

## Automated molecular platforms

<b>Part 1 of 11</b>	Abbott Laboratories, Abbott Molecular Division Francisco Cline francisco.cline@abbott.com 1300 E. Touhy Ave., Des Plaines, IL 60018 224-361-7000 www.abbottmolecular.com
See <a href="http://captodayonline.com/productguides">captodayonline.com/productguides</a> for an interactive version of guide	
<b>Name of instrument</b>	m2000 RealTime System composed of the m2000sp and m2000rt
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	U.S./Switzerland, Singapore/U.S. yes/preanalytical and analytical 2007/2005/2005
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b> <b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	m2000sp: 66.2 × 69.5 × 31.3; m2000rt: 19.3 × 13.4 × 17.8/15; 1.6/—; <85 (1m) yes/m2000sp: 4,100 BTU (1,200 Wh); m2000rt: 3,241.5 BTU per hour (950 W) instrument hood; extraction platform process flow design; 50-μL aspiration air gap in each pipette tip; aerosol barrier pipette tips; others
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/Length of training/Retraining at company facility</b>	\$199,900/sample extraction: \$149,900; amplification detection: \$69,000 straight purchase, reagent rental, lease/none yes/m2000sp: 100–240 VAC at 50–60 Hz; m2000rt: 100–240 VAC at 50–60 Hz 1 year/yes 1–4 weeks/\$1,500 (destination)/Abbott Molecular/sp: 3 days; rt: 1 day on site and off site/2/3 days/yes
<b>Test menu</b> <b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b>	HIV VL, HIV Qual, HCV VL, HCV GT, HBV VL, CT/NG, CT, CMV, EBV, HPV, ms9, KIF6 4/11 HIV VL*, HIV Qual**, HCV VL*, HBV VL*, CT/NG*, HCV GT****/HIV VL**, HIV Qual****, HCV VL**, HCV GT**, HBV VL**, CT/NG**, CT**, CMV**, EBV**, HPV**, ms9**, KIF6**, Parvo B19**, VZV**, M. tuberculosis**, SARS**, C. Difficile**, VanR**, HSV 1/2**
<b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b>	—/CT**, HPV**, ms9**, KIF6**, Parvo B19**, VZV**, M. tuberculosis**, SARS**, C. Difficile**, VanR**, HSV 1/2**
<b>Research-use-only assays/Tests in development</b> <b>Open-channel capabilities/Start-up and preparation time</b>	HCV GT****, HIV Qual****/CMV, VRE, C. Difficile, HSV 1/2, Flu A/B RSV yes/15 minutes for batch of 24 samples
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b>	m2000sp/96 samples 0.4 mL/yes (FDA protocols include 0.2, 0.4, 0.5, 0.6, and 1.0 mL)/0.05–4.0 mL 0.2 mL/0.2 mL/yes 11.5 mm–16 mm diameter/yes/no 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 yes/yes/plasma, serum, urine, whole blood, swabs, dry blood spots, others
<b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b> <b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container/Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	real-time polymerase chain reaction chaotropic lysis w/nucleic acid isolation via magnetic separation/yes/yes/yes one w/standard operation, two w/MaxCycle†, 12 w/open mode 24–96/nucleic acid: DNA, RNA, total nucleic acid; master mix: up to 4 reagents yes/no yes/yes/yes yes/yes yes/— no/not required yes/no yes/yes yes/yes 18 months at -10°C/18 months at 15°–30°C -10°C/15°–30°C frozen on dry ice/15°–30°C 3 months/18 months
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	no/yes yes/yes yes/every 6 months, after any reagent lot changes, or any major service event up to 6 months/every 6 months yes/yes yes/sample extraction: none; amplification detection: 15 minutes/yes Only three controls needed regardless of batch size (24, 42, 72, and 96)
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	up to 3.5 hours/<1 hour yes/864 for a CT/NG batch of 48 samples: 4 hours, 41 minutes/yes no/yes/plastic and liquid; waste containers onboard yes/mouse/yes
<b>Service contracts available/Mean time between failures/To repair failures</b> <b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	phone, on-site service/samp. extract.: 30 wks; ampli. detect.: 162 wks/4 hours 1 minute–4 hours/10 minutes–24 hours/30 hours within tech arriving on site 7/within 48 hours/M-F, 8 AM–5 PM all time zones yes (when requested)/yes yes varies/yes/yes daily: <10 minutes; weekly: 60 minutes; monthly: 15 minutes/yes 2/1 4–8 hours/yes
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability <b>Interfaces operational in active user sites</b> <b>Rules-based control subsystem/Process control via control subsystem</b> <b>LIS operates simultaneously with assays running</b> <b>Uses LOINC to transmit orders and results/Unidirectional interface capability</b> <b>Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system</b> <b>Stores QC lot files/Worklist edit capability/Viewable PCR graphs</b> <b>Can print, archive, transmit data</b>	no yes yes/yes no no/yes no/no no/—/— no no/— yes/yes yes yes/yes yes no/yes yes/no yes/yes/yes yes
<b>Distinguishing features (supplied by company)</b>	enables consolidation of many NAAT tests and a range of sample types onto a single system, while providing bar-coded primary tube sampling, contamination control and maxRatio (a proprietary built-in PCR curve validation software)
<small>*for calibration and controls Note: a dash in lieu of an answer means company did not answer question or question is not applicable</small>	<small>* FDA, ** CE Mark, *** ASR, **** RUO, † program enables cocycling of HIV and HCV in same batch</small>

## Automated molecular platforms

<b>Part 2 of 11</b>	<b>AutoGenomics, Inc.</b> Min Ding mding@autogenomics.com 2980 Scott St., Vista, CA 92081 760-477-2248 www.autogenomics.com	<b>BD Diagnostic Systems</b> Doug Jones douglas_jones@bd.com 7 Loveton Circle, Sparks, MD 21512 410-316-3665 www.bd.com/ds
See captodayonline.com/productguides for an interactive version of guide		
<b>Name of instrument</b>	<b>INFINITI PLUS Analyzer</b>	<b>BD MAX</b>
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	<b>U.S./U.S./U.S.</b> yes/analytical 2011/2011/2011	<b>U.S./U.S./U.S. and Canada</b> yes/preanalytical and analytical 2010/2010/2010
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b> <b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	26 × 44 × 24/7.3/— no/— no aspiration tubing, disposable tips	28.5 × 37 × 29.7/5/64 at 48 dB background yes/— unitized reagent strip; dedicated pipette tips, microfluidic PCR cartridge with microvalves; pipettor flight path avoids crossing strips/tubes
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/</b> <b>Length of training/Retraining at company facility</b>	— straight purchase, reagent rental, lease/1 µL yes/110V and 220V, 50–60 Hz 1 year/no 1 week/—/AGI/1–2 days on site and off site/1/2.5 days/yes	\$150,500/— straight purchase, reagent rental, lease/specimen dependent (low as 10–15 µL) yes/100–240 VAC ~50–60 Hz, 10A 1 year (≤3 year contracts optional)/yes 90 day, or less from contract/—/BD/1.5 days on site/flexible/1 day/yes
<b>Test menu/No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b> <b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b> <b>Research-use-only assays/Tests in development</b>	CYP2C19 (IVD), CYP450 2D6, warfarin assay (IVD), KRAS-BRAF, HPV genotyping, HPV-HR, STD-6 panel, bacterial vaginosis, candida vaginitis, and more/6/23 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 — factor II plus, factor V genotyping, MTHFR, many others/—	—/GBS, MRSA/GBS, MRSA, C. difficile; 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/— GBS, MRSA/GBS, MRSA, C. difficile  C. difficile/— —/MRSA+ MSSA+ mecA, MRSA + mecA, CT+GC+Trich, enteric bacterial panel, enteric O&P panel, flu A-B-RSV, pertussis, atypical pneumonia panel, more yes/ready 24 hours, 7 days
<b>Open-channel capabilities/Start-up and preparation time</b>	yes/20 minutes	
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b>	—/48 1 µL/no/— —/—/no —/yes/— —	fully automated pre-analytical and PCR functions/24 specimen dependent (low as 10 to 15 µL)/yes/volumes range up to 750 µL 50–200 µL/specimen dependent/no uses standard 4-mL tube format/yes/— Codabar, codes 39, Interleave 2 of 5, EAN/UCC code 128/swab, swab in transport medium, whole blood, urine, plasma, stool no/yes/swab, swab in transport medium, urine, plasma, CSF, stool
<b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	—/yes/—	
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b> <b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container/Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	— — 4/50 48/— yes/yes yes/yes/yes yes/yes yes/liquid no/— yes/yes no/no no/no — -20°C/— -20°C/— 12 months/24 months	real-time PCR for most probe types, melt analysis yes/yes/in development (Q2 2013) designed for multiple assays up to 24 samples/significant number unitized reagent strips; one test per strip; 24 strips per kit/yes yes/yes yes/yes/yes yes/yes yes/liquid and dry no/no (system has a closed-unit test format disposable) yes/no yes/yes yes (with user-supplied primers and probes in open system format)/on terms 12 months/12 months room temperature/room temperature room temperature/room temperature 3 months/12–24 months
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	no/yes no/no — — yes/no no/—/— —	no/yes —/no yes/determined and validated by user determined and validated by user/determined and validated by user no/no no/none/— user validates and defines external run control protocol
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b>	5 hours/15 minutes yes/504 3 hours/no	MRSA: 1–12 samples in <1.5 hours; 24 samples in 2 hours/~1 min. per sample yes/self-contained in unitized reagent strip MRSA: 1–12 samples in <1.5 hours; 24 samples in 2 hours/automatic move to standby no/no/biohazard waste no/mouse/no
<b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	no/no/built-in waste tray; solid state waste products yes/mouse/yes	
<b>Service contracts available/Mean time between failures/To repair failures</b> <b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	annual/—/— 24 hours/24 hours/48 hours —/24–48 hours/6 AM–6 PM (PDT) yes, within 24 hours/no yes no/yes/no daily: 5 min.; weekly: 10 min.; monthly: 20 min.; yearly: 45 min./no —/1 1 day/no	5 and 7 days per week/180 days/<24 hours from field service visit <1 hour after hours/same day (next day after hours)/next business day —/next business day/24 hours, 7 days —/no yes no/yes/no weekly: 10 minutes/— 1/1 (for total system) 4 hours/no
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability Interfaces operational in active user sites Rules-based control subsystem/Process control via control subsystem LIS operates simultaneously with assays running Uses LOINC to transmit orders and results/Unidirectional interface capability Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system Stores QC lot files/Worklist edit capability/Viewable PCR graphs Can print, archive, transmit data	no yes no/yes yes — yes/no yes/no/— no yes/— —/yes yes yes/yes yes no/no yes/no —/yes/no yes	no — no/yes no yes/— yes/no no/no/no — — — yes — — — — yes/yes/yes yes
<b>Distinguishing features (supplied by company)</b>	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	fully automated processing from sample lysis to PCR interpretation for FDA-cleared IVD assays and user-defined protocols
<small>*for calibration and controls Note: a dash in lieu of an answer means company did not answer question or question is not applicable</small>		

## Automated molecular platforms

<b>Part 3 of 11</b>	<b>BD Diagnostic Systems</b>	<b>BD Diagnostics</b>
<i>See captodayonline.com/productguides for an interactive version of guide</i>	John S. Favara john_favara@bd.com 7 Loveton Circle, Sparks, MD 21512 410-316-3597 www.bd.com/ds	Germán Núñez german_nunez@bd.com 54 Loceton Circle, Sparks, MD 21152 410-316-3568 www.bd.com/ds
<b>Name of instrument</b>	<b>Affirm VPIII Microprocessor</b>	<b>BD Viper System with XTR Technology</b>
<b>Country where designed/Manufactured/Reagents manufactured Instrument FDA cleared or approved/Platform First year sold in U.S./Sold internationally/Installed</b>	<b>U.S./U.S./U.S. yes/analytical 1996/1996/1996</b>	<b>U.S./U.S./U.S. yes/analytical 2009/2008/2009</b>
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB Supplied with UPS/BTU Physical contamination control features</b>	<b>6 × 10 × 9/.63/quiet no/— —</b>	<b>83 × 75 × 42/262/&lt;65 yes/2,048 per hour closed solid barrier amplification</b>
<b>List price/Price for sample extraction and amplification detection modules Purchase options/Minimum test volume requirements Co. performs installation, operation, and performance qualifications/Electrical req. Labor and parts warranties/Advanced operator training Delivery time/Delivery charges/Installer/Time to install on site Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility</b>	<b>\$12,990/— straight purchase, reagent rental/three tests per day no/120V 1 year/no 2 weeks/none for instrumentation/BD field applications/4 hours on site/6/4 hours/no</b>	<b>\$345,000/— straight purchase, reagent rental, lease/12,000 specimens per year yes/208–240 VAC 1 year/yes 30 days/FOB (origin)/field service engineer/3 days on site and off site/1/3 days/yes</b>
<b>Test menu/No. of tests for which analyzer has FDA-cleared applications/CE-mark 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 Research-use-only assays/Tests in development</b>	<b>Candida species (six different), Gardnerella vaginalis, Trichomonas vaginalis/3/3 3/3 — —</b>	<b>Chlamydia, gonorrhea, HSV-1, HSV-2  4/5 Trichomonas —</b>
<b>Open-channel capabilities/Start-up and preparation time</b>	<b>no/immediate</b>	<b>no/10 minutes</b>
<b>Model type of sample-handling system/Maximum sample load capacity Minimum specimen volume/Sample volume flexibility/Other sample volumes available Minimum dead volume/Pediatric sample volume/Primary tube sampling Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D Sample bar-code languages/Sample types available in open mode Clot detection/Open extraction platform/Sample types (open extraction)</b>	<b>swab, tube, and cap/6 —/no/— —/—/yes 5 mL/no/no — no/no/—</b>	<b>sample rack/96 samples 2.5 mL/no/— 800 μL/—/yes 2.5 mL/yes/no 2 of 5, Codabar, codes 39 and 128/vaginal and endocervical swabs, urethral swabs, urine, liquid-base cytology (SurePath, ThinPrep) yes/no/vaginal and endocervical swabs, urethral swabs, urine, and more</b>
<b>Amplification reagents or methods supported Extraction methods supported for: RNA extract./DNA extract./total nucleic acid No. of different assays onboard at once/Programmed or calibrated at once Tests per container set/Multiple reagent configurations supported Reagent container placed directly on system/Onboard test auto inventory Determines reagent volume in container Reagent bar-code reading/Reagents bar coded Monitors expiration date/Auto lot recognition or calibration Auto detection of adequate reagent or specimen/Reagents available Reagent reconstitution required/Chemical contamination control Onboard test auto inventory/Capable of inventory monitoring by bar code System is open to homebrew/General-purpose reagents allowed Same capabilities when third-party reagent used/Lot sequestering available 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</b>	<b>— — 3/3 24 or 120/— yes/no no no/no no/no no/dry no/— no/no no/no no/no — — — 6 months/14 months</b>	<b>strand displacement amplification yes/yes/yes 5/5 CT: 1,152; GC: 1,152; HSV1 and 2: 96/no yes/no no yes/yes yes/no yes/liquid and dry no/— no/no no/no no/yes 18 months/18 months room temperature/room temperature room temperature/room temperature 3 months/24 months</b>
<b>Autocalibration or autocalibration alert/Multipoint calibration supported Assay calibrations required by end-user/Calibrants can be stored onboard Multiple calibrant lots stored for same assay/Required calibration frequency Length of assay calibration/Typical calibration frequency Onboard real-time QC/Supports multiple QC lot numbers per assay Auto shutdown*/Instrument warm-up time/Onboard software reviews QC Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	<b>no/no no/no no/factory calibrated only — no/no no/—/no —</b>	<b>no/no no/no no/— — no/yes no/—/no 2/2/4/4</b>
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples) Uses disposable pipette tips/Maximum number of pipette tips stored Time between start and initial result/Instrument automatic shutdown</b>	<b>6/5 minutes no/— 45 minutes/no</b>	<b>3 hours, 5 minutes/10 minutes yes/768 3 hours, 15 minutes/no</b>
<b>Startup programmable/Remote system monitoring/Waste req. for disposables Windows technology/Mouse or touchscreen/Modular add-on capability</b>	<b>no/no/bio-waste no/—/no</b>	<b>yes/yes/solid (disposable tips) and neutralized liquid waste yes/touchscreen/no</b>
<b>Service contracts available/Mean time between failures/To repair failures Turnaround time for problem solving by phone/e-mail/field service No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail. Guaranteed response time/Modem servicing available System diagnoses malfunctions Order parts via modem/Onboard error codes/Maintenance training demo module Average maintenance time for lab personnel/Onboard maintenance records Preventive maintenance per year for sample extraction/amplification detection Downtime for preventive maintenance/Spare parts on site</b>	<b>repair by replacement (normally ships same day of call to tech service)/—/single swap option within 24 hours immediate during business hours; one hour nonbusiness/immediately/as needed 10–12/—/— no/no yes no/yes/no daily: &lt;5 minutes/no — —/no</b>	<b>5 days, 8 AM–5 PM, 7 days, 24 hours/280 days/24 hours real time/—/24 hours &gt;30/24 hours/24 hours, 7 days —/yes yes no/yes/no daily, weekly, and monthly: 15 minutes/no 1/1 1 day/no</b>
<b>Software and LIS interface:</b>		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	no	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/no	yes/yes
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	no/yes
• Unique bar code per container/Multistop routing (1 tube to many workstations)	no/no	no/no
• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions	no/no/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/no	no/LIS-RS-232 serial ASTM 1381/1394
• QC results transferred automatically to LIS/Data-management capability	no/no	yes/no
Interfaces operational in active user sites	no	yes
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/yes
Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system	no/no	yes/yes
Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/no/no	yes/yes/no
Can print, archive, transmit data	no	yes
<b>Distinguishing features (supplied by company)</b>	<b>simultaneous detection/differentiation of the three organisms that cause up to 90 percent of vaginal infections; one sample with three results; quick turnaround time (45 minutes for six samples or 18 results); simultaneously detects mixed infections caused by three organisms</b>	<b>reduced hands-on time requirement for set up and maintenance; fully automated specimen processing with high walkaway time; FDA cleared for two common liquid-base cytology specimens and fully automated for FDA-cleared HSV-1 and -2 assays</b>

\*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

<b>Part 4 of 11</b>	<b>BioFire Diagnostics (formerly Idaho Technology)</b> Wade Stevenson wade.stevenson@biofiredx.com 390 Wakara Way, Salt Lake City, UT 84108 801-736-6354 www.biofiredx.com	<b>bioMérieux</b> Steve Shumoski steve.shumoski@biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-270-9356 www.biomerieux-usa.com
See captodayonline.com/productguides for an interactive version of guide		
<b>Name of instrument</b>	FilmArray	NucliSENS EasyMAG
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	U.S./U.S./U.S. yes/preanalytical and analytical 2009/2010/2009	Netherlands and Australia/Italy/France yes/preanalytical 2005/2005/2005
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b> <b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	6.5 × 10 × 15.5/1.08/74 dB — closed system	20.9 × 39.4 × 25.6/3.7/between 67 and 75 no/341 per hour maximum (less in standby) single-well processing; onboard extraction buffers in closed containers; separation of buffer dispense and aspiration functions; others
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/</b> <b>Length of training/Retraining at company facility</b>	— straight purchase, reagent rental/none yes/90–264 VAC, 10A labor and parts: 5 years/no —/origin/BioFire Diagnostics/1 hour on site/up to 5/1 hour per tech/yes	\$79,500/sample extraction: \$79,500 straight purchase, reagent rental, lease/1 yes/110V labor and parts: 1 year/yes 30 days/destination and origin, price varies/field service engineer/5 hours on site/1 or more/1.5 days/no
<b>Test menu/No. of tests for which analyzer has FDA-cleared applications/CE-mark</b>	adenovirus; coronavirus 229E, HKU1, OC43, and NL63; influenza A, A H1, A H1 2009, A H3, and B; human metapneumovirus; parainfluenza 1, 2, 3, and 4; respiratory syncytial virus; rhinovirus/enterovirus; Bordetella pertussis; Chlamydomphila pneumoniae; Mycoplasma pneumoniae/—	universal set of IVD-labeled reagents for total nucleic acid extraction on label for use with specific FDA-cleared tests from other companies/14/15
<b>Tests available on instrument in U.S./Outside U.S.</b>	—	eSensor RVP (GenMark); xTAG 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), others / HIV-1, HPV (bioMérieux) R-gene adenovirus (bioMérieux); xTAG GPP (Luminex)
<b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b> <b>Research-use-only assays/Tests in development</b> <b>Open-channel capabilities/Start-up and preparation time</b>	— —/GI panel, blood culture identification panel, meningitis panel no/2 minutes	HIV-1 RUO, HPV RUO, KPC RUO (U.S.)/— yes/10–15 minutes
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b>	—/1 300 µL/no/— —/300 µL/no —/yes/— —	EasyMAG/24 10 µL/yes (intra-run/batch range of 10–1,000 µL)/up to 1,000 µL 10 µL/same sample volume range, dependent on downstream application/no —/yes/no code 128 for reagents and disposables, EAN 8/EAN, 13 / UPC A/UPC E, Interleaved 2 of 5, standard code 39, others/various yes/yes/various
<b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	—/no/—	
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b> <b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container/Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	PCR yes/yes/yes 20/20 30/— yes/no —/yes/yes yes/yes no/dry yes/— —/no no/no no/no 4 months/4 months room temperature/room temperature room temperature/room temperature up to 4 months	— (extraction instrument) yes/yes/yes 24 positions each can extract for a distinct assay/— main components: 384 extractions/universal reagent set yes/yes yes/yes/yes yes/no yes/liquid no/— no/no yes/no no/no extraction: up to 30 days onboard the system extraction: mostly room temperature with 2 components at 2°–8°C extraction: RTI 60 days/15–24 months
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	yes/— no/— — — yes/— —/1 minute/yes —	no/no no/no no/— — no/no no/none/no 24 tests: downstream assay dependent/—/—/—
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	— no/— ~1 hour/— — yes/mouse/no	— no/— 45 minutes/no no/no/normal biohazardous waste yes/mouse and touchscreen/yes
<b>Service contracts available/Mean time between failures/To repair failures</b> <b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	parts and labor/—/— — —/—/24 hours, 7 days — — — — — — —	7 days full service, preventive maintenance/extraction: 328 days/3.5 hours immediate (30 min. after hours)/<24 hours/within 2 hours after scheduling 32/within 24 hours/24–7 phone support; 12–7 PM on-site support yes/no no no/yes/yes daily: 5 minutes; weekly: 10 minutes; yearly: performed by FSE/no extraction: 2 3 hours/no
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability <b>Interfaces operational in active user sites</b> <b>Rules-based control subsystem/Process control via control subsystem</b> <b>LIS operates simultaneously with assays running</b> <b>Uses LOINC to transmit orders and results/Unidirectional interface capability</b> <b>Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system</b> <b>Stores QC lot files/Worklist edit capability/Viewable PCR graphs</b> <b>Can print, archive, transmit data</b>	— yes no/— — — — — — — — — — — — — —/—/yes yes	no data retrieval no/no no no/no yes/no yes/no/— no yes/XML file transfer yes/yes yes no/yes yes no/yes yes/no no/yes/no yes
<b>Distinguishing features (supplied by company)</b>	user-friendly multiplex PCR; fully automated; sample to result in about one hour; two minutes hands-on time; simultaneous detection of 20 viruses and bacteria	varies sample and elution volumes from sample to sample in the same run; entire extraction process in a single sample compartment, minimizing potential sample loss and cross-contamination; doesn't use multiple racks of pipette tips or processing plates, thus reducing plastics waste

\*for calibration and controls

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

## Automated molecular platforms

<b>Part 5 of 11</b>	bioMérieux Steve Shumoski steve.shumoski@biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-270-9356 www.biomerieux-usa.com	Cepheid David Freestone MarCommGroup@cepheid.com 904 Carribean Ave., Sunnyvale, CA 94089 www.cepheid.com
See captodayonline.com/productguides for an interactive version of guide		
<b>Name of instrument</b>	NucliSENS EasyQ	GeneXpert 1, GeneXpert 2, GeneXpert 4, GeneXpert 16
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	Finland/Finland/France yes/analytical 2002/2002/2002	U.S./U.S./U.S. yes/preanalytical and analytical 2006 (2011 for GX 2)/2006/2006
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b>	8.7 × 16.5 × 16.5/1.9/—	GeneXpert 1: 4 × 12 × 11.70; GeneXpert 2: 6.35 × 12 × 11.70; GeneXpert 4: 11 × 12 × 11.70; GeneXpert 16: 22.75 × 25.80 × 13.25; 2.625/—
<b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	no/~340 per hour closed reaction tubes	yes/— closed-cartridge technology
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/</b> <b>Length of training/Retraining at company facility</b>	\$55,000/amplification detection: \$55,000 straight purchase, reagent rental, lease/1 yes/110V 1 year/yes 30 days/destination and origin: price varies/field service engineer/6 hours on site and off site/1 or more/2 days/yes	\$24,900–\$174,400/— straight purchase, reagent rental, lease/— yes/100–120 VAC, 50–60 Hz 1 year/yes less than 1 week/FOB origin/company/<1 day on site/1 or more/<1 day/yes
<b>Test menu</b>	basic NASBA reagents for laboratory-developed test plus specific company-developed assays	Xpert SA nasal complete, Xpert vanA, Xpert C. difficile, Xpert MRSA/SA SSTI, Xpert MRSA/SA BC, Xpert MRSA, Xpert GBS, Xpert EV, Xpert FII & FV, Xpert Flu, Xpert C. difficile-Epi 11/13 —/Xpert MTB/RIF, Xpert CT/NG —
<b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b> <b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b> <b>Research-use-only assays/Tests in development</b>	2/6 MRSA, enterovirus (bioMérieux) / HIV-1, HPV, enterovirus, HSV, RSV, MRSA —/HIV-1, HPV, RSV, HSV U.S.: HIV-1 RUO, HPV RUO, KPC RUO; outside U.S.: hMPV RUO/KPC RUO	— — —
<b>Open-channel capabilities/Start-up and preparation time</b>	yes/30–40 minutes	yes/<1 minute
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b>	—/48 — —/—/no —/function of extraction platform/no —	cartridge-based/up to 16, based on number of installed modules —/yes (sample-type dependent: whole blood, swab, sputum fluids, others)/— —/—/no —/yes/yes all common/no restrictions
<b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	—	no/no/no restrictions
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b> <b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container</b> <b>Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	real-time NASBA applications analytical instrument one 48/basic NASBA reagent kits and specific assay kits no/no no no/no no/liquid and dry yes/— no/no yes/yes yes/no — 2°–8°C with some at –20°C/— refrigerate (some with dry ice)/— 30 days/24 months (basic kit); —/18 months (specific assay kits)	— yes/yes/yes full menu/full menu single-use cartridges/reagents contained in cartridge yes/yes yes yes/yes yes/liquid and dry no/closed-cartridge technology yes/yes no/no no/no up to 2 years/up to 2 years amplification and extraction: room temperature (2°–8°C depending on test) room temperature/room temperature 3 months/varies
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	yes/no no/no no/assay dependent assay dependent/assay dependent no/yes no/amplification module: 15 minutes/yes 24 and 42 tests: assay dependent, but typically 2	yes/yes no/— —/2,000 tests or 1 year 2,000 tests or 1 year/once per year yes/— no/none/yes 0/0/0/0
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	— no/— assay dependent (as early as 1 hour)/no no/no/normal biohazardous waste yes/mouse/yes	— no/— 35 minutes to 2 hours, depending on test/no —/—disposable cartridges yes/mouse/yes
<b>Service contracts available/Mean time between failures/To repair failures</b> <b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	7 days full service, preventive maintenance/amplification: 1,322 days/3.5 hours immediate (30 min. after hours)/<24 hours/within 2 hours after scheduling 32/within 24 hours/24–7 phone support; 12–7 PM on-site support yes/no no no/yes/no daily: 5 minutes; weekly: 10 minutes/no amplification: 1 4 hours/no	full service, labor and parts/—/24–48 hours M-F, 5 AM–5 PM: 5 minutes to 2 hours; limited on weekend/same as phone/— 10/within 24 hours/24–7 or M-F, 5 AM–5 PM yes (M-F, 5 AM–5 PM)/no no no/yes/yes monthly: up to 30 minutes for a fully populated system (GeneXpert 16)/no — 1–2 hours/no
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability <b>Interfaces operational in active user sites</b> <b>Rules-based control subsystem/Process control via control subsystem</b> <b>LIS operates simultaneously with assays running</b> <b>Uses LOINC to transmit orders and results/Unidirectional interface capability</b> <b>Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system</b> <b>Stores QC lot files/Worklist edit capability/Viewable PCR graphs</b> <b>Can print, archive, transmit data</b>	no data retrieval no/no no no/no yes/no yes/no/— no yes/XML file transfer yes/yes yes no/yes yes no/yes yes/no no/yes/yes yes	yes yes yes/yes yes yes/yes yes/yes/yes yes yes/TCP-IP yes/yes yes yes/yes yes yes/yes yes/yes yes/yes/yes yes
<b>Distinguishing features (supplied by company)</b>	analyzes real-time NASBA applications: isothermal amplification using fluorophore-labeled molecular beacons for detection; intuitive and flexible assay-analysis software; compact footprint for 48-test capacity instrument	fully integrated real-time PCR system; automated and integrated steps for PCR-based DNA testing: sample preparation, DNA amplification and detec- tion; simplifies hands-on preparation; provides PCR test results from raw sample in ~1 hour; variety of configurations to meet broad range of demands

\*for calibration and controls

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

## Automated Molecular Platforms

<b>Part 6 of 11</b>	<b>Cepheid</b> David Freestone MarCommGroup@cepheid.com 904 Carribean Ave., Sunnyvale, CA 94079 888-336-2743 www.cepheid.com	<b>GenMark Diagnostics</b> info@genmarkdx.com 5964 La Place Court, Carlsbad, CA 92008 800-eSensor (373-6767) www.genmarkdx.com
See captodayonline.com/productguides for an interactive version of guide		
<b>Name of instrument</b>	GeneXpert Infinity-48, Infinity-48s, Infinity-80	eSensor XT-8
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	U.S./U.S./U.S. yes/preanalytical and analytical 2009/2009/2009	U.S./U.S./U.S. yes/analytical 2007/—/2007
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b> <b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	79.1 × 105.2 × 34.6 (48); 78.5 × 85 × 34.6 (48S); 78.5 × 108 × 35 (80)/25.25/— yes/— closed-cartridge technology	18 × 18 × 15/2.25/— yes/— closed-cartridge technology
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/</b> <b>Length of training/Retraining at company facility</b>	\$199,000–\$530,000/— straight purchase, reagent rental, lease/— yes/100–120 VAC, 50–60 Hz (48); 200–240 VAC, 50–60 Hz (48S, 80) 1 year/yes 2–4 weeks/FOB origin/company/<1 day on site/1 or more/1–3 days/yes	— straight purchase, reagent rental, lease/1+ yes/100–230 VAC labor and parts: standard 1 year, additional years available/yes 3 days/variable/GenMark Dx/<1 hour on site/up to 3/1–3 days/yes
<b>Test menu</b>	Xpert SA nasal complete, Xpert vanA, Xpert C. difficile, Xpert MRSA/SA SSTI, Xpert MRSA/SA BC, Xpert MRSA, Xpert GBS, Xpert EV, Xpert Fil & FV, Xpert Flu, Xpert C. difficile-Epi	eSensor cystic fibrosis genotyping test, eSensor respiratory viral panel, eSensor thrombophilia risk test, eSensor warfarin sensitivity test
<b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b> <b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b> <b>Research-use-only assays/Tests in development</b> <b>Open-channel capabilities/Start-up and preparation time</b>	11/13 —/Xpert MTB/RIF, Xpert CT/NG — — yes/<1 minute	3/— 3/— — — no/<5 minutes
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b>	cartridge-based/1,300 in 24 hours —/yes (sample-type dependent: whole blood, swab, sputum fluids, others)/— —/—/no —/yes/yes all common/no restrictions	cartridge-based/96 samples in 8-hour shift varies by test/yes/— —/—/no —/yes/no all common/—
<b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	no/no/no restrictions	—/yes/—
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b>	— yes/yes/yes	PCR no/yes/yes
<b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container</b> <b>Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	full menu/full menu single-use cartridges/reagents contained in cartridge yes/yes yes yes/yes yes/yes yes/liquid and dry no/closed-cartridge technology yes/yes no/no no/no up to 2 years/up to 2 years amplification and extraction: room temperature (2°–8°C depending on test) room temperature/room temperature 3 months/—	multiple (random access)/multiple (random access) 48 tests per kit/— no/no no yes/yes yes/yes no/liquid no/— no/— no/no no/yes up to 12 months/— -20°C/room temperature frozen/ambient up to 60 days/12 months
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	yes/yes no/— —/2,000 tests or 1 year per module 2,000 tests or 1 year per module/1 year yes/— no/none/yes 0/0/0/0	no calibration required no calibration required no calibration required no calibration required yes/— no/none/yes 1/1/1/1
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	~130 (48); ~115 (48S); ~175 (80): random access (not batch)/<2 minutes per sample: random access no/— 35 minutes to 2 hours, depending on test/no yes/no/disposable cartridges yes/mouse and touchscreen/yes	30 minutes, 24 samples/90 minutes no/— 30 minutes/no no/no/disposable cartridges yes/touchscreen/yes
<b>Service contracts available/Mean time between failures/To repair failures</b> <b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days available</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	full service, labor and parts/—/24–48 hours M-F, 5 AM–5 PM: 5 minutes–2 hours; limited on weekend/same as phone/— 10/within 24 hours/24-7 or M-F, 5 AM–5 PM yes (M-F, 5 AM–5 PM)/yes no no/yes/yes daily: <1 minute; weekly: <5 minutes; monthly: <30 minutes/no — 1–2 hours/no	field and depo service/—/within 48 hours M-F, 5 AM–8 PM PT: ≤1 hour; weekends on call/same as phone/within 48 hours 5/within 48 hours/7 AM–6 PM PT yes (within 48 hours)/no yes no/yes/no yearly: <15 minutes/yes — 60 minutes/no
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability <b>Interfaces operational in active user sites</b> <b>Rules-based control subsystem/Process control via control subsystem</b> <b>LIS operates simultaneously with assays running</b> <b>Uses LOINC to transmit orders and results/Unidirectional interface capability</b> <b>Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system</b> <b>Stores QC lot files/Worklist edit capability/Viewable PCR graphs</b> <b>Can print, archive, transmit data</b>	yes yes yes/yes yes yes/yes yes/yes yes/yes/— yes yes/TCP-IP yes/yes yes yes/yes yes yes/yes yes/yes yes/yes yes yes/yes yes/yes yes yes yes	no yes no/yes yes no/no yes/no no/no/— yes no/— no/yes yes no/yes — no/yes no/no no/yes/no yes
<b>Distinguishing features (supplied by company)</b>	fully automated, robotic, real-time PCR system integrates all steps required for PCR-based DNA testing: sample preparation, DNA amplification and detection; cartridge handling; fully integrated; built-in smart technology; fluid master scheduler prioritizes test runs; reduces hands-on labor	complete benchtop system for multiplex molecular testing; touchscreen user interface; customizable reports; no routine maintenance or calibration
<small>*for calibration and controls Note: a dash in lieu of an answer means company did not answer question or question is not applicable</small>		

# Automated Molecular Platforms

<p><b>Part 7 of 11</b></p> <p>See <a href="http://captodayonline.com/productguides">captodayonline.com/productguides</a> for an interactive version of guide</p>	<p><b>Hologic I Gen-Probe</b>                  Cliff Pollak <a href="mailto:clifford.pollak@hologic.com">clifford.pollak@hologic.com</a>                  10210 Genetic Center Dr., San Diego, CA 92121                  858-410-8000 <a href="http://www.gen-probe.com">www.gen-probe.com</a></p>	<p><b>Hologic I Gen-Probe</b>                  Brad Tieman <a href="mailto:brad.tieman@hologic.com">brad.tieman@hologic.com</a>                  10210 Genetic Center Dr., San Diego, CA 92121                  858-410-8000 <a href="http://www.gen-probe.com">www.gen-probe.com</a></p>
<p><b>Name of instrument</b></p>	<p>TIGRIS DTS Analyzer</p>	<p>PANTHER System</p>
<p><b>Country where designed/Manufactured/Reagents manufactured</b>  <b>Instrument FDA cleared or approved/Platform</b>  <b>First year sold in U.S./Sold internationally/Installed</b></p>	<p>U.S./U.S./U.S. and UK                  yes/preanalytical and analytical                  2004/2005/2004</p>	<p>U.S./Switzerland/U.S.                  yes/preanalytical and analytical                  2012/2010/2010</p>
<p><b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b>  <b>Supplied with UPS/BTU</b>  <b>Physical contamination control features</b></p>	<p>72 × 69 × 36/17.25/compliant with EN 61010-1                  yes/2,637                  closed system, liquid level sensing, pressure-dispense verification, on-board deactivation, deep-well reaction tube, single sample aspiration and dispense, penetrable cap</p>	<p>69 × 48 × 32/10.6/&lt;55                  yes/1,878 per hour                  closed system, liquid level sensing, pressure-dispense verification, on-board deactivation, deep-well reaction tube, single sample aspiration and dispense, penetrable cap</p>
<p><b>List price/Price for sample extraction and amplification detection modules</b>  <b>Purchase options/Minimum test volume requirements</b>  <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b>  <b>Labor and parts warranties/Advanced operator training</b>  <b>Delivery time/Delivery charges/Installer/Time to install on site</b>  <b>Training location/No. of techs that can receive initial training/Length of training/Retraining at company facility</b></p>	<p>—                  straight purchase, reagent rental, lease/variable                  yes/220V                  labor and parts: 1 year/yes                  &lt;1 week/variable at origin and destination/Gen-Probe/2–3 days                  on and off site/2/4 days/yes</p>	<p>—                  straight purchase, reagent rental, lease/400 µL                  yes/100–230V                  labor and parts: 1 year/yes                  ~1 week/variable at origin and destination/Hologic/1–2 days                  on and off site/2/3 days/yes</p>
<p><b>Test menu</b>  <b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b>  <b>Tests available on instrument in U.S./Outside U.S.</b></p> <p><b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b>  <b>Research-use-only assays/Tests in development</b>  <b>Open-channel capabilities/Start-up and preparation time</b></p>	<p>CT-GC, CT, GC, HPV, Trichomonas, HPV genotyping                  5/6                  CT-GC, CT, GC, HPV, Trichomonas/CT-GC, CT, GC, HPV, HPV genotyping, Trichomonas                  HPV genotyping/—                  —/HPV genotyping                  yes/~30 minutes</p>	<p>CT-GC, CT, GC, HPV, Trichomonas                  1/5                  CT-GC/CT-GC, CT, GC, HPV, Trichomonas                  Trichomonas/CT, GC, HPV, Trichomonas                  —/HPV genotyping, HSV-1 and -2, Virology                  yes/&lt;15 minutes</p>
<p><b>Model type of sample-handling system/Maximum sample load capacity</b>  <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b>  <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b>  <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b>  <b>Sample bar-code languages/Sample types available in open mode</b>  <b>Clot detection/Open extraction platform/Sample types (open extraction)</b></p>	<p>onboard automated pipettor/180                  400 µL/no/—                  800 µL/—/yes                  various/yes (automated onboard scanner to maintain positive sample ID)/no                  2 of 5 interleaved, Codabar, codes 39 and 128/—                  yes/no/—</p>	<p>automated onboard/120                  400 µL/no/—                  800 µL/—/yes                  various/yes (automated onboard scanner to maintain positive sample ID)/no                  Codabar, codes 39 and 128, interleaved 2 of 5, JAN13, Code 93, UPC/—                  yes/no/—</p>
<p><b>Amplification reagents or methods supported</b>  <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b>  <b>No. of different assays onboard at once/Programmed or calibrated at once</b>  <b>Tests per container set/Multiple reagent configurations supported</b>  <b>Reagent container placed directly on system/Onboard test auto inventory</b>  <b>Determines reagent volume in container</b>  <b>Reagent bar-code reading/Reagents bar coded</b>  <b>Monitors expiration date/Auto lot recognition or calibration</b>  <b>Auto detection of adequate reagent or specimen/Reagents available</b>  <b>Reagent reconstitution required/Chemical contamination control</b>  <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b>  <b>System is open to homebrew/General-purpose reagents allowed</b>  <b>Same capabilities when third-party reagent used/Lot sequestering available</b>  <b>Closed-vial stability for amplification reagents/Extraction reagents</b>  <b>Storage temp. requirement for amplification reagents/Extraction reagents</b>  <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b>  <b>Minimum/Maximum reagent shelf-life guarantee</b></p>	<p>transcription-mediated amplification                  yes/no/no                  4/4                  100 or 250/yes                  yes/yes                  yes                  yes/yes                  yes/yes                  yes/liquid                  yes/yes                  yes/yes                  no/no                  no/yes                  assay dependent/assay dependent                  refrigeration/refrigeration                  room temperature/room temperature                  —/up to 1.5 years after manufacture date</p>	<p>transcription-mediated amplification                  yes/yes/yes                  4/4                  100 or 250/yes                  yes/yes                  yes                  yes/yes                  yes/yes                  yes/liquid                  yes/yes                  yes/yes                  —                  —                  assay dependent/assay dependent                  refrigeration/refrigeration                  room temperature/room temperature                  —/up to 1.5 years</p>
<p><b>Autocalibration or autocalibration alert/Multipoint calibration supported</b>  <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b>  <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b>  <b>Length of assay calibration/Typical calibration frequency</b>  <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b>  <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b>  <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b></p>	<p>—/yes                  —/no                  no/assay dependent (done per worklist)                  —/assay dependent (done per worklist)                  —/—                  no/—/—                  4/4/4/4 (4 controls for up to 250 tests)</p>	<p>yes/—                  yes/yes                  no/24 hours                  24 hours/24 hours                  —/yes                  yes/&lt;15 minutes/yes                  2/2/2/2</p>
<p><b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b>  <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b>  <b>Time between start and initial result/Instrument automatic shutdown</b>  <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b>  <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b></p>	<p>up to 180 samples/&lt;19 seconds per sample                  yes/480 (1.2 tips per sample)                  3.5 hours/no                  no/yes/plastics and cardboard                  yes/mouse and touchscreen/no</p>	<p>up to 120 samples/&lt;15 sec per sample                  yes/576 (2.2 tips per sample)                  3.5 hours/no                  yes/yes/plastics and cardboard                  yes/touchscreen/yes</p>
<p><b>Service contracts available/Mean time between failures/To repair failures</b></p>	<p>premiere and standard/—/—</p>	<p>standard and premiere/—/—</p>
<p><b>Turnaround time for problem solving by phone/e-mail/field service</b>  <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b>  <b>Guaranteed response time/Modem servicing available</b>  <b>System can diagnose own malfunctions</b>  <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b>  <b>Average maintenance time for lab personnel/Onboard maintenance records</b>  <b>Preventive maintenance per year for sample extraction/amplification detection</b>  <b>Downtime for preventive maintenance/Spare parts on site</b></p>	<p>—                  —/—/premiere: 24 hours/7days; standard: M-F 8 AM–5 PM PST                  &lt;24 hours/Internet                  no                  no/yes/no                  daily: 15 minutes; weekly: 5 minutes; monthly: 3 hours/yes                  2/2                  1 day/yes</p>	<p>—                  —/24 hours/premiere: 24 hours/7 days; standard: M-F 8 AM–5 PM PST                  yes/yes                  yes                  no/yes/no                  weekly: &lt;5 minutes; monthly: &lt;45 minutes/yes                  2/2                  &lt;1 day/yes</p>
<p><b>Software and LIS interface:</b></p> <ul style="list-style-type: none"> <li>• Patient demographics and insurance data available via rules-based architecture</li> <li>• Data retrieval or Internet connectivity</li> <li>• Online real-time help, QC, stats, and management reports/Evaluates results validity</li> <li>• Priority processing</li> <li>• Supports accession No. redundancy/Specimen carrier and level identification</li> <li>• Unique bar code per container/Multistop routing (1 tube to many workstations)</li> <li>• Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions</li> <li>• Sample storage and retrieval software supports CLSI standards</li> <li>• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS</li> <li>• QC results transferred automatically to LIS/Data-management capability</li> </ul> <p><b>Interfaces operational in active user sites</b>  <b>Rules-based control subsystem/Process control via control subsystem</b>  <b>LIS operates simultaneously with assays running</b>  <b>Uses LOINC to transmit orders and results/Unidirectional interface capability</b>  <b>Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system</b>  <b>Stores QC lot files/Worklist edit capability/Viewable PCR graphs</b>  <b>Can print, archive, transmit data</b></p>	<p>no                  yes                  no/yes                  no                  no/yes                  yes/no                  no/no/—                  no                  yes/LIS1-A and LIS2-A2 (ASTM), custom flat file LIS formats                  yes/yes                  yes                  yes/yes                  yes                  yes                  yes                  no/yes                  yes/no                  yes/yes/no                  yes</p>	<p>no                  yes                  yes/yes                  yes                  yes/—                  yes/no                  no/—/—                  no                  yes/LIS1-A and LIS2-A2 (ASTM)                  yes/yes                  yes                  yes/yes                  yes                  yes                  no/yes                  yes/—                  —/yes/—                  yes</p>
<p><b>Distinguishing features (supplied by company)</b></p>	<p>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</p>	<p>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</p>
<p><small>*for calibration and controls                  Note: a dash in lieu of an answer means company did not answer question or question is not applicable</small></p>		

## Automated Molecular Platforms

<b>Part 8 of 11</b>	Life Technologies 5791 Van Allen Way Carlsbad, CA 92008 800-955-6288 www.lifetechnologies.com	Meridian Bioscience 3471 River Hills Drive Cincinnati, OH 45244 513-271-3700 www.meridianbioscience.com
See captodayonline.com/productguides for an interactive version of guide		
<b>Name of instrument</b>	7500 Fast Dx Real-Time PCR Instrument	Illumipro-10
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	U.S./Singapore/— yes/analytical 2008/2010/2009	U.S./U.S./U.S. yes/analytical 2010/2010/2010
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b> <b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	19.29 × 13.99 × 17.72/1.8/— no/maximum output: 3241.5 BTU/H (950 W) no	8.3 × 11.5 × 3.7/66/— no/— closed test devices
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/</b> <b>Length of training/Retraining at company facility</b>	\$65,900/amplification: \$65,900 straight purchase, reagent rental, lease/10 µL yes/100–240 VAC at 50 or 60 Hz and 15A circuit 1 year/yes —/—/certified applied biosystems field service agent/— on site/based on customer requirements/—/yes	\$8,300/amplification: \$8,300 straight purchase, reagent rental/100 µL yes/100–240 V AC, 50/60 Hz 1 year/no 1 business day/based on location/Meridian Bioscience (optional)/1 day on site/no limit/2 hours/no
<b>Test menu</b>	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 ProVue PSA assay	C. difficile, group B strep, group A strep
<b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b> <b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b> <b>Research-use-only assays/Tests in development</b> <b>Open-channel capabilities/Start-up and preparation time</b>	— — — — yes/<5 minutes	3/3 3/3 — —/Mycoplasma, Bordetella, Chlamydia trachomatis, Neisseria gonorrhoea no/2 minutes hands-on time per sample, 12 minutes total
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b>	—/96 10 µL (reaction volume)/yes, reaction volumes 10 µL–30 µL/10 µL–30 µL —/—/no —/no/no —/nucleic acid signals from reverse-transcribed RNA	—/10 per Illumipro module 100 µL/no/— —/100 µL/no —/yes/no Codabar, codes 39, 93-93i, 128-IBT, UPC-EAN-ISBN, 128-UCC EAN 128, interleaved 2 of 5 no/no/—
<b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	no/no/—	no/no/—
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b> <b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container</b> <b>Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	nucleic acid signals from reverse-transcribed RNA — dependent on real-time PCR reaction plate setup/— — no/no no no/no no/no no/liquid yes/no no/no yes/yes yes/no — — — —	loop mediated isothermal amplification heat treatment rather than conventional extraction 3/3 50/no no/no no no/no no/liquid and dry yes/closed test device system with internal control no/no no/no no/no no/no 18 months/— 2°–27°C/— RT/— 2 months/18 months
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	no/yes yes/no no/6 months or after service repair <1 day/6 months no/no no/none/yes end user and assay dependent	—/no no/no no/none, monthly optic verification 2 minutes for optic verification/2 minutes no/yes yes/5 minutes/no controls run with each kit lot or shipment
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	40 minutes to >2 hours/<1 hour no/— assay run mode dependent/no no/no/none yes/mouse/no	10 samples per batch per module/2 minutes per sample no/200 batches per 1,000 samples 40 minutes/yes no/no/— no/—/yes
<b>Service contracts available/Mean time between failures/To repair failures</b>	service plans, compliance services, extended warranty/—/—	3-year extended warranty/—/24 hours
<b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	— —/—/M-F, 8 AM – 5 PM — no no/yes/no — —/twice per year yes/no	10 minutes/10 minutes/none —/—/M-F, 8 AM–6 PM EST yes, 24-hour replacement shipment/no yes no/yes/yes daily: 1 minute; monthly: 2 minutes/no — none/no
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability Interfaces operational in active user sites Rules-based control subsystem/Process control via control subsystem LIS operates simultaneously with assays running Uses LOINC to transmit orders and results/Unidirectional interface capability Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system Stores QC lot files/Worklist edit capability/Viewable PCR graphs Can print, archive, transmit data	no no no/no no no/no no/no no no/— no/no no no no no no no no no no/yes/yes yes	no no no/yes no yes/no no/no no/no/no no no/— no/yes no no/no no no no/no no/no no/no no
<b>Distinguishing features (supplied by company)</b>	96-well format eases plate setup, tube strips capped immediately after pipetting each sample; runs in <40 minutes; standard-length real-time PCR assays without changing thermal cycling parameters; five-color variable excitation enables multiplex assays; security, auditing, and e-signatures allow full control over thermal cycling protocols	loop-mediated isothermal amplification technology eliminates need for thermal cycling equipment; no extensive purification or extraction required; results in under one hour
<small>*for calibration and controls Note: a dash in lieu of an answer means company did not answer question or question is not applicable</small>		



## Automated Molecular Platforms

<p><b>Part 9 of 11</b></p> <p>See <a href="http://captodayonline.com/productguides">captodayonline.com/productguides</a> for an interactive version of guide</p>	<p><b>Nanosphere</b>                  Zack Crowther zcrowther@nanosphere.us                  4088 Commercial Ave., Northbrook, IL 60062                  888-837-4436 www.nanosphere.us</p>	<p><b>Nanosphere</b>                  Zack Crowther zcrowther@nanosphere.us                  4088 Commercial Ave., Northbrook, IL 60062                  888-837-4436 www.nanosphere.us</p>
<b>Name of instrument</b>	Verigene Processor SP with Verigene Reader	Verigene Processor with Verigene Reader
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	U.S./U.S./U.S. yes/preanalytical and analytical 2009/2010/2009	U.S./U.S./U.S. yes/analytical 2007/—/2007
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b> <b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	18.7 × 19.3 × 22.9/3.1/— — —	12.4 × 37.1 × 20.5/5.3/— — —
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/Length of training/Retraining at company facility</b>	— straight purchase, reagent rental, lease/— —/standard —/no varies/varies/Nanosphere technician/1–2 days on site/1 or more/varies/—	— straight purchase, reagent rental, lease/— —/standard —/no varies/varies/Nanosphere technician/1–2 days on site/1 or more/varies/—
<b>Test menu</b> <b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b>	Verigene respiratory virus plus test and gram-positive blood culture test 2/4 Verigene respiratory virus plus test, Verigene gram-positive blood culture test/Verigene respiratory virus plus test, Verigene gram-positive blood culture test, Verigene CYP 2C19 test, Verigene warfarin metabolism test Verigene clopidogrel metabolism test/—	Verigene warfarin metabolism test; Verigene F5/F2/MTHFR test 4/— Verigene warfarin metabolism test; Verigene F5-F2-MTHFR test/—
<b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b>	—/C. difficile, gram-negative blood culture test, respiratory virus expanded panel, enteric pathogens panel, cardiac troponin I	—
<b>Research-use-only assays/Tests in development</b>	—	—
<b>Open-channel capabilities/Start-up and preparation time</b>	no/5 minutes	no/10 minutes
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b> <b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	—/1 mL 200 µL/—/1 mL —/—/yes —/yes/— — no/—/—	—/4 25 µL/—/— — — — no/—/—
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract/DNA extract/total nucleic acid</b>	proprietary —	no target amplification required —
<b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container</b> <b>Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	1/— — yes/— — yes/yes —/no no/liquid no/— — no/no no/— — —20°C/refrigerate —20°C/refrigerate —	4/— — — — yes/yes —/no no/liquid no/— — no/no no/— no target amplification required/— no target amplification required/— no target amplification required/refrigerate —
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	— no/— — — — —/sample extraction: ~2 minutes/— —	— no/— — — — — —
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	random-access system/random-access system yes/— 2.0–2.5 hours/— — no/touchscreen/yes	4 samples per processor/random-access system — 1.5–2 hours/— — no/touchscreen/yes
<b>Service contracts available/Mean time between failures/To repair failures</b> <b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	— — — — — —/yes/— daily: 1 minute/— — —	— — — — — —/yes/— daily: 1 minute/— — —
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability Interfaces operational in active user sites Rules-based control subsystem/Process control via control subsystem LIS operates simultaneously with assays running Uses LOINC to transmit orders and results/Unidirectional interface capability Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system Stores QC lot files/Worklist edit capability/Viewable PCR graphs Can print, archive, transmit data	— yes — — — — — — — — yes — — — — — — — — —	— yes — — — — — — — yes — — — — — — — — —
<b>Distinguishing features (supplied by company)</b>	FDA-cleared tests; on-demand, automated, multiplex testing for respiratory viruses and bloodstream infections, processor SP designated as CLIA moderate-complexity; scalable, random-access platform, short hands-on time	FDA-cleared tests; scalable, random-access platform; on-demand, semiautomated, multiplex testing

\*for calibration and controls

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

## Automated molecular platforms

<b>Part 10 of 11</b>	<b>QIAGEN</b>	<b>Roche Diagnostics Corporation</b>
See <a href="http://captodayonline.com/productguides">captodayonline.com/productguides</a> for an interactive version of guide	Tracy Gambrell <a href="mailto:tracy.gambrell@qiagen.com">tracy.gambrell@qiagen.com</a> 19300 Germantown Road, Germantown, MD 20874 240-686-7430 <a href="http://www.qiagen.com">www.qiagen.com</a>	Carol Hausrath <a href="mailto:carol.hausrath@roche.com">carol.hausrath@roche.com</a> 9115 Hague Road, Indianapolis, IN 46250 317-521-1839 <a href="http://www.roche-diagnostics.us">www.roche-diagnostics.us</a>
<b>Name of instrument</b>	QIASymphony RGQ	cobas 4800 system
<b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b>	Switzerland/Switzerland/Germany no/preanalytical and analytical 2011/2010/2010	Switzerland/Switzerland/U.S. yes/analytical 2011/2009/2011
<b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b>	107 × 150 × 50/27/—	cobas x 480: 35.6 × 65.55 × 30.5/19.6/<65; cobas z 480: 19.6 × 22.6 × 23.1/19.6/<65
<b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b>	no/— UV decontamination, drop catchers	yes/1,300 W Core Tip technology to reduce cross-contamination
<b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b>	— straight purchase, reagent rental, lease/— yes/110 volts	— straight purchase, reagent rental, lease/— yes/cobas x 480: line voltage 115 VAC to 230, line frequency 50 or 60 Hz; cobas z 480 analyzer: 200–240 VAC, line frequency 50 or 60 Hz
<b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/</b> <b>Length of training/Retraining at company facility</b>	labor and parts: 1 year/yes 2–4 weeks/destination/Service Solutions/2 days on site/2–4/3 days/yes	labor: 1 year; parts: covered by service contract/yes 2–4 weeks/—/Roche service engineer/5 days on site and off site/2/4 days/yes
<b>Test menu</b> <b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b>	open platform 0/8 —/CMV, EBV, HSV, VZV, HIV, HCV, HBV	cobas HPV test, cobas CT/NG test, cobas 4800 BRAF v600 mutation test 3/3 cobas HPV test, cobas CT/NG test, cobas 4800 BRAF v600 mutation test/ cobas HPV test, cobas CT/NG test, cobas 4800 BRAF v600 mutation test
<b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b> <b>Research-use-only assays/Tests in development</b> <b>Open-channel capabilities/Start-up and preparation time</b>	—/CMV, EBV, BKV, HSV, VZV, HIV, HCV, HBV BKV/9 yes/30 minutes	— cobas EGFR and cobas KRAS mutation tests/MRSA/MSSA, C.diff, HSV, PI3K no/30 minutes
<b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b>	QIASymphony SP/96 (continuous load) 200 µL/yes (varies per sample type)/400 µL, 500 µL, 800 µL, 1,000 µL 100 µL/200 µL/yes 1.5–15 mL/yes/no Codabar, codes 39 and 128/plasma, blood, stool, urine, FFPE, respiratory, CSF, swabs, LBC, transport media yes/yes/same as sample types available in open mode	cobas x 480 instrument/94 samples 1 mL/—/— 1 mL/—/yes 13 mL (PreservCyt vial)/yes/no Codabar (without check sum), code 39 (without check sum), code 128, subset B and C (without check sum)/swab, urine, liquid-based cytology yes/no/—
<b>Clot detection/Open extraction platform/Sample types (open extraction)</b>	yes/yes/same as sample types available in open mode	yes/no/—
<b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b> <b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container</b> <b>Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temp. requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b>	open system for real-time PCR yes/yes/yes 4/— 4/yes yes/yes yes yes/yes yes/yes yes/liquid no/— yes/yes yes/yes yes/yes yes/yes 1 year/1 year room temperature/room temperature room temperature/room temperature 6 months/1 year	real-time PCR TNAI one/one 24 or 96 tests/24 or 96 tests no/no yes yes/yes yes/no yes/liquid no/yes, AmpErase enzyme yes/no yes/no no/no 12–18 months/12–18 months 2°–8°C/2°–25°C cool packs/cool packs 3 months/—
<b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b>	yes/yes no/yes yes/— —/— yes/yes no/none/yes assay dependent	no/no no/no no/— —/— yes/yes no/—/yes 2 (one positive, one negative)/—/—/2 (one positive, one negative)
<b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b>	4 hours/30 minutes yes/enough for 96 samples 6.5 hours for 96/no yes/yes/separate liquid, plastic and tip waste yes/mouse and touchscreen/yes	~90 percent of run time/40 minutes yes/960 assay dependent, 96 HPV results in <5 hours/no no/yes/plastic tips, liquid yes/mouse/no
<b>Service contracts available/Mean time between failures/To repair failures</b>	24 hours, 48 hour, and 5 days/—/—	M-F business hours or 7 days per week/sample: >100 days; amplification: >300 days/<4 hours
<b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b>	24 hours/24 hours/issue dependent 75/contract dependent/24 hours, 6 days per week yes (contract dependent)/no yes no/yes/yes daily: 10/no 1/1 4 hours/no	15 minutes/15 minutes/varies 250/24 hours/24 hours/7 days yes, 24 hours/yes yes no/yes/yes daily: 2–7 minutes; weekly: <5 minutes/yes 2/1 4 hours/no
<b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability <b>Interfaces operational in active user sites</b> <b>Rules-based control subsystem/Process control via control subsystem</b> <b>LIS operates simultaneously with assays running</b> <b>Uses LOINC to transmit orders and results/Unidirectional interface capability</b> <b>Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system</b> <b>Stores QC lot files/Worklist edit capability/Viewable PCR graphs</b> <b>Can print, archive, transmit data</b>	no — yes/no yes yes/yes yes/no no/no/— no no/XML no/yes yes no/no yes no/yes yes/yes yes/yes/yes yes	no no yes/no no no/yes yes/no no/yes/yes yes yes/ASTM, HL7 no/yes no no/no yes no/yes no/no no/yes/no yes
<b>Distinguishing features (supplied by company)</b>	flexible, convenient product solutions; open assay platform; consistent, easy to use, process secure processing from sample to result	design 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

## Automated molecular platforms

<p><b>Part 11 of 11</b></p> <p>See <a href="http://captodayonline.com/productguides">captodayonline.com/productguides</a> for an interactive version of guide</p>	<p>Roche Diagnostics Corporation Keith Obye keith.obye@roche.com 9115 Hague Road, Indianapolis, IN 46250 317-521-4033 www.roche-diagnostics.us</p>	<p>Siemens Healthcare Diagnostics Kevin Culver kevin.culver@siemens.com www.usa.siemens.com/diagnostics</p>
<p><b>Name of instrument</b></p>	<p>COBAS AmpliPrep/COBAS TaqMan System</p>	<p>VERSANT 440 Molecular System</p>
<p><b>Country where designed/Manufactured/Reagents manufactured</b> <b>Instrument FDA cleared or approved/Platform</b> <b>First year sold in U.S./Sold internationally/Installed</b></p>	<p>Switzerland/Switzerland/U.S. yes/pre-analytical and analytical 2007/2005/2007</p>	<p>U.S./U.S./U.S. yes/analytical 2007/2005/2005</p>
<p><b>Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB</b> <b>Supplied with UPS/BTU</b> <b>Physical contamination control features</b></p>	<p>AmpliPrep: 37 × 65 × 29/13.1/55–60; TaqMan: 37 × 45 × 30/9.4/—; TaqMan 48: 20 × 18 × 30/3.8; cobas p 630: 35.6 × 44.3 × 40/12.3/— yes/AmpliPrep: 4,904.6 per hour; TaqMan: 2,049.1 per hour/cobas p 630: 2,160 per hour closed tube processing with dedicated consumables and pipette tips, more</p>	<p>24.2 × 59.7 × 31/—/78 yes/1,700 per hour —</p>
<p><b>List price/Price for sample extraction and amplification detection modules</b> <b>Purchase options/Minimum test volume requirements</b> <b>Co. performs installation, operation, and performance qualifications/Electrical req.</b> <b>Labor and parts warranties/Advanced operator training</b> <b>Delivery time/Delivery charges/Installer/Time to install on site</b> <b>Training location/No. of techs that can receive initial training/</b> <b>Length of training/Retraining at company facility</b></p>	<p>— straight purchase, reagent rental, lease/none yes/line voltage: 100–125 VAC; frequency: 50 or 60 Hz ± 2.0 Hz 1 year/yes up to 30 days/none/Roche/1 day on site and off site/2/4 days/yes</p>	<p>— straight purchase, reagent rental, lease/— yes/100 to 120 VAC plus 10%, 50/60 Hz, 600 VA maximum —/yes/yes —/—/Siemens/6–8 hours on site/—/yes</p>
<p><b>Test menu</b> <b>No. of tests for which analyzer has FDA-cleared applications/CE-mark</b> <b>Tests available on instrument in U.S./Outside U.S.</b>  <b>Tests not available in U.S. but submitted to FDA/Available in other countries only</b> <b>Research-use-only assays/Tests in development</b> <b>Open-channel capabilities/Start-up and preparation time</b></p>	<p>HIV-1 v2.0, HBV v2, HCV, CMV, High Pure HIV v2, High Pure HBV, High Pure HCV, more 7/10 HIV-1 v2.0 (IVD), HBV v2 (IVD), HCV (IVD), CMV (IVD), High Pure HIV v2 (IVD) High Pure HBV (IVD), High Pure HCV v2 (IVD), HIV-1 Qual (RUO)/ HIV-1 v2.0 (CE-IVD), HBV v2 (CE-IVD) HCV v2 qual. (CE-IVD) HCV v2 quant. (CE-IVD), CMV (CE-IVD), more HCV v2/— HCV v2 RUO/— yes/20 minutes for 24 samples</p>	<p>HIV, HCV, HBV viral load 2/— HIV, HCV, HBV viral load/— —/— HVB/— no/—</p>
<p><b>Model type of sample-handling system/Maximum sample load capacity</b> <b>Minimum specimen volume/Sample volume flexibility/Other sample volumes available</b> <b>Minimum dead volume/Pediatric sample volume/Primary tube sampling</b> <b>Sample tube sizes/Sample bar-code reading/Autodiscrimination in 1D or 2D</b> <b>Sample bar-code languages/Sample types available in open mode</b> <b>Clot detection/Open extraction platform/Sample types (open extraction)</b></p>	<p>sample extraction/72 (AmpliPrep); primary tube pre-analytics/320 (p 630) 1.0 mL HIV, HCV; 650 µL HBV; 500 µL CMV /yes (TNAI kit available)/— 150 µL/—/no 11 × 66, 92; 13 × 65, 75, 90, 100; 15 × 75, 92; 16 × 92, 100/yes/no Codabar, codes 39 and 128, code 2 of 5 interleaved;/serum or plasma yes/yes/serum or plasma</p>	<p>—/192 —/no/— —/—/no —/yes/— — yes/no/—</p>
<p><b>Amplification reagents or methods supported</b> <b>Extraction methods supported for: RNA extract./DNA extract./total nucleic acid</b> <b>No. of different assays onboard at once/Programmed or calibrated at once</b> <b>Tests per container set/Multiple reagent configurations supported</b> <b>Reagent container placed directly on system/Onboard test auto inventory</b> <b>Determines reagent volume in container/Reagent bar-code reading/Reagents bar coded</b> <b>Monitors expiration date/Auto lot recognition or calibration</b> <b>Auto detection of adequate reagent or specimen/Reagents available</b> <b>Reagent reconstitution required/Chemical contamination control</b> <b>Onboard test auto inventory/Capable of inventory monitoring by bar code</b> <b>System is open to homebrew/General-purpose reagents allowed</b> <b>Same capabilities when third-party reagent used/Lot sequestering available</b> <b>Closed-vial stability for amplification reagents/Extraction reagents</b> <b>Storage temp. requirement for amplification reagents/Extraction reagents</b> <b>Shipment temperature requirement for amplification reagents/Extraction reagents</b> <b>Minimum/Maximum reagent shelf-life guarantee</b></p>	<p>real-time PCR yes/yes/yes 3/4 HIV and HCV: 48 HBV and CMV: 72/three protocols run simultaneously yes/yes yes/yes/yes yes/yes yes/liquid no/AmpErase enzyme yes/yes yes/yes no/yes 18 months/18 months 2°–8°C/2°–8°C room temperature with cooling packs/room temperature with cooling packs 3 months/18 months</p>	<p>signal — 1/1 96/— yes/no yes/no/no yes/no yes/liquid no/— no/no no/no no/yes — — — —</p>
<p><b>Autocalibration or autocalibration alert/Multipoint calibration supported</b> <b>Assay calibrations required by end-user/Calibrants can be stored onboard</b> <b>Multiple calibrant lots stored for same assay/Required calibration frequency</b> <b>Length of assay calibration/Typical calibration frequency</b> <b>Onboard real-time QC/Supports multiple QC lot numbers per assay</b> <b>Auto shutdown*/Instrument warm-up time/Onboard software reviews QC</b> <b>Total number of controls per batch for 24 tests/42 tests/72 tests/96 tests</b></p>	<p>yes/yes no/— (reagents calibrated during manufacturing) — until reagent lot expires —/yes no/sample: &lt;10 minutes; amplification: &lt;3 minutes/yes 3/6/9/12</p>	<p>—/yes —/no no/— —/— —/no —/—/yes 12/12/12/12</p>
<p><b>Walkaway capacity/Tech hands-on time (both for batch of 96 samples)</b> <b>Uses disposable pipette tips/Maximum number of pipette tips stored</b> <b>Time between start and initial result/Instrument automatic shutdown</b> <b>Startup programmable/Remote system monitoring/Waste req. for disposables</b> <b>Windows technology/Mouse or touchscreen/Modular add-on capability</b></p>	<p>72 samples/47 minutes yes/72 5 hours, 9 minutes/no no/no/waste container onboard yes/mouse/yes</p>	<p>— no/— — —/no/— yes/mouse and touchscreen/no</p>
<p><b>Service contracts available/Mean time between failures/To repair failures</b>  <b>Turnaround time for problem solving by phone/e-mail/field service</b> <b>No. of U.S. field reps/Service engineer on-site response time/Hours &amp; days avail.</b> <b>Guaranteed response time/Modem servicing available</b> <b>System can diagnose own malfunctions</b> <b>Order parts via modem/Onboard error codes/Maintenance training demo module</b> <b>Average maintenance time for lab personnel/Onboard maintenance records</b> <b>Preventive maintenance per year for sample extraction/amplification detection</b> <b>Downtime for preventive maintenance/Spare parts on site</b></p>	<p>phone and on-site service/sample: 146.2 days; amplification: 211 days (TaqMan); 342 days (TaqMan 48)/2–3 hours 3–4 hours/—3–4 hours 175/24 hours/24–7–365 yes (24 hours)/yes no no/yes/yes daily: 15 minutes; weekly: 30 minutes; yearly: 20 minutes/yes 2 (AmpliPrep); 2 (p 630 pre-analytics)/1 (TaqMan, TaqMan 48) 2–4 hours/yes</p>	<p>— — —/—/8 AM–8 PM —/no no no/yes/no —/yes — 6 hours/yes</p>
<p><b>Software and LIS interface:</b> • Patient demographics and insurance data available via rules-based architecture • Data retrieval or Internet connectivity • Online real-time help, QC, stats, and management reports/Evaluates results validity • Priority processing • Supports accession No. redundancy/Specimen carrier and level identification • Unique bar code per container/Multistop routing (1 tube to many workstations) • Specimen scheduling/Routes test to workstation/Auto. reflex, repeat, dilutions • Sample storage and retrieval software supports CLSI standards • LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS • QC results transferred automatically to LIS/Data-management capability <b>Interfaces operational in active user sites</b> <b>Rules-based control subsystem/Process control via control subsystem</b> <b>LIS operates simultaneously with assays running</b> <b>Uses LOINC to transmit orders and results/Unidirectional interface capability</b> <b>Results immed. transmitted to LIS/Interface avail. to auto specimen-handling system</b> <b>Stores QC lot files/Worklist edit capability/Viewable PCR graphs</b> <b>Can print, archive, transmit data</b></p>	<p>yes yes no/yes no no/yes yes/— — — —/Ethernet no/yes yes —/yes yes —/yes yes/yes no/yes/yes yes</p>	<p>yes no no/— — — — — yes/— yes/— yes — yes no/yes yes/no no/yes/no yes</p>
<p><b>Distinguishing features (supplied by company)</b></p>	<p>parallel processing allows for up to 3 protocols (HIV-1, HCV, HBV, and/or TNAI) to be run simultaneously in a continuous load mode versus batch-processing systems; multi-layered contamination control ensures integrity of the primary tubes and results; fully automated, continuous-load IVD platform features sample in and results out capability</p>	

\*for calibration and controls

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