 × 11.70; GeneXpert 2: 6.35 × 12 × 11.70; GeneXpert 4: 11 × 12 × 11.70; GeneXpert 16: 22.75 × 25.80 × 13.25;/2.625/—
Supplied with UPS/BTU	no/~340 BTU per hour	yes/—
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	$27,100–$156,250/—
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/Advanced operator training	1 year/yes	1 year/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/Retraining at company facility	on site and off site/1 or more/2 days/yes	on site/1/<1 day/yes
Test menu	basic NASBA reagents for laboratory-developed test plus specific company-developed assays	Xpert SA nasal complete, Xpert vanA, Xpert C. difficile, Xpert MRSA/SA SSTI, Xpert MRSA/SA BC, Xpert MRSA, Xpert GBS, Xpert EV, Xpert hemosIL FII and FV Xpert flu, Xpert Xpert C. difficile-Epi, Xpert vanA, Xpert hemosIL
No. of tests for which analyzer has FDA-cleared applications/CE-mark	2/6	12/12
Tests available on instrument in U.S./Outside U.S.	MRSA, enterovirus (bioMérieux) / HIV-1, HPV, enterovirus, HSV, RSV, MRSA	12/12
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/HIV-1, HPV, RSV, HSV	—
Research-use-only assays/Tests in development	U.S.: HIV-1 RUO, HPV RUO, KPC RUO; outside U.S.: hMPV RUO/KPC RUO	—
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 volume in container	no	yes
Reagent bar-code reading/Reagents bar coded	no/no	yes/yes
Monitors expiration date/Auto lot recognition or calibration	no/no	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	no/liquid and dry	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	yes/—	no/closed-cartridge technology
Onboard test auto inventory/Capable of 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	refrigerate (some with dry ice)/—	room temperature/room temperature
Minimum/maximum reagent shelf-life guarantee	30 days/24 months (basic kit); —/18 months (specific assay kits)	3 months/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 (not batch)/random access (not batch)
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 hours	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 minutes to 2 hours; 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 PM 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
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	yes
• Data retrieval or Internet connectivity	yes to data retrieval	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/no	yes/yes
• Priority processing	no	yes
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	yes/yes
• Unique bar code per container/Multistop routing (1 tube to many workstations)	yes/no	yes/yes
• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions	yes/no/—	yes/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 transferred automatically 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
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/Viewable PCR graphs	no/yes/yes	yes/yes/yes
Can print, archive, transmit data	yes	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; automated and integrated steps for PCR-based DNA testing: sample preparation, DNA amplification and detection; simplifies hands-on preparation; provides PCR test results from raw sample in ~1 hour; variety of configurations to meet broad range of 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 10	**Cepheid** **David Freestone** MarCommGroup@cepheid.com **904 Carribean Ave., Sunnyvale, CA 94079** **888-336-2743** www.cepheid.com	**GenMark Diagnostics** info@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	yes/—	yes/—
Physical contamination control features	closed-cartridge technology	closed-cartridge technology
List price/Price for sample extraction and amplification detection modules	$220,000–$399,000/—	—
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/Advanced operator training	1 year/yes	labor and parts: standard 1 year, additional years available/yes
Delivery time/Delivery charges/Installer/Time to install on site	2–4 weeks/FOB origin/company/<1 day	3 days/variable/GenMark Dx/<1 hour
Training location/No. of techs that can receive initial training/ Length of training/ Retraining at company facility	on site/1/1–3 days/yes	on site/up to 3/1–3 days/yes
Test menu	Xpert SA nasal complete, Xpert vanA, Xpert C. difficile, Xpert MRSA/SA SSTI, Xpert MRSA/SA BC, Xpert MRSA, Xpert GBS, Xpert EV, Xpert HemosIL FII and FV, Xpert flu, Xpert C. difficile-Epi, Xpert vanA, Xpert HemosIL	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	—/—	3/—
Tests available on instrument in U.S./Outside 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 dependent: 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	all common/—
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 volume in container	yes	no
Reagent bar-code reading/Reagents bar coded	yes/yes	yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	no/liquid
Reagent reconstitution required/Chemical contamination control	no/closed cartridge technology	no/—
Onboard test auto inventory/Capable of 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/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	frozen/ambient
Minimum/maximum reagent shelf-life guarantee	3 months/—	up to 60 days/12 months
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	no calibration required
Assay calibrations required by end-user/Calibrants can be stored onboard	no/—	no calibration required
Multiple calibrant lots stored for same assay/Required calibration frequency	—/2,000 tests or 1 year per module	no calibration required
Length of assay calibration/Typical calibration frequency	2,000 tests or 1 year per module/1 year	no calibration required
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/—	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	no/none/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	0/0/0/0	1/1/1/1
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	~130: random access (not batch)/<2 minutes per sample: random access	30 minutes, 24 samples/90 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
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/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 minutes–2 hours; limited on weekend/same as phone/—	M-F, 5 AM–8 PM PT: weekdays within 1 hour; weekends on call/same as phone/within 48 hours
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	5/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: <15 minutes/yes
Preventive maintenance per year for sample extraction/amplification detection	—	—
Downtime for preventive maintenance/Spare parts on site	1–2 hours/no	60 minutes/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	yes	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/yes
• Priority processing	yes	yes
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	no/no
• Unique bar code per container/Multistop routing (1 tube to many workstations)	yes/yes	yes/no
• Specimen scheduling/Routes test to workstation/Auto. 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 transferred automatically 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	—
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/Viewable PCR graphs	yes/yes/yes	no/yes/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	fully automated, robotic, real-time PCR system integrates all steps required for PCR-based DNA testing: sample preparation, DNA amplification and detection; cartridge handling; fully integrated; built-in smart technology: fluid master scheduler prioritizes test runs; reduces hands-on labor	complete benchtop system for multiplex molecular testing; touchscreen user interface; customizable reports; no routine maintenance or calibration

**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 6 of 10	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	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2004/2005/2004	2009/2010/2009
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
Supplied with UPS/BTU	yes/2,637	—
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/Advanced operator training	labor and parts: 1 year/yes	labor and parts: 5 years/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/Retraining at company facility	on and off site/2/4 day/yes	on site/up to 5/1 hour per tech/yes
Test menu	CT-GC, CT, GC, HPV, *Trichomonas*	adenovirus, coronavirus HKU1, coronavirus NL63, influenza A, influenza A H1, influenza A H1 2009, influenza A H3, influenza B, metapneumovirus, parainfluenza 1, parainfluenza 2, parainfluenza 3, parainfluenza 4, respiratory syncytial virus, rhinovirus-enterovirus.
No. of tests for which analyzer has FDA-cleared applications/CE-mark	3/5	—
Tests available on instrument in U.S./Outside 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	—/GI track panel, STD panel, sepsis panel
Open-channel capabilities/Start-up and preparation time	no/30 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	—/300 µL/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	15/15
Tests per container set/Multiple reagent configurations supported	250/yes	30/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container	yes	—
Reagent bar-code reading/Reagents bar coded	yes/yes	yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	no/dry
Reagent reconstitution required/Chemical contamination control	yes/onboard addition of sodium hypochlorite solution	yes/—
Onboard test auto inventory/Capable of 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
Minimum/maximum reagent shelf-life guarantee	up to 1.5 years after manufacture date	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	—
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	—
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/—
• Priority processing	no	—
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	—
• Unique bar code per container/Multistop routing (1 tube to many workstations)	yes/no	—
• Specimen scheduling/Routes test to workstation/Auto. 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 transferred automatically 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	—
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/Viewable PCR graphs	yes/yes/no	—/—/yes
Can print, archive, transmit data	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

Automated Molecular Platforms

Part 7 of 10	Life Technologies 5791 Van Allen Way Carlsbad, CA 92008 800-955-6288 www.lifetechnologies.com	Meridian Bioscience Rich Connors rich.connors@meridianbioscience.com 3471 River Hills Drive, Cincinnati, OH 45244 513-271-3700 www.meridianbioscience.com
Name of instrument	7500 Fast Dx Real-Time PCR Instrument	Illumipro-10
Country where designed/Manufactured/Reagents manufactured	U.S./Singapore/—	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2008/2010/2009	2010/2010/2010
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	19.29 × 13.99 × 17.72/1.8/—	8.3 × 11.5 × 3.7/.66/—
Supplied with UPS/BTU	no/maximum output: 3241.5 BTU/H (950 W)	no/—
Physical contamination control features	no	closed test devices
List price/Price for sample extraction and amplification detection modules	$65,900/amplification: $65,900	$8,300/amplification: $8,300
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/10 µL	straight purchase, reagent rental/100 µL
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/100–240 VAC at 50 or 60 Hz and 15A circuit	yes/100–240 V AC, 50/60 Hz
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	—/—/certified applied biosystems field service agent/—	1 business day/based on location/Meridian Bioscience (optional)/1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/based on customer requirements/—/yes	on site/no limit/2 hours/no
Test menu	measures nucleic acid signals from reverse-transcribed RNA, CDC's rRT-PCR flu panel (CDC 510(k) K080570	C.difficile
No. of tests for which analyzer has FDA-cleared applications/CE-mark	—	1/1
Tests available on instrument in U.S./Outside U.S.	—	1/1
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	1-group B strep/group B strep
Research-use-only assays/Tests in development	—	—/mycoplasma, group A strep
Open-channel capabilities/Start-up and preparation time	yes/<5 minutes	no/2 minutes hands-on time per sample, 12 minutes total
Model type of sample-handling system/Maximum sample load capacity	—/96	—/10 per Illumipro module
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	10 µL (reaction volume)/yes, reaction volumes 10 µL– 30 µL/10 µL– 30 µL	100 µL/no/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/100 µL/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	—/no/no	—/yes/no
Sample bar-code languages/Sample types available in open mode	—/nucleic acid signals from reverse-transcribed RNA	Codabar, codes 39, 93-93i, 128-IBT, UPC-EAN-ISBN, 128-UCC EAN 128, interleaved 2 of 5
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—	no/no/—
Amplification reagents or methods supported	nucleic acid signals from reverse-transcribed RNA	loop mediated isothermal amplification
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	—	heat treatment rather than conventional extraction
No. of different assays onboard at once/Programmed or calibrated at once	dependent on real-time PCR reaction plate setup/—	1 (more in development)/1 (more in development)
Tests per container set/Multiple reagent configurations supported	—	50/no
Reagent container placed directly on system/Onboard test auto inventory	no/no	no/no
Determines reagent volume in container	no	no
Reagent bar-code reading/Reagents bar coded	no/no	no/no
Monitors expiration date/Auto lot recognition or calibration	no/no	no/liquid and dry
Auto detection of adequate reagent or specimen/Reagents available	no/liquid	yes/closed test device system with internal control
Reagent reconstitution required/Chemical contamination control	yes/no	no/no
Onboard test auto inventory/Capable of inventory monitoring by bar code	no/no	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/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	—	18 months/—
Storage temp. requirement for amplification reagents/Extraction reagents	—	2°–27°C/—
Shipment temp. requirement for amplification reagents/Extraction reagents	—	RT/—
Minimum/maximum reagent shelf-life guarantee	—	2 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	—/no
Assay calibrations required by end-user/Calibrants can be stored onboard	yes/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/6 months or after service repair	no/none, monthly optic verification
Length of assay calibration/Typical calibration frequency	<1 day/6 months	2 minutes for optic verification/2 minutes
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/no	no/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	yes/5 minutes/no
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	end user and assay dependent	controls run with each kit lot or shipment
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	40 minutes to >2 hours/<1 hour	10 samples per batch per module/2 minutes per sample
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/200 batches per 1,000 samples
Time between start and initial result/Instrument automatic shutdown	assay run mode dependent/no	40 minutes/yes
Startup programmable/Remote system monitoring/Waste req. for disposables	no/no/none	no/no/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/no	no/—/yes
Service contracts available/Mean time between failures/To repair failures	phone, on-site, preventive maintenance, operational and performance qualification/amplification: 24 months/—	three-year extended warranty/—/24 hours
Turnaround time for problem solving by phone/e-mail/field service	—	10 minutes/10 minutes/no field service required
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	—	—/—/M-F, 8–6 EST
Guaranteed response time/Modem servicing available	—	yes, 24-hour replacement shipment/no
System can diagnose own malfunctions	no	yes
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: 1 minute; monthly: 2 minutes/no
Preventive maintenance per year for sample extraction/amplification detection	—/twice per year	—
Downtime for preventive maintenance/Spare parts on site	—/no	none/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	no	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/no	no/yes
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	yes/no
• Unique bar code per container/Multistop routing (1 tube to many workstations)	no/no	no/no
• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions	no/no/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—	no/—
• QC results transferred automatically to LIS/Data management capability	no/no	no/yes
Interfaces operational in active user sites	no	no
Rules-based control subsystem/Process control via control subsystem	no/no	no/no
LIS operates simultaneously with assays running	no	no
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/no	no/no
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	no/no	no/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/yes	no/no/no
Can print, archive, transmit data	yes	no
Distinguishing features (supplied by company)	96-well format eases plate setup, tube strips capped immediately after pipetting each sample; runs in <40 minutes; standard length real-time PCR assays without changing thermal cycling parameters; five-color variable excitation enables multiplex assays; security, auditing, and e-signatures allow full control over thermocycling protocols	loop-mediated isothermal amplification technology eliminates need for thermocycling equipment; no extensive purification or extraction required; results in under an hour

*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 8 of 10	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	—	—
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/Advanced operator training	—/no	—/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/ Retraining at company facility	on site/1 or more/varies/—	on site/1 or more/varies/—
Test menu	Verigene respiratory virus plus test	Verigene warfarin metabolism test; Verigene F5/F2/MTHFR test
No. of tests for which analyzer has FDA-cleared applications/CE-mark	1/3	4/—
Tests available on instrument in U.S./Outside U.S.	Verigene respiratory virus plus test/Verigene respiratory virus plus test, Verigene CYP 2C19 test, Verigene warfarin metabolism test	Verigene warfarin metabolism test; Verigene F5-F2-MTHFR test/—
Tests not available in U.S. but submitted to FDA/Available in other countries only	Verigene clopidogrel metabolism test, Verigene gram-positive blood culture test/—	—
Research-use-only assays/Tests in development	—/C. difficile, gram-negative blood culture test, respiratory virus expanded panel, enteric pathogens panel, cardiac troponin I	—
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 volume in container	—	—
Reagent bar-code reading/Reagents bar coded	yes/yes	yes/yes
Monitors expiration date/Auto lot recognition or calibration	—/no	—/no
Auto detection of adequate reagent or specimen/Reagents available	no/liquid	no/liquid
Reagent reconstitution required/Chemical contamination control	no/—	no/—
Onboard test auto inventory/Capable of 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
Minimum/maximum reagent shelf-life guarantee	—	—
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	2.0–2.5 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	—	—
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	—	—
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	—	—
• Priority processing	—	—
• Supports accession No. redundancy/Specimen carrier and level identification	—	—
• Unique bar code per container/Multistop routing (1 tube to many workstations)	—	—
• Specimen scheduling/Routes test to workstation/Auto. 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 transferred automatically 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	—	—
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/Viewable PCR graphs	—	—
Can print, archive, transmit data	—	—
Distinguishing features (supplied by company)	FDA-cleared tests; processor SP designated 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

Automated molecular platforms

Part 9 of 10	QIAGEN **Tracy Gambrell** tracy.gambrell@qiagen.com 19300 Germantown Rd., Germantown, MD 20874 240-686-7430 www.qiagen.com	Roche Diagnostics Corporation **Carol Hausrath** carol.hausrath@roche.com 9115 Hague Road, Indianapolis, IN 46250 317-521-1839 www.roche-diagnostics.us
Name of instrument	**QIAsymphony RGQ**	**cobas 4800 system**
Country where designed/Manufactured/Reagents manufactured	Switzerland/Switzerland/Germany	Switzerland/Switzerland/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	2011/2009/2011
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	107 × 150 × 50/27/—	cobas x 480: 35.6 × 65.55 × 30.5/19.6/<65; cobas z 480: 19.6 × 22.6 × 23.1/19.6/<65
Supplied with UPS/BTU	no/—	yes/1,300 W
Physical contamination control features	UV decontamination, built-in tip drop catchers	CO-RE Tip technology to reduce cross-contamination
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/cobas x 480: line voltage 115 VAC to 230, line frequency 50 or 60 Hz; cobas z 480 analyzer: 200–240 VAC, line frequency 50 or 60 Hz
Labor and parts warranties/Advanced operator training	labor and parts: 1 year/yes/yes	labor: 1 year; parts: covered by service contract/yes
Delivery time/Delivery charges/Installer/Time to install on site	2–4 weeks/destination/Qiagen Service Solutions/2 days	2–4 weeks/—/Roche service engineer/5 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/2–4/3 days/yes	on site and off site/2/4 days/yes
Test menu	open system	cobas HPV
No. of tests for which analyzer has FDA-cleared applications/CE-mark	0/8	1/2
Tests available on instrument in U.S./Outside U.S.	-/CMV, EBV, BKV, HSV, VZV, HIV, HCV, HBV	cobas HPV/cobas HPV, cobas CT-NG
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/CMV, EBV, BKV, HSV, VZV, HIV, HCV, HBV	cobas CT-NG, 4800 BRAF v600 Mutation/cobas CT-NG
Research-use-only assays/Tests in development	BKV/9	—/MRSA-MSSA, C. Diff, HSV
Open-channel capabilities/Start-up and preparation time	yes/30 minutes	yes/30 minutes
Model type of sample-handling system/Maximum sample load capacity	QIAsymphony SP/96 (continuous load)	cobas x 480 instrument/94 samples
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	1 mL/—/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	100 µL/200 µL/yes	1 mL/—/yes
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	1.5–15 mL/yes/no	13 mL (PreservCyt vial)/yes/no
Sample bar-code languages/Sample types available in open mode	codes 39 and 128, Codabar/plasma, serum, blood, respiratory, stool, urine, tissue, CSF, investigator, swabs, cytology, transport media	Codabar (without check sum), code 39 (without check sum), code 128, subset B and C (without check sum)/swab, urine, liquid-based cytology
Clot detection/Open extraction platform/Sample types (open extraction)	yes/—/same as sample types available in open mode	yes/no/—
Amplification reagents or methods supported	open system	real-time PCR
Extraction methods supported for: RNA extract./DNA extract./total nucleic acid	yes/yes/yes	TNAI
No. of different assays onboard at once/Programmed or calibrated at once	4/—	one/one
Tests per container set/Multiple reagent configurations supported	—/yes	24 or 96 tests/24 or 96 tests
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	no/no
Determines reagent volume in container	yes	yes
Reagent bar-code reading/Reagents bar coded	yes/yes	yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	yes/—	no/yes, AmpErase enzyme
Onboard test auto inventory/Capable of inventory monitoring by bar code	yes/yes	yes/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/yes	no/no
Closed-vial stability for amplification reagents/Extraction reagents	1 year/1year	12–18 months/12–18 months
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	2°–8°C/2°–25°C
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	cool packs/cool packs
Minimum/maximum reagent shelf-life guarantee	6 months/1 year	3 months/—
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	no/no
Assay calibrations required by end-user/Calibrants can be stored onboard	no/yes	no/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	yes/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	no/—/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	assay dependent	2 (one positive, one negative/—/—/2 (one positive, one negative)
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	4 hours/1 hour	~90 percent of run time/40 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/sufficient for 96 samples	yes/960
Time between start and initial result/Instrument automatic shutdown	6.5 hours for 96/no	assay dependent, 96 HPV results in <5 hours/no
Startup programmable/Remote system monitoring/Waste req. for disposables	no/yes/liquid, plastic	no/yes/plastic tips, liquid
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/yes	yes/mouse/no
Service contracts available/Mean time between failures/To repair failures	24 hours, 48 hour, and 5 days/—/—	M-F business hours or 7 days per week/sample: >100 days; amplification: >300 days/<4 hours
Turnaround time for problem solving by phone/e-mail/field service	24 hours, 6 days/24 hours, 6 days/based on contract type and working day	15 minutes/15 minutes/varies according to issue
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	56/contract dependent/ M-F 8–5 PM	250/24 hours/24-7
Guaranteed response time/Modem servicing available	yes (response time depends on contract purchased)/yes	yes, 24 hours/yes
System can diagnose own malfunctions	yes	yes
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: 30 minutes; weekly: 30 minutes; monthly: 30 minutes/no	daily: 2–7 minutes; weekly: <5 minutes/yes
Preventive maintenance per year for sample extraction/amplification detection	1/1 (both could increase depending on usage)	2/1
Downtime for preventive maintenance/Spare parts on site	half day for QIAsymphony; 2–3 hours for Rotor-Gene Q/no	4 hours/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	no	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/no	yes/no
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	no/yes
• Unique bar code per container/Multistop routing (1 tube to many workstations)	yes/no	yes/no
• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions	no/no/—	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	no/XML interface	yes/ASTM, HL7
• QC results transferred automatically to LIS/Data management capability	no/yes	no/yes
Interfaces operational in active user sites	yes	no
Rules-based control subsystem/Process control via control subsystem	no/no	no/no
LIS operates simultaneously with assays running	yes	yes
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	no/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	no/yes/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	flexible, convenient product solutions; open assay platform; limited hands-on, reliable processing from sample to result	design for dependable performance/results; CO-RE tip technology; total aspirate reduces cross-contamination risk; dispense monitoring for valid results, LightCycler technology; simplified workflow efficiency; minimal hands-on time, primary tube loading; AmpErase reduces cross-contamination risk

**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 10 of 10	**Roche Diagnostics Corporation** **Joni Zurawinski** joni.zurawinski@roche.com **9115 Hague Road, Indianapolis, IN 46250** **317-521-1839** www.roche-diagnostics.us	**Siemens Healthcare Diagnostics** **Kevin Culver** kevin.culver@siemens.com www.usa.siemens.com/diagnostics
Name of instrument	**COBAS AmpliPrep/COBAS TaqMan System**	**VERSANT 440 Molecular System**
Country where designed/Manufactured/Reagents manufactured	Switzerland/Switzerland/U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/pre-analytical and analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2007/2005/2007	2007/2005/2005
Dimensions in inches (H × W × D)/Footprint in sq. ft./Noise generated in dB	AmpliPrep: 37 × 65 × 29/13.1/55–60; TaqMan: 37 × 45 × 30/9.4/—; TaqMan 48: 20 × 18 × 30/3.8/—	24.2 × 59.7 × 31/—/78
Supplied with UPS/BTU	yes/AmpliPrep: 4904.6 per hour; TaqMan: 2049.1 per hour	yes/1,700 per hour
Physical contamination control features	closed tube processing with dedicated consumables and pipette tips, more	—
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/none	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical req.	yes/line voltage: 100–125 VAC; frequency: 50 or 60 Hz ± 2.0 Hz	yes/100 to 120 VAC plus 10%, 50/60 Hz, 600 VA maximum 1,700 BTU per hour
Labor and parts warranties/Advanced operator training	yes/yes	—/yes/yes
Delivery time/Delivery charges/Installer/Time to install on site	up to 30 days/none/Roche Diagnostics/1 day	—/—/Siemens/6–8 hours
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site and off site/2/4 days/yes	on site/—/yes
Test menu	HIV-1, HCV, HBV, HIV-1 v2.0, CMV viral load (RUO) and HIV-1 qual (RUO)	HIV, HCV, HBV viral load
No. of tests for which analyzer has FDA-cleared applications/CE-mark	4/5	2/—
Tests available on instrument in U.S./Outside U.S.	HIV-1 (IVD), HCV (IVD), HBV (IVD), HIV-1 v2.0 (IVD), CMV viral load (RUO) and HIV-1 Qual (RUO)/HIV-1 (CE-IVD), HCV (CE-IVD), HBV (CE-IVD), HIV-1 v2.0 (CE-IVD), CMV viral load (CE-IVD) and HIV qual (RUO)	HIV, HCV, HBV viral load/—
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—/—
Research-use-only assays/Tests in development	CMV viral load, HIV-1 qual/—	HVB/—
Open-channel capabilities/Start-up and preparation time	yes/20 minutes for 24 samples	no/—
Model type of sample-handling system/Maximum sample load capacity	COBAS AmpliPrep/72 samples	—/192
Min. specimen volume/Sample volume flexibility/Other sample volumes avail.	1.0 mL HIV, HCV; 650 µL HBV/yes (TNAI kit available)/—	—/no/—
Min. dead volume/Pediatric sample volume/Primary tube sampling	150 µL/—/no	—/—/no
Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D	—/yes/no	—/yes/—
Sample bar-code languages/Sample types available in open mode	code 2 of 5 interleaved; code 39 (3 of 9 interleaved), Codabar, code 128/ serum or plasma	—/—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/serum or plasma	yes/no/—
Amplification reagents or methods supported	real-time PCR	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	3/4	1/1
Tests per container set/Multiple reagent configurations supported	HIV and HCV: 48 HBV and CMV: 72/three protocols run simultaneously	96/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container	yes	yes
Reagent bar-code reading/Reagents bar coded	yes/yes	no/no
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/AmpErase enzyme	no/—
Onboard test auto inventory/Capable of 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	no/yes	no/yes
Closed-vial stability for amplification reagents/Extraction reagents	18 months/18 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	2°–8°C/2°–8°C	—
Shipment temp. requirement for amplification reagents/Extraction reagents	HIV v2.0 and HCV VL at 2°-8°C, all others are shipped ambient	—
Minimum/maximum reagent shelf-life guarantee	3 months/18 months	—
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	—/yes
Assay calibrations required by end-user/Calibrants can be stored onboard	no/— (reagents calibrated during manufacturing)	—/no
Multiple calibrant lots stored for same assay/Required calibration frequency	—	no/—
Length of assay calibration/Typical calibration frequency	until reagent lot expires	—/—
Onboard real-time QC/Supports multiple QC lot numbers per assay	—/yes	—/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/sample: <10 minutes; amplification: <3 minutes/yes	—/—/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	3/6/9/12	12/12/12/12
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	72 samples/47 minutes	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/72	no/—
Time between start and initial result/Instrument automatic shutdown	5 hours, 9 minutes/no	—
Startup programmable/Remote system monitoring/Waste req. for disposables	no/no/waste container onboard	—/no/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/mouse and touchscreen/no
Service contracts available/Mean time between failures/To repair failures	phone and on-site service/sample: 126 days; amplification: 337 days/2–3 hours	—
Turnaround time for problem solving by phone/e-mail/field service	3–4 hours/—3–4 hours	—
No. of U.S. field reps/Service engineer on-site response time/Hours & days avail.	175/24 hours/24-7-365	—/—/8 AM–8 PM
Guaranteed response time/Modem servicing available	yes (24 hours)/no	—/no
System can diagnose own malfunctions	no	no
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: 15 minutes; weekly: 30 minutes; yearly: 20 minutes/yes	—/yes
Preventive maintenance per year for sample extraction/amplification detection	AmpliPrep: 2; TaqMan: 2; TaqMan 48: 1	—
Downtime for preventive maintenance/Spare parts on site	2–4 hours/yes	6 hours/yes
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	yes	yes
• Data retrieval or Internet connectivity	yes	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/—
• Priority processing	no	—
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	—
• Unique bar code per container/Multistop routing (1 tube to many workstations)	yes/—	—
• Specimen scheduling/Routes test to workstation/Auto. 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	—/Ethernet	yes/—
• QC results transferred automatically 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	—/yes	—
LIS operates simultaneously with assays running	yes	yes
Uses LOINC to transmit orders and results/Unidirectional interface capability	—/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/Viewable PCR graphs	no/yes/yes	no/yes/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	parallel processing allows for multi-tasking of up to 3 protocols (HIV-1, HCV, HBV and/or TNAI) to be run simultaneously in a continuous load mode versus batch-processing systems; multi-layered contamination control ensures integrity of the primary tubes and results; fully automated, continuous-load IVD platform features sample in and results out capability	

**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.