AUTOMATED MOLECULAR PLATFORMS

Part 1 of 13 *See* **captodayonline.com/productguides** *for an interactive version of guide*	**Abbott Laboratories, Abbott Molecular Division** **Vladimir Nozinic** vladimir.nozinic@abbott.com **1350 East Touhy Ave., Suite 300W, Des Plaines, IL 60018** **224-361-7000** www.abbottmolecular.com	**AutoGenomics** **Min Ding** mding@autogenomics.com **2980 Scott St., Vista, CA 92081** **760-477-2248** www.autogenomics.com
Name of instrument	m2000 RealTime System composed of m2000sp and m2000rt modules	INFINITI High Throughput System
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	2014/—/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	m2000sp: 73.6 × 57.1 × 31.3/12.4/—; m2000rt: 19.3 × 13.4 × 17.8/1.7/<85 (1m)	—
Supplied with UPS/BTU	yes/m2000sp: 4,100 (1,200 Wh); m2000rt: 3,241.5 (950 Wh)	no/—
Physical contamination control features	instrument hood, unidirectional process flow design, optimized anti-drip pipetting and rinse steps, confined waste containers, aerosol barrier pipette tips, sealed PCR plate	discreet units
List price/Price for sample extraction and amplification detection modules	—	$227,447/—
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 requirements	yes/m2000sp: 100–240 VAC at 50–60 Hz; m2000rt: 100–240 VAC at 50–60 Hz	yes/—
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	as requested/—/Abbott Molecular/m2000sp: 24 hours; m2000rt: 8 hours	—
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/3 days/yes	on site/—/—/—
Test menu	HIV-1, HIV-1 qual, HCV, HCV Gt, HBV, CTNG, CT, CMV, HR HPV, mS9, EBV, VZV, parvo B19, MTB	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	5/13	6/23
Tests available on instrument in U.S./Outside U.S.	CTNG, HBV, HCV, HCV GT, HIV-1, HIV-1 qual (RUO), CMV (ASR), EBV (ASR)/CMV, CT, CTNG, EBV, HBV, HCV, HCV GT, HR HPV, HIV-1, HIV qual, VZV (LDA), parvo B19 (LDA), MTB, MTB RIF/INH resistance, KRAS, BRAF	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, HR HPV, mS9, parvo B19, VZV	—
Research-use-only assays/Tests in development	HIV-1 qual (U.S.)/RealTime CMV	factor II plus, factor V genotyping, MTHFR, many others/—
Open-channel capabilities/Start-up and preparation time	yes/20 minutes for intial setup (24 samples)	—/1 hour for 96 tests
Model type of sample-handling system/Maximum sample load capacity	m2000sp/96	—/96 each plate (up to 8 plates)
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	0.4 mL/yes (FDA protocols include 0.2, 0.4, 0.5, 0.6, and 1.0 mL)/0.05–4.0 mL	2 µL/yes/can be adjusted by user as needed
Minimum dead volume/Pediatric sample volume/Primary tube sampling	0.2 mL/0.2 mL/yes	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	11.5–16 mm diameter/yes/no	—/—/no
Sample barcode languages/Sample types available in open mode	Codabar codes 39, 128, and 93, UPCA, 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	no/yes/blood, buccal, saliva, tissue, liquid cytology media, culture
Amplification reagents or methods supported	real-time polymerase chain reaction	—
No. of different assays onboard at once/Programmed or calibrated at once	1 with standard operation, 2 with MaxCycle†, 12 with open mode/—	—/50+
Tests per container set/Multiple reagent configurations supported	24–192/nucleic acid: DNA, RNA, total nucleic acid; master mix: up to 4 reagents	—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	—
Determines reagent volume in container/Reagent barcode reading/ Reagents barcoded	yes/yes/yes	—
Monitors expiration date/Auto lot recognition or calibration	yes/yes	—
Auto detection of adequate reagent or specimen/Reagents available	yes/—	—/liquid
Reagent reconstitution required/Chemical contamination control	no/not required	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/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/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	—
Minimum/Maximum reagent shelf-life guarantee	3 months/18 months	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/calibration curves stored for up to 6 months	—
Length of assay calibration/Typical calibration frequency	valid for 6 months/6 months	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/sample extraction: none; amplification detection: 15 minutes/yes	no/—/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	2–3 controls dependent on assay regardless of batch size (1–96)	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	89 percent walkaway time (assay and run-size dependent)/30 minutes	—/1 hour
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/864	no/—
Time between start and initial result/Instrument automatic shutdown	for a CT-NG batch of 48 samples: 4 hours, 41 minutes/yes	—/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/plastic and liquid waste containers onboard	no/yes/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	no/mouse/no
Service contracts available/Mean time between failures/To repair failures	standard, extended, premium/m2000sp: 209 days; m2000rt: 745 days/m2000sp: 3.6 hours; m2000rt: 4.5 hours	standard, none/—/—
Turnaround time for problem solving by phone/Email/Field service	time to answer less <30 seconds/24-hour response/variable	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	65/based on contract/M–F 8 AM–5 PM, extended hours based on contract	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes/yes (when requested)/yes	—
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	—
Average maintenance time for lab personnel/Onboard maintenance records	daily: <10 minutes; weekly: 45 minutes; monthly: 15 minutes/yes	—
Preventive maintenance per year for sample extraction/Amplification detection	2/1	—
Downtime for preventive maintenance/Spare parts on site	4–12 hours/yes	—
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity/Priority processing	yes/no	yes/no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/yes
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	yes/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	—	no/—
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/—/—	yes/yes/—
• Sample storage and retrieval software supports CLSI standards	no	—
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—	yes/wireless or Ethernet
• QC results transferred automatically to LIS/Data-management capability	yes/yes	yes/no
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	—
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/yes	yes/—
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	yes/yes/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	automates and enables consolidation of multiple commercial NAAT tests, LDTs, and third-party assays; accomodates a diverse sample type flexibility while providing barcoded traceability of primary or laboratory tubes; run control and calibrator efficiency, multiple contamination control safeguards, and maxRatio (proprietary PCR curve analysis and validation of result algorithm); new mPlus features allow for runs of 1–96 samples with customized workflow and extended reagent use	scaleable high-throughput genetic testing, from 1 to 864 multiplexed microarrays tested in 8 hours; broad spectrum of 50+ assays; easy results interpretation removes need to set own cutoffs (all are done by the built-in algorithms)

**for calibration and controls*

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

†program enables co-cycling of HIV and HCV in same batch

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Name of instrument	INFINITI PLUS Analyzer	BD Viper LT
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/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2011/2011/2011	2014/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	26 × 44 × 24/7.3/—	46 × 51 × 36/12.75/65
Supplied with UPS/BTU	no/—	no/up to 3,000 (1,000 when idle)
Physical contamination control features	no aspiration tubing, disposable tips	closed system
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/1 µL	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/110 V and 220 V, 50–60 Hz	yes/100V–240 V, 50–60 Hz
Labor and parts warranties/Advanced operator training	1 year/no	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	1 week/—/AGI/1–2 days	2–3 weeks/origin/BD service engineer/<2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/1/2.5 days/yes	off site/2–4/2 days/no
Test menu	CYP2C19 (IVD), CYP450 2D6, warfarin assay (IVD), KRAS-BRAF, HPV genotyping, HPV-HR, STD-6 panel, bacterial vaginosis, Candida vaginitis, and more	chlamydia trachomatis, neisseria gonorrhoeae
No. of tests for which analyzer has FDA-cleared applications/CE mark	6/23	2/3
Tests available on instrument in U.S./Outside U.S.	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/—	U.S. CT-GC/Exus CT-GC, HPV
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	0/1
Research-use-only assays/Tests in development	factor II plus, factor V genotyping, MTHFR, many others/—	0/HPV for U.S. market
Open-channel capabilities/Start-up and preparation time	yes/20 minutes	no/<10 minutes
Model type of sample-handling system/Maximum sample load capacity	—/48	Hamilton pipettor/120
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	1 µL/no/—	2 mL/no/swabs: 2 mL; urine: 2–3 mL; liquid-based cytology: 2.2 mL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	<400 µL/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/—	4 mL tubes/—/—
Sample barcode languages/Sample types available in open mode	—	—/swabs, urine, liquid-based cytology
Clot detection/Open extraction platform/Sample types (open extraction)	—/yes/—	no/no/none
Amplification reagents or methods supported	—	SDA, PCR
No. of different assays onboard at once/Programmed or calibrated at once	4/50	2/2
Tests per container set/Multiple reagent configurations supported	48/—	2/no
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/Reagent barcode reading/ Reagents barcoded	yes/yes/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 and dry
Reagent reconstitution required/Chemical contamination control	no/—	no/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/yes
Same capabilities when third-party reagent used/Lot sequestering available	no/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	—	—
Storage temp. requirement for amplification reagents/Extraction reagents	-20°C/—	room temperature/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	-20°C/—	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	12 months/24 months	6 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	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	—	—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no	no/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/—	yes/—/—
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	—	1/2/3/4
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	5 hours/15 minutes	30 samples/<5 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/504	yes/480
Time between start and initial result/Instrument automatic shutdown	3 hours/no	~3 hours/—
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/built-in waste tray, solid state waste products	—/yes/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	annual/—/—	multiyear/—/—
Turnaround time for problem solving by phone/Email/Field service	24 hours/24 hours/48 hours	<1 day/<2 days/variable
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	—/24–48 hours/6 AM–6 PM (PDT)	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes (within 24 hours)/no/yes	—/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: 5 min.; weekly: 10 min.; monthly: 20 min.; yearly: 45 min./no	—
Preventive maintenance per year for sample extraction/Amplification detection	—/1	—
Downtime for preventive maintenance/Spare parts on site	1 day/no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity/Priority processing	yes/yes	yes/no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/no
• Supports accession No. redundancy/Specimen carrier and level identification	—	yes/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/no/—	no/no/no
• 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/—	—
• QC results transferred automatically 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	—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/no	—
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	—
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—/yes/no	—/—/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	load-and-go automation increases lab productivity by freeing up personnel; built-in replicate testing on each BioFilmChip microarray ensures assay result integrity; more than 50 applications available on same instrument	automated, integrated molecular testing, tabletop analyzer, BD SurePath and Hologic Thin Prep compatible

**for calibration and controls*

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Name of instrument	BD MAX System	BD Affirm VPIII Microprocessor
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S., 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 square feet/Noise generated in dB	28.5 × 37 × 29.7/5/64 at 48 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 or tubes	—
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/specimen dependent (as low as 10–15 µL)	straight purchase, reagent rental, lease/72 tests per month
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC, ~50–60 Hz, 10 A	no/120 V
Labor and parts warranties/Advanced operator training	1 year (≤3 year contracts optional)/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	90 day, or less from contract/—/BD/1.5 days	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	GBS, MRSA XT, C. difficile, StaphSR, enteric bacterial panel, enteric parasite panel; open system general-purpose reagents for user-defined protocols: DNA and RNA extraction kits and generic DNA master mix with and without internal process control	Candida species (six different), Gardnerella vaginalis, trichomonas vaginalis
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	3/3
Tests available on instrument in U.S./Outside U.S.	GBS, MRSA, C. difficile, staph SR, enteric bacterial, enteric parasite, CRE RUO/—	3/3
Tests not available in U.S. but submitted to FDA/Available in other countries only	vaginitis, CT-GC/—	—
Research-use-only assays/Tests in development	CRE/—	—
Open-channel capabilities/Start-up and preparation time	yes/less than 1 minute per specimen	no/immediate
Model type of sample-handling system/Maximum sample load capacity	fully automated, integrated extraction and amplification detection/24	swab, tube, and cap/6
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	specimen dependent (as low as 10–15 µL)/yes/volumes range up to 750 µL	—/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	50–200 µL/specimen dependent/no	—/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	uses standard 4-mL tube format/yes/—	5 mL/no/no
Sample barcode languages/Sample types available in open mode	Codabar codes 39, Interleaved 2 of 5, EAN, UCC code 128/2-D capability	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/yes/swab, swab in transport medium, urine, plasma, CSF, stool	no/no/—
Amplification reagents or methods supported	real-time PCR for most probe types, melt analysis	—
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/Reagent barcode reading/ Reagents barcoded	yes/yes/yes	no/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 barcode	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 (with user-supplied primers and probes in open-system format)/on terms	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	user validates and defines external run control protocol	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	1–12 samples in <1.5 hours; 24 samples in 2 hours/~1 min. per sample	30 minutes/3 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	1–12 samples in <1.5 hours; 24 samples in 2 hours/automatic move to standby	45 minutes/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/biohazardous waste	no/no/biohazardous 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/Email/Field service	<1 hour after hours/same day (next day after hours)/next business day	immediate during business hours; 1 hour nonbusiness/immediately/as needed
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	—/next business day/24 hours, 7 days	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	—/no/yes	no/no/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 barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic 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	yes	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 immediately transmitted to LIS/Interface available 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)	next-generation platform for molecular testing, automating cell lysis, nucleic acid extraction, PCR setup, amplification, and detection	simultaneous detection/differentiation of the three organisms that cause up to 90 percent of vaginal infections in 1 swab; quick turnaround time (45 minutes for 6 samples or 18 results); simultaneously detects mixed infections caused by 3 organisms; objective, visual results

**for calibration and controls*

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

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Part 4 of 13 *See* **captodayonline.com/productguides** *for an interactive version of guide*	**BD Diagnostic Systems** **William Hardy** william_hardy@bd.com **7 Loveton Circle, Sparks, MD 21152** **410-316-4237** www.moleculardiagnostics.bd.com	**BioFire Diagnostics** **Wade Stevenson** wade.stevenson@biofiredx.com **390 Wakara Way, Salt Lake City, UT 84108** **801-736-6354** www.biofiredx.com
Name of instrument	BD Viper System with XTR Technology	FilmArray
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/analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2009/2008/2009	2009/2010/2009
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	83 × 75 × 42/262/<65	6.5 × 10 × 15.5/1.08/74
Supplied with UPS/BTU	yes/2,048 per hour	no/no
Physical contamination control features	closed solid barrier amplification	closed system
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/12,000 specimens per year	straight purchase, reagent rental/none
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/208–240 VAC	yes/10 A
Labor and parts warranties/Advanced operator training	1 year/yes	yes/no
Delivery time/Delivery charges/Installer/Time to install on site	30 days/FOB (origin)/field service engineer/3 days	—/origin/BioFire Diagnostics/1 hour
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/1/3 days/yes	on site/up to 5/1 hour per tech/yes
Test menu	chlamydia, gonorrhea, HSV-1, HSV-2, trichomonas	respiratory panel, blood culture identification panel, gastrointestinal panel
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	3/3
Tests available on instrument in U.S./Outside U.S.	5/5	3/3
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	1/0
Research-use-only assays/Tests in development	—	meningitis-encephalitis panel, lower respiratory tract panel/meningitis-encephalitis panel, lower respiratory tract panel
Open-channel capabilities/Start-up and preparation time	no/10 minutes	no/2 minutes
Model type of sample-handling system/Maximum sample load capacity	sample rack/96	—/8
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	2.5 mL/no/—	respiratory panel: 300 µL; blood culture identification panel: 200 µL; gastrointestinal panel: 200 µL/—/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	800 µL/—/yes	—/respiratory panel: 300 µL; blood culture identification panel: 200 µL; gastrointestinal panel: 200 µL/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	2.5 mL/yes/no	—/yes/—
Sample barcode languages/Sample types available in open mode	Interleaved 2 of 5, Codabar codes 39 and 128/vaginal and endocervical swabs, urethral swabs, urine, liquid-base cytology (SurePath, ThinPrep)	—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/vaginal and endocervical swabs, urethral swabs, urine, and more	—/no/—
Amplification reagents or methods supported	strand displacement amplification	PCR
No. of different assays onboard at once/Programmed or calibrated at once	5/5	respiratory panel: 20; blood culture ID panel: 27; gastrointestinal panel: 22/ respiratory panel: 20; blood culture ID panel: 27; gastrointestinal panel: 22
Tests per container set/Multiple reagent configurations supported	CT: 1,152; GC: 1,152; HSV-1 and HSV-2: 96/no	30/no
Reagent container placed directly on system/Onboard test auto inventory	yes/no	yes/no
Determines reagent volume in container/Reagent barcode reading/ Reagents barcoded	no/yes/yes	no/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/no	no/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	no/dry
Reagent reconstitution required/Chemical contamination control	no/—	yes/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	no/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	18 months/18 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	3 months/24 months	2 months/12 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	yes/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/—	—
Length of assay calibration/Typical calibration frequency	—	—
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/—/no	—/1 minute/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	2/2/4/4	—
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	~1 hour/—
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/solid (disposable tips) and neutralized liquid waste	—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/no	yes/mouse/no
Service contracts available/Mean time between failures/To repair failures	5 days, 8 AM–5 PM and 7 days, 24 hours/280 days/24 hours	yearly/—/—
Turnaround time for problem solving by phone/Email/Field service	real time/—/24 hours	within 24 hours/within 24 hours/—
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	>30/24 hours/24 hours, 7 days	—/—/24 hours, 7 days
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	—/yes/yes	24 hours/—/—
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	—
Average maintenance time for lab personnel/Onboard maintenance records	daily, weekly, and monthly: 15 minutes/no	—
Preventive maintenance per year for sample extraction/Amplification detection	1/1	—
Downtime for preventive maintenance/Spare parts on site	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	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	—
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	yes/—
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	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/LIS-RS-232 serial ASTM 1381-1394	no/XML ASTM 1394-97 via shared folder protocol or FTP over network
• 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	yes/yes
LIS operates simultaneously with assays running	no	yes
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/yes	yes/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/no	—/—/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	reduced hands-on time for setup and maintenance; fully automated specimen processing with high walkaway time; FDA cleared for 2 common liquid-base cytology specimens for CT-GC and fully automated for FDA-cleared HSV-1 and HSV-2 assays	user-friendly multiplex PCR; fully automated; sample to result in about 1 hour; 2 minutes hands-on time; simultaneous detection of 24 pathogens and 3 antibiotic-resistant genes for blood culture identification panel, 17 viral and 3 bacterial pathogens for respiratory panel, and 13 bacterial, 4 parasites, and 5 viral for gastrointestinal panel

**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 5 of 13 *See* **captodayonline.com/productguides** *for an interactive version of guide*	**bioMérieux** **Gregory Porter** gregory.porter@biomerieux.com **100 Rodolphe St., Durham, NC 27712** **919-479-3630** www.biomerieux-usa.com	**bioMérieux** **Gregory Porter** gregory.porter@biomerieux.com **100 Rodolphe St., Durham, NC 27712** **919-479-3630** www.biomerieux-usa.com
Name of instrument	NucliSENS EasyMAG	easySTREAM
Country where designed/Manufactured/Reagents manufactured	Netherlands, Australia/Italy/France	Germany, France/Germany/—
Instrument FDA cleared or approved/Platform	yes/preanalytical	—/preanalytical
First year sold in U.S./Sold internationally/Installed	2005/2005/2005	2015/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	20.9 × 39.4 × 25.6/3.7/between 67 and 75	18.5 × 23.6 × 20.3/3.32/42.5
Supplied with UPS/BTU	no/341 per hour maximum (less in standby)	yes/204
Physical contamination control features	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	$79,500/sample extraction: $79,500	$55,000/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/1	—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/110 V	yes/100–250 VAC, 50–60 Hz, 60 W
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	30 days/destination and origin, price varies/field service engineer/5 hours	1 month/$1,000/bioMérieux service engineer and FAS/1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1 or more/1.5 days/no	on site/2/0.5 days/no
Test menu	universal set of IVD-labeled reagents for total nucleic acid extraction on label for use with specific FDA-cleared tests from other companies	Class I exempt
No. of tests for which analyzer has FDA-cleared applications/CE mark	18/19	—
Tests available on instrument in U.S./Outside U.S.	eSensor RVP (GenMark); xTAG GPP and RVP, MultiCode-RTx HSV (Luminex); Prodesse assays (Gen-Probe/Hologic); Influenza RT-PCR Panel (CDC); Molecular Influenza A+B and hMPV (Quidel); MRSA/SA ELITe MGB (ELITech); Adenovirus R-gene (bioMérieux)/MERS coronavirus rRT-PCR assay (CDC); simplexa flu A-B and RSV (Focus)	—
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—
Research-use-only assays/Tests in development	HPV, KPC (U.S.)/—	—
Open-channel capabilities/Start-up and preparation time	yes/10–15 minutes	yes/5 minutes
Model type of sample-handling system/Maximum sample load capacity	EasyMAG/24	—/112
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	10 µL/yes (intra-run/batch range of 10–1,000 µL)/up to 1,000 µL	25 µL/yes, liquid level detection allows mixture of input volumes/5–1,000 µL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	10 µL/same sample volume range, dependent on downstream application/no	10 µL/5 µL/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/no	easyMAG vessels (cartridges: 0.5, 1, 1.5, 2.0)/yes/—
Sample barcode languages/Sample types available in open mode	code 128 for reagents and disposables, EAN-8, EAN-13, UPC-A, UPC-E, Interleaved 2 of 5, standard code 39, others/various	code 128 for reagents and disposables, EAN-8, EAN-13, UPC-A, UPC-E, Interleaved 2 of 5, standard code 39/various
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/various	no/no/—
Amplification reagents or methods supported	extraction instrument	liquid handling instrument
No. of different assays onboard at once/Programmed or calibrated at once	24 positions each can extract for a distinct assay/—	48, assuming 1 control/>12
Tests per container set/Multiple reagent configurations supported	main components: 384 extractions/universal reagent set	96/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	no/no
Determines reagent volume in container/Reagent barcode reading/ Reagents barcoded	yes/yes/yes	—
Monitors expiration date/Auto lot recognition or calibration	yes/no	—
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	—
Reagent reconstitution required/Chemical contamination control	no/—	—
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	—
System is open to homebrew/General-purpose reagents allowed	yes/no	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	no/no	yes/—
Closed-vial stability for amplification reagents/Extraction reagents	—/up to 30 days onboard the system	—
Storage temp. requirement for amplification reagents/Extraction reagents	—/mostly room temperature with 2 components at 2°–8°C	—
Shipment temp. requirement for amplification reagents/Extraction reagents	—/RTI	—
Minimum/Maximum reagent shelf-life guarantee	60 days/15–24 months	—
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	—
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	—
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/no	—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/no	yes/—/—
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	24 tests: downstream assay dependent/—/—/—	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	—	1/5 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	yes/192
Time between start and initial result/Instrument automatic shutdown	45 minutes/no	—
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/normal biohazardous waste	—/—/yes
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/yes	yes/mouse/yes
Service contracts available/Mean time between failures/To repair failures	7 days full service, preventive maintenance/extraction: 328 days/3.5 hours	7 days full service, preventive maintenance and amplification: 1,322 days; 3.5 hours, immediate (30 minutes after hours); <24 hours, within 2 hours after scheduling/—/—
Turnaround time for problem solving by phone/Email/Field service	immediate (30 min. after hours)/<24 hours/within 2 hours after scheduling	yes/yes/yes
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	32/within 24 hours/24–7 phone support, 12–7 PM on-site support	2/<24 hours within 2 hours after scheduling/yes
Guaranteed response time/Modem servicing available	yes/no	—/yes
System diagnose own malfunctions	no	no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/—/—
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 minutes; weekly: 10 minutes; yearly: performed by FSE/no	daily: 5 minutes; weekly: 20 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	2/—	—
Downtime for preventive maintenance/Spare parts on site	3 hours/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	data retrieval	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/no	no/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/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	yes/XML file transfer, WIN 7 environment	yes/XML file transfer
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/yes
Interfaces operational in active user sites	yes	no
Rules-based control subsystem/Process control via control subsystem	no/yes	no/yes
LIS operates simultaneously with assays running	yes	—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/no
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	—
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/no	—/yes/—
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	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	automated PCR setup and transfer of easyMAG eluates direct from cartridges; open system supports frequently used thermocycler consumables from ABI, Roche, BioRad, and Qiagen; uses software that thinks like you do, e.g. combines samples plus master mixes to create reactions

**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 13 *See* **captodayonline.com/productguides** *for an interactive version of guide**	**Cepheid** **Glen Tinevez** MarCommGroup@cepheid.com **904 Caribbean Ave., Sunnyvale, CA 94089** **888-336-2743** www.cepheid.com	**Cepheid** **Glen Tinevez** MarCommGroup@cepheid.com **904 Caribbean Ave., Sunnyvale, CA 94089** **888-336-2743** www.cepheid.com
Name of instrument	GeneXpert 1, GeneXpert 2, GeneXpert 4, GeneXpert 16	GeneXpert Infinity-48s, Infinity-80
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/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2006 (2011 for GX 2)/2006/2006	2012/2012/2012
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	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/—	79.1 × 105.2 × 34.6 (48); 78.5 × 85 × 34.6 (48s); 78.5 × 108 × 35 (80)/25.25/—
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	$24,900–$174,400/—	$199,000–$530,000/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–120 VAC, 50–60 Hz	yes/100–120 VAC, 50–60 Hz (48); 200–240 VAC, 50–60 Hz (48s, 80)
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	less than 1 week/FOB origin/company/<1 day	2–4 weeks/FOB origin/company/<1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1 or more/<1 day/no	on site/1 or more/1–3 days/no
Test menu	Xpert MTB/RIF, Xpert CT/NG, Xpert SA nasal complete, Xpert vanA, Xpert C. difficile, Xpert C. difficile-Epi, Xpert MRSA/SA SSTI, Xpert MRSA/SA BC, Xpert MRSA, Xpert GBS, Xpert EV, Xpert FII & FV, Xpert Flu, Xpert Flu/RSV XC, Xpert GBS LB, Xpert Norovirus, Xpert Ebola (emergency use authorization)	Xpert MTB/RIF, Xpert CT/NG, Xpert SA nasal complete, Xpert vanA, Xpert C. difficile, Xpert C. difficile-Epi, Xpert MRSA/SA SSTI, Xpert MRSA/SA BC, Xpert MRSA, Xpert GBS, Xpert EV, Xpert FII & FV, Xpert Flu, Xpert Flu/RSV XC, Xpert GBS LB, Xpert Norovirus, Xpert Ebola (emergency use authorization)
No. of tests for which analyzer has FDA-cleared applications/CE mark	17/23	17/23
Tests available on instrument in U.S./Outside U.S.	—	—
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/carba-R, HCV viral load, HIV-1 qual, HIV-1 viral load, trichomonas vaginalis, HPV, BCR-ABL monitor	—/carba-R, HCV viral load, HIV-1 qual, HIV-1 viral load, trichomonas vaginalis, HPV, BCR-ABL monitor
Research-use-only assays/Tests in development	—	—
Open-channel capabilities/Start-up and preparation time	yes/<1 minute	yes/<1 minute
Model type of sample-handling system/Maximum sample load capacity	cartridge based/up to 16, based on number of installed modules	cartridge based/>2,000 per day
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	—/yes (sample-type dependent: whole blood, swab, sputum fluids, others)/—	—/yes (sample-type dependent: whole blood, swab, sputum fluids, others)/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/yes	—/yes/yes
Sample barcode languages/Sample types available in open mode	all common/no restrictions	all common/no restrictions
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/no restrictions	no/no/no restrictions
Amplification reagents or methods supported	—	—
No. of different assays onboard at once/Programmed or calibrated at once	full menu/full menu	full menu/full menu
Tests per container set/Multiple reagent configurations supported	single-use cartridges/reagents contained in cartridge	single-use cartridges/reagents contained in cartridge
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container	yes	yes
Reagent barcode reading/Reagents barcoded	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	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/closed-cartridge technology	no/closed-cartridge technology
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	yes/yes
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/no
Closed-vial stability for amplification reagents/Extraction reagents	up to 2 years/up to 2 years	up to 2 years/up to 2 years
Storage temp. requirement for amplification reagents/Extraction reagents	amplification and extraction: room temperature (2°–8°C depending on test)	amplification and extraction: room temperature (2°–8°C depending on test)
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	3 months/varies	3 months/—
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	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	—/2,000 tests per module	—/2,000 tests or 1 year per module
Length of assay calibration/Typical calibration frequency	2,000 tests or 1 year/1 year	2,000 tests or 1 year per module/1 year
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	—	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	—	119 (48s); 183 (80): random access (not batch)/<2 min. per sample: random access
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	35 minutes–2 hours, depending on test/no	35 minutes–2 hours, depending on test/no
Startup programmable/Remote system monitoring/Waste required for disposables	—/—/disposable cartridges	yes/no/disposable cartridges
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/mouse and touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	full service, labor and parts/—/24–48 hours	5 days (standard) or 6 days (preferred) labor and parts/—/24–48 hours
Turnaround time for problem solving by phone/Email/Field service	yes/yes/yes	yes/yes/yes
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	14/within 24 hours/24–7 or M–F, 5 AM–5 PM	14/within 24 hours/8 AM–7 PM, M–F; Saturday with preferred
Guaranteed response time/Modem servicing available	yes (M–F, 5 AM–5 PM)/no	yes (M–F, 5 AM–5 PM)/no
System diagnose own malfunctions	no	no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 minutes; weekly: 5 minutes; monthly: based on system configuration; yearly: up to 30 minutes (based on number of modules)/yes	daily: 5 minutes; weekly: 10 minutes; monthly: based on system configuration; yearly: 30–60 minutes (based on number of modules)/yes
Preventive maintenance per year for sample extraction/Amplification detection	—	—
Downtime for preventive maintenance/Spare parts on site	6–8 hours per year/no	6–8 hours per year/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	yes	yes
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/yes
• Priority processing	yes	yes
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	yes/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/yes	yes/yes
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/yes/yes	yes/yes/—
• 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	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	yes/yes	yes/yes
LIS operates simultaneously with assays running	yes	yes
Uses LOINC to transmit orders and results/Unidirectional interface capability	yes/yes	yes/yes
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/yes	yes/yes
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	yes/yes/yes
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	fully integrated real-time PCR system; automated and integrated steps for PCR-based DNA testing: sample preparation and 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	fully automated, robotic, real-time PCR system integrates all steps required for PCR-based DNA testing: sample preparation and DNA amplification and detection; cartridge handling; fully integrated; built-in smart technology: fluid master scheduler prioritizes test runs; reduces hands-on labor

**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 13 *See* **captodayonline.com/productguides** *for an interactive version of guide**	**Dako, an Agilent Technologies Co.** **Nicole Wootton** nicole.wootton@dako.com **6392 Via Real, Carpinteria, CA 93013** **800-400-3256** www.dako.com	**ELITech** **370 West 1700 South** **Logan, UT 84321** **800-453-2725, option 2** www.elitechgroup.com/north-america/home
Name of instrument	Dako Omnis	ELITe InGenius
Country where designed/Manufactured/Reagents manufactured	Switzerland/Austria/Denmark, U.S.	U.S., Italy, Japan/U.S., Italy, Japan/U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical	no/combined integrated platform
First year sold in U.S./Sold internationally/Installed	2013/2013/2013	2015/2015/2015
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	60.4 × 57.1 × 31.2/—/63.7 dBA	33 × 39 × 29/8.1/55 dB
Supplied with UPS/BTU	yes/1,200 V	yes/—
Physical contamination control features	yes	unitized, single-use reagents cassettes, aerosol barrier pipette tips, programmable UV decontamination cycle
List price/Price for sample extraction and amplification detection modules	$195,000/—	$130,000 (single, combined extraction and real-time PCR system)/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/test mix dependent	straight purchase, reagent rental, lease/20–200 µL patient specimen
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/120, 220–240 VAC	yes/120 VAC, 50–60 Hz
Labor and parts warranties/Advanced operator training	1 year/no	1 year; 3–5 years with contract/yes
Delivery time/Delivery charges/Installer/Time to install on site	1 week/$5,000/Dako field engineer/3 days	45 days/origin/ELITech MDx/~1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/4 days off site/yes	on site/1–3/1 day for operational training/yes
Test menu	FISH probes	infectious diseases, transplant (SOT/HSCT), STD/STI, HAI, respiratory, meningitis, oncology, human genetics
No. of tests for which analyzer has FDA-cleared applications/CE mark	none/1	—/>8 (CMV, BKV, HSV 1/2, VZV, HAIs, meningitis)
Tests available on instrument in U.S./Outside U.S.	yes/yes	>20 (infectious diseases, transplant [SOT/HSCT], HAI, respiratory, meningitis)/>20 (infectious diseases, transplant [SOT/HSCT], STD/STI, HAI, respiratory, meningitis oncology, human genetics)
Tests not available in U.S. but submitted to FDA/Available in other countries only	yes/yes	—/MRSA mecC, BCR-ABL, Factor II/V, HHV-7, HHV-8, aspergillus, rubella, MtB, C. difficile
Research-use-only assays/Tests in development	yes (user's choice)/—	>12/>6
Open-channel capabilities/Start-up and preparation time	yes/1–10 minutes	yes/~1 minute per sample
Model type of sample-handling system/Maximum sample load capacity	automated prepared on glass slide/15 ISH	fully automated and integrated specimen DNA-RNA extraction and real-time PCR; operate in extraction only, real-time PCR only, and extraction-PCR combined/1–12
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	1 sample per glass slide/yes (sample can be small or large, instrument will stain slide, sample size can vary)/—	200 µL/yes (200–1,000 µL)/1,000 µL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/adult or pediatric samples/no	10 µL/20–200 µL patient specimen/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/yes	6.0 mL, 13 x 100 mm; 4.0 mL, 13 x 75 mm; 3.0 mL, 13 x 75 mm/yes/yes
Sample barcode languages/Sample types available in open mode	—	>12/whole blood, plasma, serum, CSF, urine, stool, sputum, BAL, nasal, rectal, wound, and urogenital swabs
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—	yes/yes/whole blood, plasma, serum, CSF, urine, stool, nasal, and urogenital swabs
Amplification reagents or methods supported	FISH	MGB, TaqMan, multiplex, qualitative and quantitative results with programmable melt-curve analysis on DNA or RNA targets (most real-time PCR probes and chemistries)
No. of different assays onboard at once/Programmed or calibrated at once	15/15	≤24/>60
Tests per container set/Multiple reagent configurations supported	21 tests per vial/yes	48/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container	yes	yes
Reagent barcode reading/Reagents barcoded	yes/yes	yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/no	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	yes/yes, washes probe between	no/yes
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	yes/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes	yes/no
Closed-vial stability for amplification reagents/Extraction reagents	—	18 months to >2 years/>1 year
Storage temperature requirement for amplification reagents/Extraction reagents	—	–20°C/room temperature
Shipment temperature requirement for amplification reagents/Extraction reagents	—	frozen/room temperature
Minimum/Maximum reagent shelf-life guarantee	2 years/3 years	>15–18 months minimum from ship date/>2 years
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	yes/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	yes/yes
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	yes/6 months
Length of assay calibration/Typical calibration frequency	—	2 hours/2–3 times per year
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no	yes/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/yes	no/<2 minutes/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	—	operator defined and validated
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	yes (slide based on 15 samples)/1–10 minutes	yes (batch processing for 12 samples)/—
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	yes/200
Time between start and initial result/Instrument automatic shutdown	3:45–4 hours/no	2 hours/no
Startup programmable/Remote system monitoring/Waste required for disposables	yes/no/no	yes/yes/self-contained unitized reagent cassettes, on-board solid waste storage
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/no	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	M–F 8 AM–5 PM/—/5.1 hours	1–5 years/—/—
Turnaround time for problem solving by phone/Email/Field service	yes/yes/problem dependent	<3 hours, same day (after hours)/<3 hours, same day (after hours)/24 hours response
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	29/1–2 days/M–F 7 AM–5 PM	—/next day/24 hours, 7 days
Guaranteed response time/Modem servicing available	no/yes	yes/yes
System diagnose own malfunctions	yes	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: 10 minutes; bi-weekly: 25 minutes; monthly: 56 minutes; yearly: dependent on amount of ISH run yearly/yes	daily: empty waste container; weekly: <10 minutes; monthly: <5 minutes
Preventive maintenance per year for sample extraction/Amplification detection	—	1/1 for combined platform
Downtime for preventive maintenance/Spare parts on site	20 hours annually/no	1 day/—
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	no/no	yes/no
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	yes/—
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	—/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/yes/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/—	—
• QC results transferred automatically to LIS/Data-management capability	no/yes	no/no
Interfaces operational in active user sites	yes	no
Rules-based control subsystem/Process control via control subsystem	yes/yes	no/no
LIS operates simultaneously with assays running	yes	no
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	no/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/no	yes/yes/yes
Can print, archive, transmit data	yes	no
Distinguishing features (supplied by company)	automated ISH platform with results in less than 4 hours; high-throughput combined with the IQFISH Fast Hybridization Buffer enables an IHC-like turnaround time for ISH; IQFISH Fast Hybridization Buffer reduces hybridization to 75 minutes and enables a 4-hour turnaround time for FISH	fully integrated and automated; DNA/RNA specimen extraction and real-time PCR system; walkaway system that fully automates specimen results; flexible system that adapts to lab workflows operating in multiple modes: extraction/PCR, extraction only, or PCR only; independently controlled tracks that simultaneously allow 12 different real-time PCR profiles per batch; mutliplex PCR up to 6 targets per track and multiple PCR from a single extract to create customer-defined disease state panels

**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 13 *See* **captodayonline.com/productguides** *for an interactive version of guide**	**Focus Diagnostics** marketingcomm@focusdx.com **11331 Valley View St., Cypress, CA 90630** **562-240-6500** www.focusdx.com	**GenMark Diagnostics** info@genmarkdx.com **5964 La Place Court, Carlsbad, CA 92008** **800-eSensor (373-6767)** www.genmarkdx.com
Name of instrument	Integrated Cycler	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/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 square feet/Noise generated in dB	12 × 8 × 12/1/≤50	18 × 18 × 15/2.25/—
Supplied with UPS/BTU	no/~450 per hour	yes/—
Physical contamination control features	disc sealers	closed-cartridge technology
List price/Price for sample extraction and amplification detection modules	$60,000/—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental/as low as 2–5 µL	straight purchase, reagent rental, lease/1+
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/voltage input range: 100–120 V; frequency: 50–60 Hz; current: 4.5 A	yes/100–230 VAC
Labor and parts warranties/Advanced operator training	standard 1 year (additional years available)/yes	standard 1 year (additional years available)/yes
Delivery time/Delivery charges/Installer/Time to install on site	as scheduled/none/Focus/1 hour	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/flexible/<1 day/yes	on site/up to 3/1–3 days/yes
Test menu	Simplexa HSV 1 & 2 assay for CSF and genital swabs sample types, Simplexa group A strep assay	eSensor cystic fibrosis genotyping test, eSensor respiratory viral panel, eSensor thrombophilia risk test, eSensor warfarin sensitivity test
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/10	4/—
Tests available on instrument in U.S./Outside U.S.	~50/~50	4/—
Tests not available in U.S. but submitted to FDA/Available in other countries only	2/1	—
Research-use-only assays/Tests in development	0/8+	—
Open-channel capabilities/Start-up and preparation time	yes/2–3 minutes	no/<5 minutes
Model type of sample-handling system/Maximum sample load capacity	—/up to 96	cartridge based/96 in 8-hour shift
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	direct method: 50 µL; universal direct: 2–3 µL; extracted: 200 µL/no/—	varies by test/yes/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/yes	—/yes/no
Sample barcode languages/Sample types available in open mode	most 1-D and 2-D symbologies/user defined, including NPS, stool, serum, whole blood, plasma, urine	all common/—
Clot detection/Open extraction platform/Sample types (open extraction)	no/—/—	—/yes/—
Amplification reagents or methods supported	yes	PCR
No. of different assays onboard at once/Programmed or calibrated at once	up to 96 wells/up to 96 wells	multiple (random access)/multiple (random access)
Tests per container set/Multiple reagent configurations supported	universal: 96; direct: 8/up to 96 wells	varies, 24–48/—
Reagent container placed directly on system/Onboard test auto inventory	no/no	no/no
Determines reagent volume in container	no	no
Reagent barcode reading/Reagents barcoded	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/liquid
Reagent reconstitution required/Chemical contamination control	no/direct: one time use	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	—	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/yes
Closed-vial stability for amplification reagents/Extraction reagents	yes/—	up to 12 months/—
Storage temp. requirement for amplification reagents/Extraction reagents	frozen/—	-20°C/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	frozen/—	frozen/ambient
Minimum/Maximum reagent shelf-life guarantee	30 days refrigerated, frozen up to expiration date/30 days refrigerated, frozen up to expiration date	up to 60 days/12 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/moderate complex: daily; high complex: each run	—
Length of assay calibration/Typical calibration frequency	2–3 minutes/monthly	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/amplification detection module: 2–3 minutes/yes	no/none/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	0–3/0–3/0–3/0–3	1/1/1/1
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	yes/15–30 minutes	up to 3.5 hours/up to 2.5 hours
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/up to 96 wells	no/—
Time between start and initial result/Instrument automatic shutdown	~1 hour/no	30 minutes/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/yes	no/no/disposable cartridges
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/—	yes/touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	3-year extended warranty/amplification: >12 months/1 hour on site	field and depo service/—/within 48 hours
Turnaround time for problem solving by phone/Email/Field service	<1 hour during business hours/<1 hour during business hours/within 48 hours	M–F, 5 AM–8 PM PT: ≤1 hour; weekends on call/same as phone/within 48 hours
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	11/within 48 hours/M–F, 7:30 AM–5 PM PST	6/within 48 hours/7 AM–6 PM PT
Guaranteed response time/Modem servicing available	yes, M–F/no	yes (within 48 hours)/no
System 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: 5–15 minutes; yearly: ~1 hour/no	yearly: <15 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	—/yes	—
Downtime for preventive maintenance/Spare parts on site	~1 hour/yes	60 minutes/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	no/yes	no/yes
• Priority processing	no	yes
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/—	no/no/—
• 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/ASTM, TCP-IP	no/—
• QC results transferred automatically to LIS/Data-management capability	no/yes	no/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	yes	—
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	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)	moderate complexity assays without extraction available; scalable and flexible system for qualitative and quantitative assays with small footprint; multiple assays can be performed at one time in approximately 1 hour	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

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Part 9 of 13 *See* **captodayonline.com/productguides** *for an interactive version of guide**	**Great Basin Scientific** **Sandra Nielsen** sales@gbscience.com **2441 S. 3850 W., Salt Lake City, UT 84120** **385-215-3355** www.gbscience.com	**Hologic I Gen-Probe** **Cliff Pollak** clifford.pollak@hologic.com **10210 Genetic Center Dr., San Diego, CA 92121** **858-410-8000** www.gen-probe.com
Name of instrument	Great Basin PA500 Benchtop Analyzer	TIGRIS DTS Analyzer
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S	U.S./U.S./U.S., U.K.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2012/2012/2012	2004/2005/2004
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	17.2 × 6.3 × 21.4/.94/—	72 × 69 × 36/17.25/compliant with EN 61010-1
Supplied with UPS/BTU	no/—	yes/2,637
Physical contamination control features	closed-cartridge technology	closed system, liquid level sensing, pressure-dispense verification, onboard deactivation, deep-well reaction tube, single sample aspiration and dispense, penetrable cap
List price/Price for sample extraction and amplification detection modules	instrument placed at no cost/—	—
Purchase options/Minimum test volume requirements	—/no	straight purchase, reagent rental, lease/variable
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/input 100–240 V ~1.0 A, 50/60 Hz	yes/220 V
Labor and parts warranties/Advanced operator training	—	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	overnight/none/Great Basin/30 minutes	<1 week/variable at origin and destination/Gen-Probe/2–3 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1–3/2 hours/yes	on and off site/2/4 days/yes
Test menu	toxigenic C. difficile, group B streptococcus	CT-GC, CT, GC, HPV, trichomonas, HPV genotyping
No. of tests for which analyzer has FDA-cleared applications/CE mark	2/2	6/6
Tests available on instrument in U.S./Outside U.S.	2/2	CT-GC, CT, GC, HPV, trichomonas, HPV genotyping/CT-GC, CT, GC, HPV, trichomonas, HPV genotyping
Tests not available in U.S. but submitted to FDA/Available in other countries only	1 (staph ID/R blood culture panel)/0	—
Research-use-only assays/Tests in development	1 (shiga toxin direct test)/3 (SA nasal screen, GI panel, fungal panel)	—
Open-channel capabilities/Start-up and preparation time	no/~2 minutes	yes/~30 minutes
Model type of sample-handling system/Maximum sample load capacity	closed-cartridge technology/1 per analyzer	onboard automated pipettor/180
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	50–250 µL, depending on test/no/—	400 µL/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	800 µL/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/yes	various/yes (automated onboard scanner to maintain positive sample ID)/no
Sample barcode languages/Sample types available in open mode	code 128/—	Interleaved 2 of 5, Codabar codes 39 and 128/—
Clot detection/Open extraction platform/Sample types (open extraction)	—	yes/no/—
Amplification reagents or methods supported	HDA, PCR	transcription-mediated amplification
No. of different assays onboard at once/Programmed or calibrated at once	1/1	4/4
Tests per container set/Multiple reagent configurations supported	single-use cartridge with reagents onboard/—	100 or 250/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/—	yes/yes
Determines reagent volume in container	yes	yes
Reagent barcode reading/Reagents barcoded	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	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/closed-cartridge technology	yes/yes
Onboard test auto inventory/Capable of inventory monitoring by barcode	—	yes/yes
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/yes
Closed-vial stability for amplification reagents/Extraction reagents	6 months/6 months	assay dependent/assay dependent
Storage temp. requirement for amplification reagents/Extraction reagents	refrigeration/room temperature	refrigeration/refrigeration
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	—/6 months	—/up to 1.5 years after manufacture date
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	—/1 minute/yes	no/—/—
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)	—	up to 180 samples/<19 seconds per sample
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/—	yes/480 (1.2 tips per sample)
Time between start and initial result/Instrument automatic shutdown	~90 minutes/—	3.5 hours/no
Startup programmable/Remote system monitoring/Waste required for disposables	—/—/disposable single-use cartridge	no/yes/plastics and cardboard
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	support is included with no service contracts/—/—	premiere and standard/—/—
Turnaround time for problem solving by phone/Email/Field service	6 AM–6 PM, M–F (holidays and weekends on call)/6 AM–6 PM, M–F (holidays and weekends on call)/24 hours	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	—/—/6 AM–6 PM MT	—/—/premiere: 24 hours, 7 days; standard: M–F, 8 AM–5 PM PST
Guaranteed response time/Modem servicing available	no/yes	yes (<24 hours)/yes
System 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	weekly: ~5 minutes/no	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	—/no	1 day/yes
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	no/yes
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	—	no/yes
• Unique barcode per container/Multistop routing (1 tube to many 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/—	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 immediately transmitted to LIS/Interface available to auto specimen-handling system	—	yes/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—	yes/yes/no
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	placed at no cost; uses proprietary low-cost cartridges to provide an easy-to-use, cost-effective, sample-to-result system capable of performing low-plex, multiplex, and direct from specimen molecular diagnostic testing; closed system to fully process, analyze, and report findings from reagents fully contained within these single-use cartridges and is capable of running all current and future planned tests and panels; future enhancement to deliver test results directly to the hospital information systems, which will further the efficiency and functionality of this versatile system	totally integrated platform; high-throughput CT/GC, HPV, and trichomonas platform; flexible worklist size from 1–246 patient samples; sample positive ID for confidence in results; scalable for menu expansion and lab growth; built-in process controls to minimize crossover contamination

**for calibration and controls*

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

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Part 10 of 13 *See* **captodayonline.com/productguides** *for an interactive version of guide**	**Hologic I Gen-Probe** **Glenn Sawyer** glenn.sawyer@hologic.com **10210 Genetic Center Dr., San Diego, CA 92121** **858-410-8000** www.gen-probe.com	**HTG Molecular Diagnostics** **Steve Hagan** shagan@htgmolecular.com **3430 E. Global Loop, Tucson, AZ 85706** **877-289-2615** www.htgmolecular.com
Name of instrument	PANTHER System	HTG EdgeSeq system
Country where designed/Manufactured/Reagents manufactured	U.S./Switzerland/U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	no/analytical
First year sold in U.S./Sold internationally/Installed	2012/2010/2010	2014/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	69 × 48 × 32/10.6/<55	17 × 36 × 24/6/<65
Supplied with UPS/BTU	yes/1,878 per hour	no/—
Physical contamination control features	closed system, liquid level sensing, pressure-dispense verification, onboard deactivation, deep-well reaction tube, single sample aspiration and dispense, penetrable cap	self-contained waste capture
List price/Price for sample extraction and amplification detection modules	—	$99,000
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/400 µL	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–230 V	yes/120–240 V
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	~1 week/variable at origin and destination/Hologic/1–2 days	1–4 days/$800/HTG/2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/3 days/yes	on and off site/1–3/2 days/yes
Test menu	CT-GC, CT, GC, HPV, trichomonas, HPV genotyping, HIV-1 viral load	miRNA expression, oncology biomarker panel, lung fusions assay, DLBCL, FGFR expression, immuno-oncology assay
No. of tests for which analyzer has FDA-cleared applications/CE mark	4/7	—
Tests available on instrument in U.S./Outside U.S.	CT-GC, HPV, trichomonas, HPV genotyping/CT-GC, CT, GC, HPV, trichomonas, HPV genotyping, HIV-1 viral load	7/7
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/CT, GC, HIV-1 viral load	—
Research-use-only assays/Tests in development	—/HSV-1 and HSV-2, virology	7/8
Open-channel capabilities/Start-up and preparation time	yes/<15 minutes	yes/<30 minutes
Model type of sample-handling system/Maximum sample load capacity	automated onboard/120	manual (lysis only prep)/96
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	400 µL/no/—	single 5-micron FFPE section, 15 µL plasma or serum, 2,000 cells/yes (assay and tissue dependent)/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	800 µL/—/yes	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	various/yes (automated onboard scanner to maintain positive sample ID)/no	uses 96-well microtiter plate/yes/no
Sample barcode languages/Sample types available in open mode	Codabar codes 39 and 128, Interleaved 2 of 5, JAN13, Code 93, UPC/—	—/various
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/—	no/no/various
Amplification reagents or methods supported	transcription-mediated amplification	PCR for addition of sequencing primers
No. of different assays onboard at once/Programmed or calibrated at once	4/4	1/7
Tests per container set/Multiple reagent configurations supported	100 or 250/yes	up to 8, 24, 48, 96/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container	yes	no
Reagent barcode reading/Reagents barcoded	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/liquid
Reagent reconstitution required/Chemical contamination control	yes/yes	no/onboard waste capture
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	—	no/no
Same capabilities when third-party reagent used/Lot sequestering available	—	no/yes
Closed-vial stability for amplification reagents/Extraction reagents	assay dependent/assay dependent	—
Storage temp. requirement for amplification reagents/Extraction reagents	refrigeration/refrigeration	—
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Minimum/Maximum reagent shelf-life guarantee	—/up to 1.5 years	reagent dependent/reagent dependent
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/—	no/—
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	no/24 hours	no/at install
Length of assay calibration/Typical calibration frequency	24 hours/24 hours	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	—/yes	no/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/<15 minutes/yes	no/—/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	2/2/2/2	user determined
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	up to 120 samples/<15 seconds per sample	up to 96 samples/10 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/576 (2.2 tips per sample)	yes/384
Time between start and initial result/Instrument automatic shutdown	3.5 hours/no	~20 hours/no
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/plastics and cardboard	no/no/plastic, contained liquid
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/yes	yes/mouse/yes
Service contracts available/Mean time between failures/To repair failures	standard and premiere/—/—	yearly (parts and labor)/—/>120 days
Turnaround time for problem solving by phone/Email/Field service	—	<1 hour/<1 hour/24–72 hours
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/24 hours/premiere: 24 hours, 7 days; standard: M–F, 8 AM–5 PM PST	—/24–72 hours/M–F, 10 hours
Guaranteed response time/Modem servicing available	yes/yes	no/no
System 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	weekly: <5 minutes; monthly: <45 minutes/yes	daily: 10 minutes; weekly: 90 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	2/2	—
Downtime for preventive maintenance/Spare parts on site	<1 day/yes	8 hours/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	yes
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/no
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/—	yes/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	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	yes/LIS1-A and LIS2-A2 (ASTM)	no/—
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/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	no
Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/—
Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/—	no/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—/yes/—	—
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	random access, fully integrated; scheduled/automated maintenance for rapid startup; lean, out-of-the-box workflow; no return visits required for up to 120 samples per day; eliminates constraints of batching; runs multiple assays from a single sample loaded onboard; true positive sample ID	low sample input requirements without the need for nucleic acid extraction; multi-plexed (>2,000 targets) results with walkaway automation; simplified data reporting for targeted next-generation sequencing

**for calibration and controls*

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

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Name of instrument	Illumipro-10	Verigene Processor SP 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/analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2010/2010/2010	2009/2010/2009
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	8.3 × 11.5 × 3.7/.66/—	18.7 × 19.3 × 22.9/3.1/—
Supplied with UPS/BTU	no/—	—
Physical contamination control features	closed test devices	—
List price/Price for sample extraction and amplification detection modules	$8,300/amplification: $8,300	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental/100 µL	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC, 50–60 Hz	—/standard
Labor and parts warranties/Advanced operator training	1 year/no	—/no
Delivery time/Delivery charges/Installer/Time to install on site	1 business day/based on location/Meridian Bioscience (optional)/1 day	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/no limit/2 hours/no	on site/1 or more/varies/—
Test menu	C. difficile, group B strep, group A strep, mycoplasma pneumoniae, pertussis, HSV 1/2	Verigene: gram-positive blood culture test, gram-negative blood culture test, C. difficile test, enteric pathogens test, respiratory pathogens flex
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/5	5/5
Tests available on instrument in U.S./Outside U.S.	C. difficile, group A strep, group B strep, mycoplasma, bordetella pertussis, HSV 1/2/chlamydia trachomatis, neiserria gonorrhea	Verigene: gram-positive blood culture test, gram-negative blood culture test, C. difficile test, enteric pathogens test, respiratory pathogens flex test/Verigene: gram-positive blood culture test, gram-negative blood culture test, C. difficile test, enteric pathogens test
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—
Research-use-only assays/Tests in development	—/malaria	—/Verigene enteric parasites test
Open-channel capabilities/Start-up and preparation time	no/2 minutes hands-on time per sample, 12 minutes total	no/<5 minutes hands-on time
Model type of sample-handling system/Maximum sample load capacity	—/10 per Illumipro module	—/1 mL
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	100 µL/no/—	200 µL/—/1 mL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/100 µL/no	—/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/no	—/yes/—
Sample barcode languages/Sample types available in open mode	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/—/—
Amplification reagents or methods supported	loop-mediated isothermal amplification	proprietary
No. of different assays onboard at once/Programmed or calibrated at once	5/5	1/—
Tests per container set/Multiple reagent configurations supported	50/no	—
Reagent container placed directly on system/Onboard test auto inventory	no/no	yes/—
Determines reagent volume in container	no	—
Reagent barcode reading/Reagents barcoded	no/no	yes/yes
Monitors expiration date/Auto lot recognition or calibration	no/liquid and dry	—/no
Auto detection of adequate reagent or specimen/Reagents available	yes/closed test device system with internal control	no/liquid
Reagent reconstitution required/Chemical contamination control	no/no	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/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/—
Closed-vial stability for amplification reagents/Extraction reagents	18 months/—	—
Storage temp. requirement for amplification reagents/Extraction reagents	2°–27°C/—	-20°C/refrigerate
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/—	-20°C/refrigerate
Minimum/Maximum reagent shelf-life guarantee	2 months/18 months	—
Autocalibration or autocalibration alert/Multipoint calibration supported	—/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	no/none, monthly optic verification	—
Length of assay calibration/Typical calibration frequency	2 minutes for optic verification/2 minutes	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/yes	—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/5 minutes/no	—/sample extraction: ~2 minutes/—
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	controls run with each kit lot or shipment	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	10 samples per batch per module/2 minutes per sample	random-access system/<5 minutes hands-on time
Uses disposable pipette tips/Maximum number of pipette tips stored	no/200 batches per 1,000 samples	yes/—
Time between start and initial result/Instrument automatic shutdown	40 minutes/yes	2–2.5 hours/—
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/—	—
Windows technology/Mouse or touchscreen/Modular add-on capability	no/—/yes	no/touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	3-year extended warranty/—/24 hours	—
Turnaround time for problem solving by phone/Email/Field service	10 minutes/10 minutes/none	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	—/—/M–F, 8 AM–6 PM EST	—
Guaranteed response time/Modem servicing available	24-hour replacement shipment/no	—
System diagnose own malfunctions	yes	—
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	—/yes/—
Average maintenance time for lab personnel/Onboard maintenance records	daily: 1 minute; monthly: 2 minutes/no	daily: 1 minute/—
Preventive maintenance per year for sample extraction/Amplification detection	—	—
Downtime for preventive maintenance/Spare parts on site	none/no	—
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	—
• Data retrieval or Internet connectivity/Priority processing	no/no	yes/—
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	—
• Supports accession No. redundancy/Specimen carrier and level identification	yes/no	—
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	—
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	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/—	—
• QC results transferred automatically to LIS/Data-management capability	no/yes	—
Interfaces operational in active user sites	no	yes
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 immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	—
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/no/no	—
Can print, archive, transmit data	no	—
Distinguishing features (supplied by company)	loop-mediated isothermal amplification technology eliminates need for thermal cycling equipment; no extensive purification or extraction required; results in less than 1 hour	FDA-cleared tests; on-demand, automated, multiplex testing for bloodstream, gastrointestinal tract, and respiratory tract infections; Processor SP designated as CLIA moderate complexity; scalable, random-access platform; short 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

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	QIAGEN **19300 Germantown Rd.** **Germantown, MD 20874** **240-686-7430** www.qiagen.com	**Roche Diagnostics Corporation** **Lynda Denney** lynda.denney@roche.com **9115 Hague Rd., Indianapolis, IN 46250** **317-521-4335** www.usdiagnostics.roche.com
Name of instrument	QIAsymphony RGQ	cobas 4800 system
Country where designed/Manufactured/Reagents manufactured	Switzerland, Germany, U.K./Switzerland/Germany	Switzerland/Switzerland/U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2008/2007/2007	2011/2009/2011
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	QIAsymphony SP: 128 × 103 × 73 cm; QIAsymphony AS: 59 × 103 × 73 cm; QIAsymphony SP/AS (integrated operation): 185 × 103 × 73 cm; Rotor-Gene Q: 28.6 × 37 × 42 (depth without cables) 53.8 (depth with door open) cm/—/—	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	disposable filter tips, drop catchers, UV lamp	Core 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/—	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/110V–230 V	yes/cobas x 480: line voltage 115–230 VAC, 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	1 year/yes	labor: 1 year; parts: covered by service contract/yes
Delivery time/Delivery charges/Installer/Time to install on site	4 weeks/—/Qiagen service engineers/1–2 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 and off site/4/2 days/yes	on and off site/2/4 days/yes
Test menu	open platform	CT-NG, HSV 1/2, HPV, MRSA/MSSA, Cdiff, BRAF V600 mutation, EGFR mutation, KRAS mutation
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/15	8/8
Tests available on instrument in U.S./Outside U.S.	C. difficile, HSV 1/2/HIV, HCV, HBV, C. difficile, MRSA, VanR, GBS, CMV, EBV, BKV, VZV, HSV 1/2, RespiFast, CT-NG	CT-NG, HSV 1/2, HPV, MRSA/MSSA, Cdiff, BRAF V600 mutation, EGFR mutation, KRAS mutation
Tests not available in U.S. but submitted to FDA/Available in other countries only	MRSA/HIV, HCV, HBV, C. difficile, MRSA, VanR, GBS, CMV, EBV, BKV, VZV, HSV 1/2, RespiFast, CT-NG	—
Research-use-only assays/Tests in development	—/multiple	cobas PIK3CA mutation, cobas EGFR mutation/cobas KRAS mutation, trichomonas vaginalis, myocoplasma genitalium, factor V/II
Open-channel capabilities/Start-up and preparation time	yes/15 minutes	yes/30 minutes
Model type of sample-handling system/Maximum sample load capacity	QIAsymphony SP/96	cobas x 480 instrument/94
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	200 µL/yes/400 µL, 500 µL, 800 µL, 4 mL	1 mL/—/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	100 µL/200 µL/yes	1 mL/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	1.5–15 mL/yes/no	13 mL (PreservCyt vial)/yes/no
Sample barcode languages/Sample types available in open mode	diverse, e.g. Codabar codes 39 and 128/plasma, blood, stool, urine, FFPE, respiratory, CSF, swabs, LBC, 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, FFPE tissue
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/plasma, blood, stool, urine, FFPE, respiratory, CSF, swabs, LBC, transport media	yes
Amplification reagents or methods supported	yes	real-time PCR
No. of different assays onboard at once/Programmed or calibrated at once	4/4	1/1
Tests per container set/Multiple reagent configurations supported	—/yes	CT-NG and HPV: 240 and 960 test kits; HSV 1/2, MRSA/SA, Cdiff: 80 and 240 test kits; oncology: 24 test kits/CT-NG and HPV: runs of 24, 48, 72, 96; HSV 1/2, MRSA/SA, Cdiff: mixed run of 8 or more; oncology: average runs of 3 or more
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container	yes	yes
Reagent barcode reading/Reagents barcoded	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	no/no	no/yes, AmpErase enzyme
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	yes/yes
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes	yes/yes
Closed-vial stability for amplification reagents/Extraction reagents	minimum 1 year/minimum 1year	12–18 months/12–18 months
Storage temp. requirement for amplification reagents/Extraction reagents	refrigerator/room temperature	2°–8°C/2°–25°C
Shipment temp. requirement for amplification reagents/Extraction reagents	cool packs/room temperature	cool packs/cool packs
Minimum/Maximum reagent shelf-life guarantee	9 months/2 years	3 months/—
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	no/yes
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	—	no/—
Length of assay calibration/Typical calibration frequency	—/assay dependent	—
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	24, 42, 72, and 96: 2 (1 positive, 1 negative)
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	80 percent of run time/30 minutes	~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	typically 6–7 hours for 96 samples/no	assay dependent, 8 HSV results in <3 hours; 96 CT-NG results in <4 hours/no
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/separate liquid, plastic, and tip waste	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 hours, 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/Email/Field service	yes/yes/yes	15 minutes/15 minutes/varies
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	75/contract dependent/24 hours, 7 days per week	250/24 hours/24 hours, 7 days
Guaranteed response time/Modem servicing available	yes/yes	24 hours/yes
System diagnose own malfunctions	yes	yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/no/yes	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: 10 minutes; weekly: 30 minutes; monthly: 30 minutes/yes	daily: 2–7 minutes; weekly: <5 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	1/1	2/1
Downtime for preventive maintenance/Spare parts on site	4 hours/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/Priority processing	yes/yes	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/no
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	—/yes	no/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/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	yes/QIAlink and HL7	yes/ASTM, HL7
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/yes
Interfaces operational in active user sites	yes	no
Rules-based control subsystem/Process control via control subsystem	no/yes	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 immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	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)	runs FDA-cleared content from sample to result as well as being a flexible, convenient system for independent modular operation; process security and ease of use make this an ideal investment for a molecular diagnostic laboratory	designed for dependable performance/results; Core 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

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

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Name of instrument	QuantStudio Dx Real-Time PCR Instrument	7500 Fast Dx Real-Time PCR Instrument
Country where designed/Manufactured/Reagents manufactured	U.S./Singapore/U.S.	U.S./Singapore/—
Instrument FDA cleared or approved/Platform	yes/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2012/2012/2012	2008/2010/2009
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	75 cm × 53 cm × 70 cm/4/—	19.29 × 13.99 × 17.72/1.8/—
Supplied with UPS/BTU	no/—	no/maximum output: 3241.5 per hour (950 W)
Physical contamination control features	imaging through sealed reaction plate	no
List price/Price for sample extraction and amplification detection modules	$79,900/amplification: $79,900	$65,900/amplification: $65,900
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/10 µL	straight purchase, reagent rental, lease/10 µL
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC at 50 or 60 Hz	yes/100–240 VAC at 50 or 60 Hz and 15 A circuit
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	—/—/certified applied biosystems service engineer/—	—/—/certified applied biosystems field service agent/—
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/based on customer requirements/yes/based on customer requirements/ yes	on site/based on customer requirements/—/yes
Test menu	influenza A/B, RSV + hMPV, C. difficile	measures nucleic acid signals from reverse-transcribed RNA, CDC rRT-PCR flu panel (CDC 510(k) K080570), CDC DENV-1–4, MRSA/SA ELITe MGB, Quidel Pro hMPV+ assay, NAi ProsVue PSA assay
No. of tests for which analyzer has FDA-cleared applications/CE mark	3/3	—
Tests available on instrument in U.S./Outside U.S.	3/3	—
Tests not available in U.S. but submitted to FDA/Available in other countries only	HSV 1+2, VZV/—	—
Research-use-only assays/Tests in development	measures nucleic acid signals from DNA or reverse-transcribed RNA/—	—
Open-channel capabilities/Start-up and preparation time	yes/<5 minutes	yes/<5 minutes
Model type of sample-handling system/Maximum sample load capacity	—/96 (Dx mode), 96, 384, TaqMan Array Card (test development mode)	—/96
Minimum specimen volume/Sample volume flexibility/ Other sample volumes available	10 µL (reaction volume)/yes, 10–30 µL rxn volume/—	10 µL (reaction volume)/yes, reaction volumes 10–30 µL/10–30 µL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—	—/no/no
Sample barcode languages/Sample types available in open mode	—	—/nucleic acid signals from reverse-transcribed RNA
Clot detection/Open extraction platform/Sample types (open extraction)	—/—/DNA or reverse-transcribed RNA	no/no/—
Amplification reagents or methods supported	qPCR	nucleic acid signals from reverse-transcribed RNA
No. of different assays onboard at once/Programmed or calibrated at once	depends on customer requirement/depends on customer requirement	dependent on real-time PCR reaction plate setup/—
Tests per container set/Multiple reagent configurations supported	—	—
Reagent container placed directly on system/Onboard test auto inventory	no/no	no/no
Determines reagent volume in container	no	no
Reagent barcode reading/Reagents barcoded	no/no	no/no
Monitors expiration date/Auto lot recognition or calibration	no/no	no/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/no	yes/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	yes/no	yes/no
Closed-vial stability for amplification reagents/Extraction reagents	—	—
Storage temp. requirement for amplification reagents/Extraction reagents	—	—
Shipment temp. requirement for amplification reagents/Extraction reagents	—	—
Minimum/Maximum reagent shelf-life guarantee	—	—
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	no/yes
Assay calibrations required by end user/Calibrants can be stored onboard	yes/no	yes/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/3 months	no/6 months or after service repair
Length of assay calibration/Typical calibration frequency	<1 day/—	<1 day/6 months
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/yes/—	no/none/yes
Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests	—	end user and assay dependent
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	run dependent/<1 hour	40 minutes to >2 hours/<1 hour
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	run dependent/no	assay run-mode dependent/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/—	no/no/none
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/no	yes/mouse/no
Service contracts available/Mean time between failures/To repair failures	service and compliance plans, extended warranty/—/—	service plans, compliance services, extended warranty/—/—
Turnaround time for problem solving by phone/Email/Field service	—	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days avail.	—/—/M–F, 8 AM–5 PM	—/—/M–F, 8 AM–5 PM
Guaranteed response time/Modem servicing available	—/no	—
System diagnose own malfunctions	no	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	—	—
Preventive maintenance per year for sample extraction/Amplification detection	—/twice per year	—/twice per year
Downtime for preventive maintenance/Spare parts on site	<1 day/no	yes/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/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic 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/no
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 immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	no/no
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	no/yes/yes
Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	can be operated using Dx software with the approved test menu or with test development software for assay develop.; interchangeable thermal blocks provide flexibility during assay develop., enabling 96-well standard, 96-well fast, 384-well, and TaqMan Array Card formats; decoupled excitation and emission filters for more color options; instrument-to-instrument normalization ensures consistent performance; security, auditing, and e-signature controls allow efficient management and traceability for run protocols executed by many users	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; 5-color variable excitation enables multiplex assays; security, auditing, and e-signatures allow full control over thermal cycling protocols

**for calibration and controls*

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