Part 1 of 17

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	Abbott Laboratories, Abbott Molecular Division **Vladimir Nozinic** vladimir.nozinic@abbott.com **Des Plaines, IL** **224-361-7338** www.abbottmolecular.com	**Agilent Technologies** contact_us@agilent.com **Santa Clara, CA** **408-345-8886** www.genomics.agilent.com
Name of instrument	m2000 RealTime System composed of m2000sp and m2000rt modules	4200 TapeStation
Country where designed/Manufactured/Reagents manufactured	U.S./Switzerland, Singapore/U.S.	Germany/Germany/Germany, U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	no/analytical
First year sold in U.S./Sold internationally/Installed	2007/2005/2005	2015/2015/2015
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	m2000sp: 73.6 × 57.1 × 31.3/12.4/—; m2000rt: 19.3 × 13.4 × 17.8/1.7/<85 (1m)	17.1 × 20 × 17.5/2.4/<70 dBA
Supplied with UPS/BTU	yes/m2000sp: 4,100 (1,200 Wh); m2000rt: 3,241.5 (950 Wh)	yes/170 per hr.
Physical contamination control features	instrument hood, unidirectional process flow design, optimized anti-drip pipetting and rinse steps, confined waste containers, aerosol barrier pipette tips, sealed PCR plate	lid and seal
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/none	straight purchase/≤2 µL DNA or RNA sample
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/m2000sp: 100–240 VAC at 50–60 Hz; m2000rt: 100–240 VAC at 50–60 Hz	no/100–240 V AZ, 50–60 Hz, 50 W
Labor and parts warranties/Advanced operator training	1 year/yes	1–5 years/yes
Delivery time/Delivery charges/Installer/Time to install on site	as requested/—/Abbott Molecular/m2000sp: 24 hrs.; m2000rt: 8 hrs.	4 weeks/destination included/Agilent/2 hrs.
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/3 days/yes	on site/1–5/2–3 hrs./no
Test menu	HIV-1, HIV-1 qual, HCV, HCV Gt, HBV, CTNG, CT, CMV, high-risk HPV, EBV, VZV, parvo B19, MTB, MTB RIF/INH resistance, Zika, IDH2, HBV sequencing	genomic DNA, D1000, HS D1000, D5000, HS D5000, RNA, HS RNA
No. of tests for which analyzer has FDA-cleared applications/CE mark	7/15	none/all available tests
Tests available on instrument in U.S./Outside U.S.	CTNG, HBV, HCV, HCV GT, HIV-1, HIV-1 qual (RUO), CMV, Zika, IDH1, IDH2/CMV, CT, CTNG, EBV, HBV, HCV, HCV GT, HR HPV, HIV-1, HIV qual, VZV, MTB, MTB RIF/INH resistance, Zika, IDH2, HBV sequencing	all tests/all tests
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/CT, high-risk HPV, parvo B19, VZV, MTB, MTB RIF/INH resistance, HIV-1 qual, HIV-1 viral load with DBS sample type, HBV sequencing	none/none
Research-use-only assays/Tests in development	HIV-1 qual (U.S.)/—	all tests/—
Open-channel capabilities/Start-up and preparation time	yes/20–30 min. for initial setup	no/5–30 min.
Model type of sample-handling system/Maximum sample load capacity	m2000sp/96	4200 TapeStation (G2991AA)/96
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	0.2 mL/yes (FDA protocols include 0.2, 0.4, 0.5, 0.6, and 1.0 mL)/0.05–4.0 mL	1–2 µL DNA or RNA sample/no/no
Minimum dead volume/Pediatric sample volume/Primary tube sampling	0.2 mL/0.2 mL/yes	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	11.5–16 mm diameter/yes/no	—/no/no
Sample barcode languages/Sample types available in open mode	Codabar, codes 39, 128, and 93, UPCA, Interleaved 2 of 5/plasma, serum, urine, whole blood, swabs, dried blood spots, CSF, breast milk, semen, others	—/DNA and RNA samples
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/plasma, serum, urine, whole blood, swabs, dried blood spots, CSF, breast milk, semen, others	no/no/DNA and RNA samples
Amplification reagents or methods supported	real-time PCR	—
No. of different assays onboard at once/Programmed or calibrated at once	1 with standard operation, 2 with MaxCycle†, 12 with open mode/—	1/7
Tests per container set/Multiple reagent configurations supported	24–192/nucleic acid: DNA, RNA, total nucleic acid; master mix: up to 4 reagents	1/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/no
Auto detection of adequate reagent or specimen/Reagents available	yes/—	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/not required (UNG optional)	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	yes/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes	no/no
Closed-vial stability for amplification reagents/Extraction reagents	18 months at -10°C/18 months at 15°–30°C	4 months/4 months
Storage temp. requirement for amplification reagents/Extraction reagents	-10°C/15°–30°C	36°–46°F/36°–46°F
Shipment temp. requirement for amplification reagents/Extraction reagents	frozen on dry ice/15°–30°C	36°–46°F/36°–46°F
Minimum/Maximum reagent shelf-life guarantee	3 months/18 months	4 months/4 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	yes/no
Assay calibrations required by end user/Calibrants can be stored onboard	yes/yes	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	yes/calibration curves stored for up to 6 months	no/ladder for sizing and internal markers for the quantification are used in each run
Length of assay calibration/Typical calibration frequency	valid for 6 months/6 months	1 sample per consumable (Tape)/each run
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/sample extraction: none; amplification detection: 15 min./yes	no/—/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	2–3 controls dependent on assay regardless of run size (1–96)	2/3/5/7
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	up to 6 hrs. or 89 percent walkaway time/30 min.	yes/5–30 min.
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/864	yes/112
Time between start and initial result/Instrument automatic shutdown	assay and run-size dependent/yes	15 min./no
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/plastic and liquid waste containers onboard	no/no/Labwaste
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/mouse/no
Service contracts available/Mean time between failures/To repair failures	standard, extended, premium/m2000sp: 275 days; m2000rt: 688 days/m2000sp: 3.8 hrs.; m2000rt: 3.3 hrs.	preventive maintenance and extended warranty/—/—
Turnaround time for problem solving by phone/Email/Field service	immediate response/24-hr. response/variable, as per contract	M–F, 7 AM–5 PM/M–F, 7 AM–5 PM/M–F, 7 AM–5 PM
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	37/based on contract/M–F, 8 AM–5 PM, extended hrs. based on contract	>10/—/M–F, 7 AM–5 PM
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes/yes (when requested)/yes	no/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: <10 min.; weekly: 45 min.; monthly: 15 min./yes	yearly: 0–5 min./yes
Preventive maintenance per year for sample extraction/Amplification detection	1/1	—
Downtime for preventive maintenance/Spare parts on site	4–12 hrs./yes	4 hrs./no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/yes
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	—	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/—/—	no/no/no
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—	no/—
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/no
• Interfaces operational in active user sites	yes	no
• Rules-based control subsystem/Process control via control subsystem	yes/yes	no/no
• LIS operates simultaneously with assays running	yes	no
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/no
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/yes	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	no/no/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	automates and enables consolidation of multiple commercial NAAT tests, LDTs, and third-party assays; accommodates a diverse sample type flexibility while providing barcoded traceability of primary or laboratory tubes; run control and calibrator efficiency, multiple contamination control safeguards, and maxRatio (proprietary PCR curve analysis and validation of result algorithm); mPlus features allow for runs of 1–96 samples with customized workflow and extended reagent use	automated: unattended walkaway operation with fully automated sample processing for up to 96 samples; flexible: ready-to-use ScreenTape technology enables easy switching between DNA and RNA assays; fast: simplify your workflow without any system setup procedures and obtain reliable results in as few as 1–2 min.

**for calibration and controls*

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

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

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AUTOMATED MOLECULAR PLATFORMS

Part 2 of 17

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	Agilent Technologies contact_us@agilent.com **Santa Clara, CA** **408-345-8886** www.genomics.agilent.com	**AutoGenomics** **Rajasri Chandra** rchandra@autogenomics.com **Carlsbad, CA** **760-477-2248** www.autogenomics.com
Name of instrument	Dako Omnis	INFINITI High Throughput System
Country where designed/Manufactured/Reagents manufactured	Switzerland/Switzerland/Denmark, U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2013/2013/2013	2014/—/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	60.4 × 57.1 × 31.2/—/63.7 dBA	—
Supplied with UPS/BTU	yes/1,200 V	no/—
Physical contamination control features	yes	discrete units
List price/Price for sample extraction and amplification detection modules	$195,000/—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/test mix dependent	straight purchase, reagent rental, lease/1 µL
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/120, 220–240 VAC	yes/—
Labor and parts warranties/Advanced operator training	1 year/no	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	1 week/$5,000/Dako field engineer/3 days	—
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/4 days off site/yes	on site/—/—/—
Test menu	Dako Omnis validated probes; open for third-party probes	>70 tests on women's health, infectious diseases, pharmacogenomics, oncology, and genetic disorders
No. of tests for which analyzer has FDA-cleared applications/CE mark	none/4	5/29
Tests available on instrument in U.S./Outside U.S.	yes/yes	IVD assays: CYP2C19, warfarin assay, factor II, factor V, factor II–V Leiden panel/ MDR-TB, ApoE, CFTR-31, FMF panel, 5-FU, UGT1A1/HPV genotyping, STD6, bacterial vaginosis, candida vaginitis, H. pylori, HCV genotyping, respiratory viral panel, respiratory bacterial panel, GBS, genital ulcer disease, NTM, CYP450-2C9-VKORC1, 2D6, 2B6, 1A2, 3A4-3A5, neurotransmitter panel, neural response panel, age-related macular degeneration, KRAS-BRAF, EGFR, NRAS, Ashkenazi Jewish panel, more
Tests not available in U.S. but submitted to FDA/Available in other countries only	yes/yes	—
Research-use-only assays/Tests in development	yes (user's choice)/—	65/5
Open-channel capabilities/Start-up and preparation time	yes/1–10 min.	—/<1 hr. for 96 tests
Model type of sample-handling system/Maximum sample load capacity	automated prepared on glass slide/15 ISH	—/96 each plate (up to 8 plates)
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	1 sample per glass slide/yes (any sample placed in the slide's recommended area)/—	2 µL/yes/can be adjusted by user as needed
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/adult or pediatric samples/no	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/yes/yes	—/—/no
Sample barcode languages/Sample types available in open mode	—	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—	no/yes/variable, assay dependent: blood, buccal, saliva, tissue, liquid cytology media, culture, vaginal swabs, sputum, stool, more
Amplification reagents or methods supported	FISH, CISH, immunofluorescence, IHC, double stains, magenta detection	—
No. of different assays onboard at once/Programmed or calibrated at once	15/15	all 70 assay types/50+
Tests per container set/Multiple reagent configurations supported	21 tests per vial/yes	—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	—
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	—
Monitors expiration date/Auto lot recognition or calibration	yes/yes	—
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	—/liquid
Reagent reconstitution required/Chemical contamination control	yes/yes (concentrated probes and buffers for Dako Omnis validated probes)	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	—/yes
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes	no/yes
Closed-vial stability for amplification reagents/Extraction reagents	—	—
Storage temp. requirement for amplification reagents/Extraction reagents	—	—
Shipment temp. requirement for amplification reagents/Extraction reagents	—	—
Minimum/Maximum reagent shelf-life guarantee	2 years/3 years	3 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	—
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	—
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/yes	no/—/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	yes (slide based on 15 samples)/1–10 min.	—/1 hr.
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	3:45–4 hrs./no	—/no
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/yes	no/yes/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/no	no/mouse/no
Service contracts available/Mean time between failures/To repair failures	M–F, 8 AM–5 PM/—/5.1 hrs.	standard/—/—
Turnaround time for problem solving by phone/Email/Field service	yes/yes/problem dependent	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	29/1–2 days/M–F, 7 AM–5 PM	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	no/yes/yes	—
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	—
Average maintenance time for lab personnel/Onboard maintenance records	daily: 10 min.; bi-weekly: 25 min.; monthly: 56 min.; yearly: dependent on amount of ISH run yearly/yes	—
Preventive maintenance per year for sample extraction/Amplification detection	—	—
Downtime for preventive maintenance/Spare parts on site	20 hrs. annually/no	—
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	yes	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/no	yes/yes
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	yes/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/—
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/yes/no	yes/yes/—
• Sample storage and retrieval software supports CLSI standards	no	—
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/—	yes/wireless or Ethernet
• QC results transferred automatically to LIS/Data-management capability	no/yes	yes/no
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/yes	yes/yes
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	—
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	yes/—
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/no	yes/yes/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	45 slides per day including overnight run; nontoxic hybridization means no formamide exposure to the operator, minimizing health risks to technicians; low probe dispensation value, below 100 µL; protocol flexibility to adapt to preanalytical conditions of the sample	scalable high-throughput molecular testing from 1 to 864 multiplexed microarrays tested in 8 hrs.; broad spectrum of 70 assays; built-in replicate testing on each BioFilmChip microarray ensures assay result integrity and accuracy; easy and automated result interpretation

**for calibration and controls*

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

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Part 3 of 17

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	AutoGenomics	**BD Diagnostic Systems**
	Rajasri Chandra rchandra@autogenomics.com	**Chris Busa** christopher.busa@bd.com
	Carlsbad, CA	**Sparks, MD**
	760-477-2248 www.autogenomics.com	**410-316-3860** moleculardiagnostics.bd.com
Name of instrument	INFINITI PLUS Analyzer	BD Viper LT
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2011/2011/2011	2014/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	26 × 44 × 24/7.3/—	46 × 51 × 36/12.75/65
Supplied with UPS/BTU	no/—	yes/up to 3,000 (1,000 when idle)
Physical contamination control features	no aspiration tubing, disposable tips	closed system
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/1 µL	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/110 V and 220 V, 50–60 Hz	yes/100V–240 V, 50–60 Hz
Labor and parts warranties/Advanced operator training	1 year/no	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	1 week/—/AGI/1–2 days	2–3 weeks/origin/BD service engineer/<2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/1/2.5 days/yes	off site/2–4/2 days/no
Test menu	>70 tests on women's health, infectious diseases, pharmacogenomics, oncology, and genetic disorders	Chlamydia trachomatis, Neisseria gonorrhoeae, human papillomavirus
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/29	3/3
Tests available on instrument in U.S./Outside U.S.	IVD assays: CYP2C19, warfarin assay, factor II, factor V, factor II–V Leiden panel/ MDR-TB, ApoE, CFTR-31, FMF panel, 5-FU, UGT1A1/HPV genotyping, STD6, bacterial vaginosis, candida vaginitis, H. pylori, HCV genotyping, respiratory viral panel, respiratory bacterial panel, GBS, genital ulcer disease, NTM, CYP450-2C9-VKORC1, 2D6, 2B6, 1A2, 3A4-3A5, neurotransmitter panel, neural response panel, age-related macular degeneration, KRAS-BRAF, EGFR, NRAS, Ashkenazi Jewish panel, more	Chlamydia trachomatis, Neisseria gonorrhoeae, human papillomavirus/ Chlamydia trachomatis, Neisseria gonorrhoeae, human papillomavirus
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	0/0
Research-use-only assays/Tests in development	65/5	0/0
Open-channel capabilities/Start-up and preparation time	yes/20 min.	no/<10 min.
Model type of sample-handling system/Maximum sample load capacity	—/48	Hamilton pipettor/120
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	1 µL/no/—	500 µL/no/swabs: 2 mL; urine: 2–3 mL; liquid-based cytology: 2.2 mL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	<400 µL/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/yes/—	4 mL tubes/—/—
Sample barcode languages/Sample types available in open mode	—	—
Clot detection/Open extraction platform/Sample types (open extraction)	—/yes/variable, assay dependent: blood, buccal, saliva, tissue, vaginal swabs, liquid cytology media, culture, sputum, stool, more	no/no/none
Amplification reagents or methods supported	—	SDA, PCR
No. of different assays onboard at once/Programmed or calibrated at once	4/70	3/2
Tests per container set/Multiple reagent configurations supported	48/—	2/no
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/—	no/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/yes
Same capabilities when third-party reagent used/Lot sequestering available	no/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	—	—
Storage temp. requirement for amplification reagents/Extraction reagents	-20°C/—	room temperature/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	-20°C/—	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	12 months/24 months	8 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	yes/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	—
Multiple calibrant lots stored for same assay/Required calibration frequency	—	—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no	no/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/—	yes/—/—
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	1/2/3/4
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	5 hrs./15 min.	30 samples/<5 min.
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/504	yes/480
Time between start and initial result/Instrument automatic shutdown	3 hrs./no	~3 hrs./—
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/built-in waste tray, solid state waste products	—/yes/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	annual/—/—	multiyear/—/—
Turnaround time for problem solving by phone/Email/Field service	24 hrs./24 hrs./48 hrs.	<1 day/<2 days/variable
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/24–48 hrs./6 AM–6 PM (PDT)	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes (within 24 hrs.)/no/yes	—/yes/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 min.; weekly: 10 min.; monthly: 20 min.; yearly: 45 min./no	—
Preventive maintenance per year for sample extraction/Amplification detection	—/1	—
Downtime for preventive maintenance/Spare parts on site	1 day/no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/no
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	—	yes/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/no/—	no/no/no
• Sample storage and retrieval software supports CLSI standards	no	yes
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/—	—
• QC results transferred automatically to LIS/Data-management capability	—/yes	—
• Interfaces operational in active user sites	yes	—
• Rules-based control subsystem/Process control via control subsystem	yes/yes	—
• LIS operates simultaneously with assays running	yes	—
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/no	—
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	—
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—/yes/no	—/—/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	load-and-go automation increases lab productivity by freeing up personnel; built-in replicate testing on each BioFilmChip microarray ensures assay result integrity and accuracy; broad menu of 70 assays on same instrument; easy and automated result interpretation	benchtop, integrated molecular platform for HPV and CT/GC in a compact package; offers standardized, ready-to-use reagents, LIS connectivity with automated result reporting, and remote connectivity for faster serviceability; BD Onclarity Assay provides genotyping results for HPV 16, 18, and 45 and is FDA approved for ASCUS reflex testing, cotesting, and primary screening

**for calibration and controls*

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

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AUTOMATED MOLECULAR PLATFORMS

Part 4 of 17

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	BD Diagnostic Systems **Chris Busa** christopher.busa@bd.com **Sparks, MD** **410-316-3860** moleculardiagnostics.bd.com	**BD Diagnostic Systems** **Chris Busa** christopher.busa@bd.com **Sparks, MD** **410-316-3860** moleculardiagnostics.bd.com
Name of instrument	BD MAX System	BD Affirm VPIII Microprocessor
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S., Canada	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2010/2010/2010	1996/1996/1996
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	28.5 × 37 × 29.7/5/64 at 48 background	6 × 10 × 9/0.63/quiet
Supplied with UPS/BTU	yes/—	no/—
Physical contamination control features	unitized reagent strip, dedicated pipette tips, microfluidic PCR cartridge with microvalves, pipettor flight path avoids crossing strips or tubes	—
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/specimen dependent (as low as 10–15 µL)	straight purchase, reagent rental, lease/72 tests per month
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC, ~50–60 Hz, 10 A	no/120 V
Labor and parts warranties/Advanced operator training	1 year (≤3 year contracts optional)/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	90 day, or less from contract/—/BD/1.5 days	2 weeks/none for instrumentation/BD field applications/4 hrs.
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/flexible/1 day/yes	on site/6/4 hrs./no
Test menu	GBS, MRSA XT, C. difficile, StaphSR, enteric bacterial panel, extended bacterial panel, enteric parasite panel, CT-GC-TV, vaginal panel; open system general-purpose reagents for user-defined protocols: DNA and TNA extraction kits and generic DNA and TNA master mix with and without internal process control	Candida species (six different), Gardnerella vaginalis, Trichomonas vaginalis
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	3/3
Tests available on instrument in U.S./Outside U.S.	GBS, MRSA XT, C. difficile, StaphSR, enteric bacterial, extended bacterial panel, enteric parasite, CT-GC-TV, vaginal panel/—	3/3
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—
Research-use-only assays/Tests in development	CRE/—	—
Open-channel capabilities/Start-up and preparation time	yes/less than 1 min. per specimen	no/immediate
Model type of sample-handling system/Maximum sample load capacity	fully automated, integrated extraction and amplification detection/24	swab, tube, and cap/6
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	specimen dependent (as low as 10–15 µL)/yes/volumes range up to 750 µL	—/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	50–200 µL/specimen dependent/no	—/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	uses standard 4 mL tube format/yes/—	5 mL/no/no
Sample barcode languages/Sample types available in open mode	Codabar codes 39, Interleaved 2 of 5, EAN, UCC code 128, 2D capability/—	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/yes/swab, swab in transport medium, urine, plasma, CSF, stool	no/no/—
Amplification reagents or methods supported	real-time PCR for most probe types, melt analysis	—
No. of different assays onboard at once/Programmed or calibrated at once	designed for multiple assays up to 24 samples/significant number	3/3
Tests per container set/Multiple reagent configurations supported	unitized reagent strips, one test per strip, 24 strips per kit/yes	24 or 120/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	no/no/no
Monitors expiration date/Auto lot recognition or calibration	yes/yes	no/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	no/dry
Reagent reconstitution required/Chemical contamination control	no/no (system has a closed-unit test format disposable)	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/no	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes (with user-supplied primers and probes in open-system format)/on terms	no/no
Closed-vial stability for amplification reagents/Extraction reagents	12 months/12 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Minimum/Maximum reagent shelf-life guarantee	3 months/12–24 months	6 months/14 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	no/no
Assay calibrations required by end user/Calibrants can be stored onboard	—/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	yes/determined and validated by user	no/factory calibrated only
Length of assay calibration/Typical calibration frequency	determined and validated by user/determined and validated by user	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/no	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/—	no/—/no
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	user validates and defines external run control protocol	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	1–12 samples in <1.5 hrs.; 24 samples in 2 hrs./~1 min. per sample	30 min./3 min.
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/self-contained in unitized reagent strip	no/—
Time between start and initial result/Instrument automatic shutdown	1–12 samples in <1.5 hrs.; 24 samples in 2 hrs./automatic move to standby	45 min./no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/biohazardous waste	no/no/biohazardous waste
Windows technology/Mouse or touchscreen/Modular add-on capability	no/mouse/no	no/—/no
Service contracts available/Mean time between failures/To repair failures	5 and 7 days per week/180 days/<24 hrs. from field service visit	repair by replacement (normally ships same day of call to tech service)/—/single swap option within 24 hrs.
Turnaround time for problem solving by phone/Email/Field service	<1 hr. after hours/same day (next day after hours)/next business day	immediate during business hours; 1 hr. nonbusiness/immediately/as needed
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/next business day/24–7	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	—/no/yes	no/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	weekly: 10 min./—	daily: <5 min./no
Preventive maintenance per year for sample extraction/Amplification detection	1/1 (for total system)	—
Downtime for preventive maintenance/Spare parts on site	4 hrs./no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	—	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/—	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	—	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	—	no/no
• QC results transferred automatically to LIS/Data-management capability	—	no/no
• Interfaces operational in active user sites	yes	no
• Rules-based control subsystem/Process control via control subsystem	—	no/no
• LIS operates simultaneously with assays running	—	no
• Uses LOINC to transmit orders and results/Unidirectional interface capability	—	no/no
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	—	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	no/no/no
• Can print, archive, transmit data	yes	no
Distinguishing features (supplied by company)	next-generation platform for molecular testing, automating cell lysis, nucleic acid extraction, PCR setup, amplification, and detection	simultaneous detection/differentiation of the 3 organisms that cause up to 90 percent of vaginal infections in 1 swab; quick turnaround time (45 min. for 6 samples or 18 results); simultaneously detects mixed infections caused by 3 organisms; objective, visual results

**for calibration and controls*

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Part 5 of 17

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	BD Diagnostic Systems **Chris Busa** christopher.busa@bd.com **Sparks, MD** **410-316-3860** moleculardiagnostics.bd.com	**Biocartis US** **Vishal Sikri** customerserviceUS@biocartis.com **Jersey City, NJ** **844-4-IDYLLA (844-443-9552)** www.biocartis.com/US
Name of instrument	BD Viper System with XTR Technology	Idylla
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	Belgium/Belgium/Belgium
Instrument FDA cleared or approved/Platform	yes/analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2009/2008/2009	2017/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	83 × 75 × 42/262/<65	12 × 7.5 × 19.9/1.036 instrument + 0.694 console/max. 54
Supplied with UPS/BTU	yes/2,048 per hr.	no/—
Physical contamination control features	closed solid barrier amplification	closed, sealed cartridge
List price/Price for sample extraction and amplification detection modules	—	$49,000/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/12,000 specimens per year	straight purchase, reagent rental, lease/1 tissue slide; 1 mL of plasma
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/208–240 VAC	yes/100–240 V
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	30 days/FOB (origin)/field service engineer/3 days	immediate/shipping costs (destination)/Biocartis US/2 hrs.
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/1/3 days/yes	on site/5/2 hrs./no
Test menu	chlamydia, gonorrhea, HSV-1, HSV-2, trichomonas	EGFR, MSI, KRAS, NRAS, NRAS-BRAF, BRAF, ctKRAS, ctNRAS-BRAF, ctBRAF
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	0/7
Tests available on instrument in U.S./Outside U.S.	5/5	EGFR, MSI, KRAS, NRAS-BRAF, BRAF, ctKRAS, ctNRAS-BRAF, ctBRAF/EGFR, MSI, KRAS, NRAS, NRAS-BRAF, BRAF, ctKRAS, ctNRAS-BRAF, ctBRAF
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	1/—
Research-use-only assays/Tests in development	—	EGFR, MSI, KRAS, NRAS-BRAF, BRAF, ctKRAS, ctNRAS-BRAF, ctBRAF/ctEGFR
Open-channel capabilities/Start-up and preparation time	no/10 min.	no/<2 min.
Model type of sample-handling system/Maximum sample load capacity	sample rack/96	—/cartridge-based system with 1 sample per cartridge
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	2.5 mL/no/—	1 tissue slide, 1 mL of plasma/yes/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	800 µL/—/yes	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	2.5 mL/yes/no	—/yes/yes
Sample barcode languages/Sample types available in open mode	Interleaved 2 of 5, Codabar codes 39 and 128/vaginal and endocervical swabs, urethral swabs, urine, liquid-base cytology (SurePath, ThinPrep)	various/—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/vaginal and endocervical swabs, urethral swabs, urine, more	no/no/—
Amplification reagents or methods supported	strand displacement amplification	—
No. of different assays onboard at once/Programmed or calibrated at once	5/5	1/1
Tests per container set/Multiple reagent configurations supported	CT: 1,152; GC: 1,152; HSV-1 and HSV-2: 96/no	—
Reagent container placed directly on system/Onboard test auto inventory	yes/no	yes/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	no/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/no	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/—	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/yes	no/no
Closed-vial stability for amplification reagents/Extraction reagents	18 months/18 months	>1 year/>1 year
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	3 months/24 months	>12 months/>12 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	yes/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	no/yes
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	yes/built into run
Length of assay calibration/Typical calibration frequency	—	built into run/built into run
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/yes	yes/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/no	yes/<5 min./yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	2/2/4/4	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	3 hrs., 5 min./10 min.	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/768	no/—
Time between start and initial result/Instrument automatic shutdown	3 hrs., 15 min./no	BRAF: minimum 90 min.; EGFR: maximum 150 min./yes
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/solid (disposable tips) and neutralized liquid waste	no/yes/according to laboratory procedures
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/no	yes/touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	5 days, 8 AM–5 PM, and 7 days, 24 hrs./280 days/24 hrs.	yearly/>18 months/depot replacement model 1–3 days
Turnaround time for problem solving by phone/Email/Field service	real time/—/24 hrs.	1 day/1 day/3 days
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	>30/24 hrs./24–7	—/—/8 hrs., 5 days
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	—/yes/yes	1 business day/yes/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily, weekly, and monthly: 15 min./no	monthly: <1 min.; yearly: 10 min./no
Preventive maintenance per year for sample extraction/Amplification detection	1/1	yes/—
Downtime for preventive maintenance/Spare parts on site	1 day/no	2 hrs./no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/yes
• Priority processing	no	yes
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	—
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/no/yes
• Sample storage and retrieval software supports CLSI standards	no	yes
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/LIS-RS-232 serial ASTM 1381-1394	yes/—
• QC results transferred automatically to LIS/Data-management capability	yes/no	—
• Interfaces operational in active user sites	yes	—
• Rules-based control subsystem/Process control via control subsystem	no/no	—
• LIS operates simultaneously with assays running	no	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	yes/—
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/yes	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/no	yes/—/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	reduced hands-on time for setup and maintenance; fully automated specimen processing with high walkaway time; FDA cleared for 2 common liquid-base cytology specimens for CT-GC and fully automated for FDA-cleared HSV-1 and HSV-2 assays	fully automated sample-in/result-out molecular system; accurate results in minutes, not days; versatile sample type: FFPE tissue or plasma; hands-on time of <2 min. for tissue or plasma; extensive menu for oncology; low running costs

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AUTOMATED MOLECULAR PLATFORMS

Part 6 of 17

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	BioFire Diagnostics **Wade Stevenson** wade.stevenson@biofiredx.com **Salt Lake City, UT** **801-736-6354** www.biofiredx.com	**BioFire Diagnostics** **Wade Stevenson** wade.stevenson@biofiredx.com **Salt Lake City, UT** **801-736-6354** www.biofiredx.com
Name of instrument	FilmArray 2.0	FilmArray Torch
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2015/2015/2015	2016/2016/2016
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	6.5 × 10 × 15.5 (instrument only)/—/—	34 × 19 × 30 for 12 modules/—/—
Supplied with UPS/BTU	no/—	no/—
Physical contamination control features	closed system	closed system
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	—	—
Labor and parts warranties/Advanced operator training	—	—
Delivery time/Delivery charges/Installer/Time to install on site	—/origin/BioFire Diagnostics/<1 day	—/origin/BioFire Diagnostics/<1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1 or more/—/no	on site/1 or more/—/no
Test menu	respiratory panel, blood culture identification panel, gastrointestinal panel, meningitis-encephalitis panel	respiratory panel, blood culture identification panel, gastrointestinal panel, meningitis-encephalitis panel
No. of tests for which analyzer has FDA-cleared applications/CE mark	6/6	6/6
Tests available on instrument in U.S./Outside U.S.	6/6	6/6
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—
Research-use-only assays/Tests in development	pneumonia panel/—	pneumonia panel/—
Open-channel capabilities/Start-up and preparation time	—/2 min.	—/2 min.
Model type of sample-handling system/Maximum sample load capacity	—/8	—/12
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	respiratory panel: 300 µL; blood culture identification panel: 200 µL; gastrointestinal panel: 200 µL; meningitis-encephalitis panel: 200 µL/no/—	respiratory panel: 300 µL; blood culture identification panel: 200 µL; gastrointestinal panel: 200 µL; meningitis-encephalitis panel: 200 µL/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—	—
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/yes/yes	—/yes/—
Sample barcode languages/Sample types available in open mode	—	—
Clot detection/Open extraction platform/Sample types (open extraction)	—	—
Amplification reagents or methods supported	PCR	PCR
No. of different assays onboard at once/Programmed or calibrated at once	respiratory panel: 21; blood culture ID panel: 27; gastrointestinal panel: 22; meningitis-encephalitis panel: 14/—	respiratory panel: 21; blood culture ID panel: 27; gastrointestinal panel: 22; meningitis-encephalitis panel: 14/—
Tests per container set/Multiple reagent configurations supported	single use pouch/yes	single use pouch/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/no	yes/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	no/yes/yes	no/yes/yes
Monitors expiration date/Auto lot recognition or calibration	no/yes	no/yes
Auto detection of adequate reagent or specimen/Reagents available	no/liquid and dry	no/liquid and dry
Reagent reconstitution required/Chemical contamination control	yes/—	yes/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/—	no/—
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/—	no/—
Closed-vial stability for amplification reagents/Extraction reagents	4 months minimum, 12 months maximum/4 months minimum, 12 months maximum	4 months minimum, 12 months maximum/4 months minimum, 12 months maximum
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	4 months/12 months	4 months/12 months
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	yes/—	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	—	—
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	—
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	~1 hr./—	~1 hr./—
Startup programmable/Remote system monitoring/Waste required for disposables	—	—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	—	—
Turnaround time for problem solving by phone/Email/Field service	within 24 hrs./within 24 hrs./—	within 24 hrs./within 24 hrs./—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—	—
Guaranteed response time/Modem servicing avail./System diagnose own 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	—	—
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	—	—
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/—	no/—
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/—	yes/—
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/—/—	no/—/—
• 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	yes/yes	yes/yes
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/yes	yes/yes
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—/—/yes	—/—/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	user-friendly multiplex PCR; fully automated; sample to result in about 1 hr.; 2 min. hands-on time; 4 FDA-cleared panels (respiratory, blood culture identification, gastrointestinal, meningitis-encephalitis); high throughput; scalable; random access performance; LIS capable; single database management	compatible with all existing FilmArray panels, providing quick, comprehensive, and accurate results; fully integrated, random access system designed to meet your laboratory's syndromic infectious disease testing needs; high throughput with reduced footprint; scalable; LIS capable; single database management

**for calibration and controls*

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

AUTOMATED MOLECULAR PLATFORMS

Part 7 of 17

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Name of instrument	EMAG	NUCLISENS easyMAG
Country where designed/Manufactured/Reagents manufactured	France/Italy/France	Netherlands, Australia/Italy/France
Instrument FDA cleared or approved/Platform	no/preanalytical	yes/preanalytical
First year sold in U.S./Sold internationally/Installed	2016/2016/2016	2005/2005/2005
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	71 × 56 × 32/12/~67–75	20.9 × 39.4 × 25.6/3.7/~67–75
Supplied with UPS/BTU	no/1,400 per hr. maximum (less in standby)	no/341 per hr. maximum (less in standby)
Physical contamination control features	single-well processing, onboard extraction buffers in closed containers, separation of buffer dispense and aspiration functions, HEPA filtration and UV light	single-well processing, onboard extraction buffers in closed containers, separation of buffer dispense and aspiration functions, others
List price/Price for sample extraction and amplification detection modules	$135,000/sample extraction: $135,000	$79,500/sample extraction: $79,500
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/1	straight purchase, reagent rental, lease/1
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/110 V	yes/110 V
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	30 days/destination and origin, price varies/field service engineer/5 hrs.	30 days/destination and origin, price varies/field service engineer/5 hrs.
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site and off site/1 or more/1.5 days/no	on site/1 or more/1.5 days/no
Test menu	new platform with universal set of IVD-labeled reagents for total nucleic acid extraction for downstream molecular testing	universal set of IVD-labeled reagents for total nucleic acid extraction on label for use with specific FDA-cleared tests from other companies
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	18/19
Tests available on instrument in U.S./Outside U.S.	—	eSensor RVP (GenMark); xTAG GPP and RVP, MultiCode-RTx HSV (Luminex); Prodesse assays (Hologic); Influenza RT-PCR Panel (CDC); Molecular Influenza A+B and hMPV (Quidel); MRSA/SA ELITe MGB (ELITech); Adenovirus R-gene (bioMérieux)/ MERS coronavirus rRT-PCR assay (CDC); Simplexa flu A-B and RSV (Focus)
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—
Research-use-only assays/Tests in development	various/various	various/various
Open-channel capabilities/Start-up and preparation time	yes/15–20 min.	yes/10–15 min.
Model type of sample-handling system/Maximum sample load capacity	EMAG/48	easyMAG/24
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	10 µL/yes (intra-run/batch range of 10–1,000 µL)/up to 1,000 µL	10 µL/yes (intra-run/batch range of 10–1,000 µL)/up to 1,000 µL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	10 µL/10–1,000 µL/yes	10 µL/same sample volume range, dependent on downstream application/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	1.5–14 mL/yes/no	—/yes/no
Sample barcode languages/Sample types available in open mode	Codabar, Interleaved 2 of 5, codes 128 and 39, UPC, EAN/JAN for reagents and sample tubes, plus EAN8 for output tubes/various	code 128 for reagents and disposables, EAN-8, EAN-13, UPC-A, UPC-E, Interleaved 2 of 5, standard code 39, others/various
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/various	yes/yes/various
Amplification reagents or methods supported	extraction instrument	extraction instrument
No. of different assays onboard at once/Programmed or calibrated at once	48 positions each can extract for a distinct assay/—	24 positions each can extract for a distinct assay/—
Tests per container set/Multiple reagent configurations supported	main components: 384 extractions, varies for others/universal reagent set	main components: 384 extractions/universal reagent set
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/no	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/no
Same capabilities when third-party reagent used/Lot sequestering available	no/—	no/—
Closed-vial stability for amplification reagents/Extraction reagents	—/up to 30 days onboard the system	—/up to 30 days onboard the system
Storage temp. requirement for amplification reagents/Extraction reagents	—/mostly room temperature with 2 components at 2°–8°C	—/mostly room temperature with 2 components at 2°–8°C
Shipment temp. requirement for amplification reagents/Extraction reagents	—/room temperature	room temperature or 2°–8°C depending on reagent/room temperature or 2°–8°C depending on reagent
Minimum/Maximum reagent shelf-life guarantee	60 days/15–24 months	60 days/15–24 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	no/no
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	no/—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/no	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/no	no/none/no
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	48/—	24/—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/576	no/—
Time between start and initial result/Instrument automatic shutdown	~98 min./no	45 min./no
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/normal biohazardous waste	no/no/normal biohazardous waste
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/no	yes/mouse and touchscreen/no
Service contracts available/Mean time between failures/To repair failures	7 days full service, preventive maintenance/extraction: >100 days/3.5 hrs.	7 days full service, preventive maintenance/extraction: 328 days/3.5 hrs.
Turnaround time for problem solving by phone/Email/Field service	immediate (30 min. after hours)/<24 hrs./within 2 hrs. after scheduling	immediate (30 min. after hours)/<24 hrs./within 2 hrs. after scheduling
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	32/within 24 hrs./24–7 phone support, 12–7 PM on-site support	32/within 24 hrs./24–7 phone support, 12–7 PM on-site support
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes/no/yes	yes/no/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 min.; weekly: 10 min.; monthly: 10 min.; yearly: performed by FSE/no	daily: 5 min.; weekly: 10 min.; yearly: performed by FSE/no
Preventive maintenance per year for sample extraction/Amplification detection	1/—	2/—
Downtime for preventive maintenance/Spare parts on site	4 hrs./no	3 hrs./no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/no	no/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/no/no	yes/no/—
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/XML file transfer, Windows environment	yes/XML file transfer, WIN 7 environment
• QC results transferred automatically to LIS/Data-management capability	yes/yes	yes/yes
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	no/yes	no/yes
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/no	no/yes/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	fully automated total nucleic acid extraction platform for a wide variety of clinical sample types; state-of-the-art process with single sample compartment, minimizing potential sample loss and cross-contamination; management of 3 internal controls per sample for downstream molecular testing applications	various 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

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

Part 8 of 17

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	Cepheid **Scott Stiles** MarCommGroup@cepheid.com **Sunnyvale, CA** **888-336-2743** www.cepheid.com	**Cepheid** **Scott Stiles** MarCommGroup@cepheid.com **Sunnyvale, CA** **888-336-2743** www.cepheid.com
Name of instrument	GeneXpert 1, GeneXpert 2, GeneXpert 4, GeneXpert 16	GeneXpert Infinity-48s, Infinity-80
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2006 (2011 for GX 2)/2006/2006	2012/2012/2012
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	GeneXpert 1: 4 × 12 × 11.70; GeneXpert 2: 6.35 × 12 × 11.70; GeneXpert 4: 11 × 12 × 11.70; GeneXpert 16: 22.75 × 25.80 × 13.25/2.625/—	79.1 × 105.2 × 34.6 (48); 78.5 × 85 × 34.6 (48s); 78.5 × 108 × 35 (80)/25.25/—
Supplied with UPS/BTU	yes/—	yes/—
Physical contamination control features	closed-cartridge technology	closed-cartridge technology
List price/Price for sample extraction and amplification detection modules	$24,900–$174,400/—	$199,000–$530,000/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–120 VAC, 50–60 Hz	yes/100–120 VAC, 50–60 Hz (48); 200–240 VAC, 50–60 Hz (48s, 80)
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	less than 1 week/FOB origin/company/<1 day	2–4 weeks/FOB origin/company/<1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1 or more/<1 day/no	on site/1 or more/1–3 days/no
Test menu	Xpert: Carba-R, C. difficile, C. difficile/Epi, MRSA, MRSA/SA BC, MRSA/SA SSTI, Norovirus, SA Nasal Complete, vanA, Ebola (emergency use authorization), EV, Flu, Flu/RSV XC, MTB/RIF, CT-NG, GBS, GBS LB, TV, FII & FV	Xpert: Carba-R, C. difficile, C. difficile/Epi, MRSA, MRSA/SA BC, MRSA/SA SSTI, Norovirus, SA Nasal Complete, vanA, Ebola (emergency use authorization), EV, Flu, Flu/RSV XC, MTB/RIF, CT-NG, GBS, GBS LB, TV, FII & FV
No. of tests for which analyzer has FDA-cleared applications/CE mark	20/23	20/23
Tests available on instrument in U.S./Outside U.S.	—	—
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/carba-R, HCV viral load, HIV-1 qual, HIV-1 viral load, Trichomonas vaginalis, HPV, BCR-ABL monitor	—/carba-R, HCV viral load, HIV-1 qual, HIV-1 viral load, Trichomonas vaginalis, HPV, BCR-ABL monitor
Research-use-only assays/Tests in development	—	—
Open-channel capabilities/Start-up and preparation time	—/<1 min.	—/<1 min.
Model type of sample-handling system/Maximum sample load capacity	cartridge based/up to 16, based on number of installed modules	cartridge based/2,300 per day
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	—/yes (sample-type dependent: whole blood, swab, sputum fluids, others)/—	—/yes (sample-type dependent: whole blood, swab, sputum fluids, others)/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/yes/yes	—/yes/yes
Sample barcode languages/Sample types available in open mode	all common/no restrictions	all common/no restrictions
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/no restrictions	no/no/no restrictions
Amplification reagents or methods supported	—	—
No. of different assays onboard at once/Programmed or calibrated at once	full menu/full menu	full menu/full menu
Tests per container set/Multiple reagent configurations supported	single-use cartridges/reagents contained in cartridge	single-use cartridges/reagents contained in cartridge
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/closed-cartridge technology	no/closed-cartridge technology
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	yes/yes
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	up to 2 years/up to 2 years	up to 2 years/up to 2 years
Storage temp. requirement for amplification reagents/Extraction reagents	amplification and extraction: room temperature (2°–8°C depending on test)	amplification and extraction: room temperature (2°–8°C depending on test)
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	3 months/varies	3 months/—
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	yes/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/—	no/—
Multiple calibrant lots stored for same assay/Required calibration frequency	—/2,000 tests per module	—/2,000 tests or 1 year per module
Length of assay calibration/Typical calibration frequency	2,000 tests or 1 year/1 year	2,000 tests or 1 year per module/1 year
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/—	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	no/none/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	—	119 (48s); 183 (80): random access (not batch)/<2 min. per sample: random access
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	35 min.–2 hrs., depending on test/no	35 min.–2 hrs., depending on test/no
Startup programmable/Remote system monitoring/Waste required for disposables	—/—/disposable cartridges	yes/no/disposable cartridges
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/mouse and touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	full service, labor and parts/—/24–48 hrs.	5 days (standard) or 6 days (preferred) labor and parts/—/24–48 hrs.
Turnaround time for problem solving by phone/Email/Field service	yes/yes/yes	yes/yes/yes
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	14/within 24 hrs./24–7 or M–F, 5 AM–5 PM	14/within 24 hrs./M–F, 8 AM–7 PM, Saturday with preferred
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes (M–F, 5 AM–5 PM)/no/no	yes (M–F, 5 AM–5 PM)/no/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 min.; weekly: 5 min.; monthly: based on system configuration; yearly: up to 30 min. (based on number of modules)/yes	daily: 5 min.; weekly: 10 min.; monthly: based on system configuration; yearly: 30–60 min. (based on number of modules)/yes
Preventive maintenance per year for sample extraction/Amplification detection	—	—
Downtime for preventive maintenance/Spare parts on site	6–8 hrs. per year/no	6–8 hrs. per year/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/yes
• Priority processing	yes	yes
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	yes/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/yes	yes/yes
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/yes/yes	yes/yes/—
• Sample storage and retrieval software supports CLSI standards	yes	yes
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/TCP-IP	yes/TCP-IP
• QC results transferred automatically to LIS/Data-management capability	yes/yes	yes/yes
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/yes	yes/yes
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	yes/yes	yes/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/yes	yes/yes
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	yes/yes/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	fully integrated real-time PCR system; automated and integrated steps for PCR-based DNA testing: sample preparation and DNA amplification and detection; simplifies hands-on preparation; provides PCR test results from raw sample in ~1 hr.; variety of configurations to meet broad range of demands	fully automated, robotic, real-time PCR system integrates all steps required for PCR-based DNA testing: sample preparation and DNA amplification and detection; cartridge handling; fully integrated; built-in smart technology: fluid master scheduler prioritizes test runs; reduces hands-on labor

for calibration and controls

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

AUTOMATED MOLECULAR PLATFORMS

Part 9 of 17

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	DiaSorin Molecular marketing-info_molecular@diasorin.com **Cypress, CA** **562-240-6500** www.molecular.diasorin.com	**ELITechGroup Molecular Diagnostics** **Deirdre Cross** d.cross@elitechgroup.com **Bothell, WA** **800-453-2725** www.elitechgroup.com/north-america
Name of instrument	LIAISON MDX	ELITe InGenius
Country where designed/Manufactured/Reagents manufactured	U.S/U.S/U.S.	U.S., Italy, Japan/U.S., Italy, Japan/U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	pending Oct. 2018/combined
First year sold in U.S./Sold internationally/Installed	2009/2009/2009	2015/2015/2015
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	12 × 8 × 12/1/≤50	33 × 39 × 29/8.1/55
Supplied with UPS/BTU	no/~450 per hr.	yes/—
Physical contamination control features	disc sealers, single-use reagents	unitized, single-use reagents cassettes, aerosol barrier pipette tips, programmable UV decontamination cycle
List price/Price for sample extraction and amplification detection modules	$60,000/—	$130,000 (single, combined extraction and real-time PCR system)/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental/per contract	straight purchase, reagent rental, lease/20–200 µL patient specimen
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–120 V (240 V international); 50–60 Hz; 4.5 A	yes/120 VAC, 50–60 Hz
Labor and parts warranties/Advanced operator training	standard 1 year (additional years available)/yes	1–3 years with contract/yes
Delivery time/Delivery charges/Installer/Time to install on site	1–2 days/none/DiaSorin Molecular/1 hr.	45 days/origin/ELITech MDx/~1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/no limit/<1 day/yes	on site/1–3/1 day for operational training/yes
Test menu	HSV 1&2 Direct, CSF, cutaneous, and mucocutaneous, swabs; VZV Direct; Group A Strep Direct; Flu A/B & RSV Direct and Universal Direct; Influenza A H1N1; *C. difficile* Direct and Universal Direct; Bordetella Direct and Universal Direct; Dengue (CE-IVD), CMV (CE-IVD), EBV (CE-IVD); >50 primer pairs	infectious diseases, transplant, STD/STI, HAI, respiratory, meningitis, mosquito-borne, gastrointestinal, onco-hematology (CE-IVD), human genetics (CE-IVD)
No. of tests for which analyzer has FDA-cleared applications/CE mark	8/14	Zika EUA, HSV 1-2 (pending Oct. 2018)/>22 (CMV, BKV, HSV 1/2, VZV, HAIs, meningitis)
Tests available on instrument in U.S./Outside U.S.	~50/~50	Zika EUA/>22 (infectious diseases, transplant [SOT/HSCT], STD/STI, HAI, respiratory, meningitis oncology, human genetics)
Tests not available in U.S. but submitted to FDA/Available in other countries only	1/6	—/MRSA mecC, BCR-ABL, Factor II/V, HHV-7, MTHFR, aspergillus, rubella, MtB, C. difficile, ESBL, CRE
Research-use-only assays/Tests in development	0/15+	>21/>6
Open-channel capabilities/Start-up and preparation time	yes/~1 min. per sample	yes/~1 min. per sample
Model type of sample-handling system/Maximum sample load capacity	—/Direct: up to 8; Universal: up to 96	fully automated and integrated specimen DNA-RNA extraction and real-time PCR; operate in extraction only, real-time PCR only, and extraction-PCR combined/1–12
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	direct method: 50 µL; universal direct: 2–3 µL; extracted: 200 µL/no/—	200 µL/yes (200–1,000 µL)/1,000 µL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—	10 µL/20–200 µL patient specimen/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/yes/yes	6.0 mL, 13 x 100 mm; 4.0 mL, 13 x 75 mm; 3.0 mL, 13 x 75 mm/yes/yes
Sample barcode languages/Sample types available in open mode	most 1D and 2D symbologies/user defined, including NPS, stool, serum, whole blood, plasma, urine, CSF, throat swabs, cutaneous/mucocutaneous swabs, genital swabs in transport media	>12/whole blood, plasma, serum, CSF, urine, stool, sputum, BAL, nasal, rectal, wound, and urogenital swabs
Clot detection/Open extraction platform/Sample types (open extraction)	—/no/—	yes/yes/whole blood, plasma, serum, CSF, urine, stool, nasal, and urogenital swabs
Amplification reagents or methods supported	real-time PCR, melt curve analysis	MGB, TaqMan, multiplex, qualitative and quantitative results with programmable melt-curve analysis on DNA or RNA targets (most real-time PCR probes and chemistries)
No. of different assays onboard at once/Programmed or calibrated at once	Direct: up to 8 wells; Universal: up to 96 wells/Direct: up to 8 wells; Universal: up to 96 wells	≤24/>60
Tests per container set/Multiple reagent configurations supported	Universal: 100; Direct: 24/up to 96 wells	48/yes
Reagent container placed directly on system/Onboard test auto inventory	no/no	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	—/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/yes	no/yes
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	yes/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	yes/—	yes/no
Closed-vial stability for amplification reagents/Extraction reagents	2 years/—	18 months to >2 years/>1 year
Storage temp. requirement for amplification reagents/Extraction reagents	frozen/—	-20°C/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	frozen/—	frozen/room temperature
Minimum/Maximum reagent shelf-life guarantee	—/18 months	>15–18 months minimum from ship date/>2 years
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	yes/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/yes	yes/yes
Multiple calibrant lots stored for same assay/Required calibration frequency	yes/no assay calibration required	yes/6 months
Length of assay calibration/Typical calibration frequency	—	2 hrs./2–3 times per year
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	yes/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/amplification detection: 2–3 min./yes	no/<2 min./yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	operator defined and validated	operator defined and validated
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	yes/15–30 min. for 96 samples	yes (batch processing for 12 samples)/~1 min. per sample
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/tips not stored on instrument	yes/200
Time between start and initial result/Instrument automatic shutdown	~1 hr./no	2–2.5 hrs./no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/biohazard disposal	yes/yes/self-contained unitized reagent cassettes, on-board solid waste storage
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	3-year extended warranty/amplification: >12 months/1 hr. on site	1–5 years/—/—
Turnaround time for problem solving by phone/Email/Field service	<1 hr. during business hours/<1 hr. during business hours/within 24 hrs.	<3 hrs., same day (after hours)/<3 hrs., same day (after hours)/24-hr. response
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	50/within 48 hrs./M–F, 7 AM–5 PM	—/next day/24–7
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes, M–F/no/yes	yes/yes/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 1 min.; weekly: 5 min.; monthly: 5–15 min.; yearly: ~1 hr./yes	daily: empty waste container; weekly: <10 min.; monthly: <5 min./—
Preventive maintenance per year for sample extraction/Amplification detection	—/2	1/1 for combined platform
Downtime for preventive maintenance/Spare parts on site	~1 hr./—	1 day/—
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/yes
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	yes/—
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	—/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	—/—/no
• Sample storage and retrieval software supports CLSI standards	no	—
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/ASTM, TCP-IP	yes/third-party middleware provider
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/no
• Interfaces operational in active user sites	yes	no
• Rules-based control subsystem/Process control via control subsystem	no/no	no/no
• LIS operates simultaneously with assays running	yes	no
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	yes/yes/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	moderate complexity assays without nucleic acid extraction; fluid check prevents false-negatives if sample is accidentally not loaded; scalable, flexible system for qual. and quant. assays with small footprint and open-channel avail.; 8-well Direct Amplification Disc for sample-to-answer testing and 96-well Universal Disc for higher volume testing; multiple assays can be performed at one time in approx. 1 hr.	16 validated specimen types for universal DNA/RNA extraction and independently controlled real-time PCR system; walkaway system fully automates specimen results; independently controlled tracks simultaneously allow 12 real-time PCR profiles per batch; multiplex PCR up to 6 targets per track and multiple PCR from a single extraction to create customer-defined disease state panels with mixed parameters

Part 10 of 17

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	GenMark Diagnostics info@genmarkdx.com **Carlsbad, CA** **800-eSensor (800-373-6767)** www.genmarkdx.com	**GenMark Diagnostics** info@genmarkdx.com **Carlsbad, CA** **800-eSensor (800-373-6767)** www.genmarkdx.com
Name of instrument	ePlex	XT-8
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2017/2016/2016	2008/—/2008
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	1 Tower: 23.5 × 21.3 × 19; 2 Tower: 23.5 × 28.5 × 19; 3 Tower: 23.5 × 35.8 × 19; 4 Tower: 23.5 × 43 × 19/1 Tower: 2.81; 2 Tower: 3.76; 3 Tower: 4.7; 4 Tower: 5.67/<60 dBA	18.11 × 15.75 × 16.14/1.77/—
Supplied with UPS/BTU	yes/1 Tower: 904; 2 Tower: 1,399; 3 Tower: 1,894; 4 Tower: 2,388	yes/—
Physical contamination control features	closed-cartridge technology	closed-cartridge technology
List price/Price for sample extraction and amplification detection modules	varies by configuration/—	varies by configuration/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC, 50–60 Hz	yes/100–230 VAC
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	<1 week/varies/GenMark/1 day	3 days/variable/GenMark/<1 hr.
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1–4/~3 hrs./yes	on site/1–4/1–3 days/yes
Test menu	Respiratory Pathogen panel (RP); Blood Culture Identification, Gram-negative panel (BCID-GN); Blood Culture Identification, Gram-positive panel (BCID-GP); Blood Culture Identification, Fungal Pathogen panel (BCID-FP)	Cystic Fibrosis Genotyping test, Respiratory Viral panel, Thrombophilia Risk test, Warfarin Sensitivity test
No. of tests for which analyzer has FDA-cleared applications/CE mark	1/4	4/1
Tests available on instrument in U.S./Outside U.S.	RP/RP, BCID-GN, BCID-GP, BCID-FP	6/1
Tests not available in U.S. but submitted to FDA/Available in other countries only	BCID-GP/BCID-GP	—
Research-use-only assays/Tests in development	—/Gastrointestinal Pathogen panel (GI), Central Nervous System panel (CNS)	HCVg Direct test, 2C19 Genotyping test/—
Open-channel capabilities/Start-up and preparation time	no/<2 min.	no/<5 min.
Model type of sample-handling system/Maximum sample load capacity	sample to answer/random access (up to 24 dependent on system configuration)	batch, cartridge based/96 in 8-hr. shift
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	varies by assay/—/no	varies by test/yes/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/yes/no	—/yes/no
Sample barcode languages/Sample types available in open mode	all common/—	all common/—
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—	—/yes/nasopharyngeal swab, whole blood, saliva
Amplification reagents or methods supported	PCR	PCR
No. of different assays onboard at once/Programmed or calibrated at once	multiple/multiple	multiple/multiple
Tests per container set/Multiple reagent configurations supported	—	varies, 24–48/—
Reagent container placed directly on system/Onboard test auto inventory	no/no	no/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	no/yes/yes	no/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	no/liquid and dry	no/liquid
Reagent reconstitution required/Chemical contamination control	no/—	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	—	up to 12 months/—
Storage temp. requirement for amplification reagents/Extraction reagents	—	-20°C/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	—	frozen/ambient
Minimum/Maximum reagent shelf-life guarantee	assay dependent/assay dependent	up to 60 days/12 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	no/no
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	no/—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	yes/—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/yes/yes	no/none/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	1/1/1/1
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	random access (up to 24 dependent on system configuration)/random access (<2 min. per sample)	up to 3.5 hrs./up to 2.5 hrs.
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	<2 hrs. (assay dependent)/no	varies by assay/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/disposable cartridges	no/no/disposable cartridges
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/yes	yes/touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	service agreement/—/varies	service agreement/—/varies
Turnaround time for problem solving by phone/Email/Field service	M–F, 7 AM–5 PM PT: ≤1 hr.; weekends on call/same as phone/within 48 hrs.	M–F, 7 AM–5 PM PT: ≤1 hr.; weekends on call/same as phone/within 48 hrs.
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	9/—/24–7	9/24–7/24–7
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	no/no/yes	yes (within 48 hrs.)/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	—/no	yearly: <15 min./yes
Preventive maintenance per year for sample extraction/Amplification detection	instrument maintenance every 6 months	—
Downtime for preventive maintenance/Spare parts on site	~2 hrs./no	60 min./no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/yes
• Priority processing	yes	yes
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/no/—
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/HL7, ASTM, flat files	no/—
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/yes
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/yes	no/no
• LIS operates simultaneously with assays running	yes	—
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/no/no	no/yes/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	The True Sample-to-Answer Solution is easy to use with least hands-on time and processing steps; bidirectional LIS with rules-based engine for customizable antimicrobial stewardship interventions and result autovalidation; scheduling of epidemiology reports; modular and scalable flexibility	complete benchtop system for multiplex molecular testing; touchscreen user interface; customizable reports; no routine maintenance or calibration

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AUTOMATED MOLECULAR PLATFORMS

Part 11 of 17

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	Hologic **Glenn Sawyer** glenn.sawyer@hologic.com **San Diego, CA** **858-410-8000** www.pantherfusion.com, www.hologic.com	**Hologic** **Glenn Sawyer** glenn.sawyer@hologic.com **San Diego, CA** **858-410-8000** www.hologic.com
Name of instrument	Panther Fusion System	Panther System
Country where designed/Manufactured/Reagents manufactured	U.S./Switzerland/U.S.	U.S./Switzerland/U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2017/2017/2017	2012/2010/2010
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	69 × 76 × 32/16.8/<60	69 × 48 × 32/10.6/<55
Supplied with UPS/BTU	yes/3,412	yes/1,878 per hr.
Physical contamination control features	closed system, liquid level sensing, pressure-dispense verification	closed system, liquid level sensing, pressure-dispense verification, onboard deactivation, deep-well reaction tube, single sample aspiration and dispense, penetrable cap
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/variable
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/190–240 VAC, 50–60 Hz, 1,800 VA single phase	yes/100–240 V ± 10%
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	~1 week/variable at origin and destination/Hologic/1–2 days	~1 week/variable at origin and destination/Hologic/1–2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	off site/2/2–3 days/yes	on and off site/2/3 days/yes
Test menu	CT-GC, CT, GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HBV viral load, M. gen, HSV 1&2, Zika, GBS, MRSA, Flu A/B/RSV, Paraflu, AdV/hMPV/RV	CT-GC, CT, GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HBV viral load, M. gen, HSV 1&2, Zika
No. of tests for which analyzer has FDA-cleared applications/CE mark	13/17	9/12
Tests available on instrument in U.S./Outside U.S.	CT-GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HBV viral load, HSV 1&2, Zika, GBS, Flu A/B/RSV, Paraflu, AdV/hMPV/RV/CT-GC, CT, GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HBV viral load, M. gen, HSV 1&2, Zika, MRSA, GBS, Flu A/B/RSV, Paraflu, AdV/hMPV/RV	CT-GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HBV viral load HSV 1&2, Zika/CT-GC, CT, GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HBV viral load, M. gen, HSV 1&2, Zika
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/CT, GC, MRSA, Bordetella, M. gen	—/CT, GC, M. gen
Research-use-only assays/Tests in development	—/BV, CV/TV, M. gen	—/BV, CV/TV, M. gen
Open-channel capabilities/Start-up and preparation time	yes/<15 min.	yes/<15 min.
Model type of sample-handling system/Maximum sample load capacity	automated onboard/120, with continuous and random access	automated onboard/120
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	400 µL/yes (varies by sample type with open channel capability)/yes	400 µL/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	250 µL/no/yes	250 µL/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	various/yes (automated onboard scanner to maintain positive sample ID)/—	various/yes/no
Sample barcode languages/Sample types available in open mode	Codabar codes 39 and 128, Interleaved 2 of 5, JAN13, code 93, UPC, NW7/—	Codabar codes 39 and 128, Interleaved 2 of 5, JAN13, code 93, UPC, NW7/—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/—	yes/no/—
Amplification reagents or methods supported	transcription-mediated amplification, real-time TMA, real-time PCR, Invader Plus	transcription-mediated amplification, real-time TMA
No. of different assays onboard at once/Programmed or calibrated at once	up to 32/up to 32	4/4
Tests per container set/Multiple reagent configurations supported	12, 100, or 250/yes	100 or 250/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/yes	yes/yes
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	yes/yes
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	—	—
Closed-vial stability for amplification reagents/Extraction reagents	assay dependent/assay dependent	assay dependent/assay dependent
Storage temp. requirement for amplification reagents/Extraction reagents	refrigeration/refrigeration	refrigeration/refrigeration
Shipment temp. requirement for amplification reagents/Extraction reagents	assay dependent/assay dependent	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	—/up to 2 years	—/up to 2 years
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/no	yes/—
Assay calibrations required by end user/Calibrants can be stored onboard	yes/yes	yes/yes
Multiple calibrant lots stored for same assay/Required calibration frequency	no/24 hrs.	no/24 hrs.
Length of assay calibration/Typical calibration frequency	can be user-defined (assay dependent)/24 hrs.	24 hrs./24 hrs.
Onboard real-time QC/Supports multiple QC lot numbers per assay	—/yes	—/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/<15 min./yes	yes/<15 min./yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	— (not a batch analyzer)	— (not a batch analyzer)
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	120 samples/<15 seconds per sample	120 samples/<15 seconds per sample
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/1,152	yes/576 (2.2 tips per sample)
Time between start and initial result/Instrument automatic shutdown	2.4 hrs./yes	2.7–3.5 hrs. (assay dependent)/no
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/plastics and cardboard	yes/yes/plastics and cardboard
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/yes	yes/touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	on-demand, PM only, standard, standard plus, premium, premium plus/—/—	on-demand, PM only, standard, standard plus, premium, premium plus/—/—
Turnaround time for problem solving by phone/Email/Field service	—	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/standard and standard plus: within 24 hrs., premium and premium plus: within 18 hrs./on-demand, PM only, and standard: M–F, 5 AM–5 PM, PT; standard plus, premium, premium plus: 24–7	—/standard and standard plus: within 24 hrs., premium and premium plus: within 18 hrs./on-demand, PM only, and standard: M–F, 5 AM–5 PM, PT; standard plus, premium, premium plus: 24–7
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes/yes/yes	yes/yes/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	weekly: <5 min.; monthly: <45 min./yes	weekly: <5 min.; monthly: <45 min./yes
Preventive maintenance per year for sample extraction/Amplification detection	2/2	2/2
Downtime for preventive maintenance/Spare parts on site	<1 day/yes	<1 day/yes
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/yes
• Priority processing	yes	yes
• Supports accession No. redundancy/Specimen carrier and level identification	yes/no	yes/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/—/yes	yes/no/yes
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/LIS1-A and LIS2-A2 (ASTM)	yes/LIS1-A and LIS2-A2 (ASTM)
• QC results transferred automatically to LIS/Data-management capability	yes/yes	yes/yes
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/yes	yes/yes
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/—	yes/—
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—/yes/yes	—/yes/—
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	full sample to result automation; random and continuous access; scheduled/automated maintenance for rapid startup; no return visits required for up to 120 samples/day; no batching requirements; multiple assays from a single sample; ready-to-use reagents for PCR assays; 5-color fluorescence detection; 12 independent onboard thermocyclers	full sample to result automation; random and continuous access; scheduled/automated maintenance for rapid startup; no return visits required for up to 120 samples/day; no batching requirements; runs multiple assays from a single sample; true positive sample ID; consolidated testing menu on a single platform; highest throughput per sq. ft.

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Part 12 of 17

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	HTG Molecular Diagnostics **Dave DeBonville** ddebonville@htgmolecular.com **Tucson, AZ** **952-465-9058** www.htgmolecular.com	**Luminex Corp.** **Christine Valle** cvalle@luminexcorp.com **Austin, TX** **512-219-8020** www.luminexcorp.com
Name of instrument	HTG EdgeSeq Processor	ARIES System
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	no (CE-IVD approved)/analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2014/2014/2014	2015/2016/2015
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	17 × 36 × 24/6/<65	38 × 61 × 100 cm/2.5/negligible
Supplied with UPS/BTU	no/—	yes/2,730
Physical contamination control features	self-contained waste capture	—
List price/Price for sample extraction and amplification detection modules	$125,000/—	$95,000/—
Purchase options/Minimum test volume requirements	straight purchase, lease/8 samples	straight purchase, reagent rental/200 µL
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/120–240 V	yes/120 V
Labor and parts warranties/Advanced operator training	1 year/yes	—/no
Delivery time/Delivery charges/Installer/Time to install on site	1–4 days/$800 destination/HTG/2 days	2–3 days/per agreement/Luminex/6 hrs.
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/2–3/2 days/yes	on site/11/1–2 days/yes
Test menu	HTG EdgeSeq: ALK*Plus* assay EU (CE-IVD), DLBCL COO assay EU (CE-IVD), Immuno-Oncology assay (RUO), Oncology Biomarker panel (RUO), Precision Immuno-Oncology panel (RUO), DLBCL COO assay (RUO), PATH panel (RUO), miRNA Whole Transcriptome assay (RUO, human), Mouse miRNA Whole Transcriptome assay (RUO; Q4), Mouse miRNA Tumor Response panel (RUO; Q4)	ARIES Bordetella assay, ARIES C. difficile assay, ARIES Flu A/B & RSV assay, ARIES GBS assay, ARIES HSV 1&2 assay, ARIES Group A strep assay, ASR Primers
No. of tests for which analyzer has FDA-cleared applications/CE mark	—/2	6/7
Tests available on instrument in U.S./Outside U.S.	8/10	ARIES Bordetella assay, ARIES C. difficile assay, ARIES GBS assay, ARIES HSV 1&2 assay, ARIES Flu A/B & RSV assay, ARIES Group A strep assay/ARIES Bordetella assay, ARIES C. difficile assay, ARIES Flu A/B & RSV assay, ARIES GBS assay, ARIES HSV 1&2 assay, ARIES Norovirus assay, ARIES Group A strep assay
Tests not available in U.S. but submitted to FDA/Available in other countries only	HTG EdgeSeq: DLBCL COO assay, ALK*Plus* assay/HTG EdgeSeq: DLBCL COO assay EU, ALK*Plus* assay EU	none/none
Research-use-only assays/Tests in development	8/3	Atopobium vaginae, Fusobacterium, Gardnerella vaginalis, group A strep, adenovirus, enterovirus, varicella zoster virus (VZV), Trichomonas vaginalis, Candida albicans, Candida glabrata/>8
Open-channel capabilities/Start-up and preparation time	no/<30 min.	yes/<2 min. per sample
Model type of sample-handling system/Maximum sample load capacity	manual (lysis only prep)/96	cartridge based/400 µL
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	single 5-micron FFPE section, 15 µL serum or plasma, PAXGene 32 µL, ≥2,000 cells, extracted RNA/yes (assay and tissue dependent)/assay and tissue dependent	200 µL/yes (200–400 µL input)/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	uses 96-well microtiter plate/no/yes	—/yes/no
Sample barcode languages/Sample types available in open mode	—/assay and tissue dependent	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/assay and tissue dependent	no/no/dependent on assay
Amplification reagents or methods supported	—	real-time PCR
No. of different assays onboard at once/Programmed or calibrated at once	1/8	up to 12/up to 12
Tests per container set/Multiple reagent configurations supported	up to 8, 24, or 96/yes	24/—
Reagent container placed directly on system/Onboard test auto inventory	yes/no	yes/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	no/yes/yes	no/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	no/liquid	no/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/onboard waste capture	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	no/yes	yes/no
Closed-vial stability for amplification reagents/Extraction reagents	—	9 months, planned to 18 months/9 months, planned to 18 months
Storage temp. requirement for amplification reagents/Extraction reagents	—	room temperature/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	—	refrigeration/refrigeration
Minimum/Maximum reagent shelf-life guarantee	reagent dependent/12 months	9 months, planned to 18 months/9 months, planned to 18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/—	yes/no
Assay calibrations required by end user/Calibrants can be stored onboard	—	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/at install	no/—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/yes	yes/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/no	yes/5 min. for initialization/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	user determined	internal sample processing control (SPC) in each cartridge
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	up to 96 samples/30 min.	2 hrs. per run, batched 12 samples per run/<2 min. per sample
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/386	yes/tips not stored on instrument
Time between start and initial result/Instrument automatic shutdown	~20 hrs./no	2 hrs./yes
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/plastic, contained liquid	yes/yes/biohazard disposal
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	yearly (parts and labor)/—/2–3 days	Bronze, Silver, Gold, Gold+, Platinum, Diamond/26 weeks/4.8 hrs.
Turnaround time for problem solving by phone/Email/Field service	<1 hr./<1 hr./24–72 hrs.	1 hr./1 hr./—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/24–72 hrs./M–F, 10 hrs.	23/varies per contract: next business day to second business day/M–F, 8 AM–6 PM
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	no/no/yes	yes, per service contract/no/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/—
Average maintenance time for lab personnel/Onboard maintenance records	daily: 10 min.; weekly: 90 min./yes	daily: 5 min.; monthly: 15 min./no
Preventive maintenance per year for sample extraction/Amplification detection	—	1/1
Downtime for preventive maintenance/Spare parts on site	8 hrs./no	4 hrs./no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	yes	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/no	yes/yes
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/no	yes/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	yes/—
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/—/no
• Sample storage and retrieval software supports CLSI standards	—	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—	yes/HL7, CSV
• QC results transferred automatically to LIS/Data-management capability	no/yes	yes/yes
• Interfaces operational in active user sites	—	yes
• Rules-based control subsystem/Process control via control subsystem	—	yes/no
• LIS operates simultaneously with assays running	no	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/—	no/—
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—	yes/yes/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	low specimen input requirements without the need for DNA or RNA extraction; highly multiplexed assay (>2,000 targets) results with walkaway automation; simplified data reporting for targeted next-generation sequencing	capability to design and run LDTs alongside IVD assays with customizable assay protocol files; SYNCT software allows for visibility/communication to any networked ARIES instruments; ARIES onboard software allows for bidirectional communication to LIS

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AUTOMATED MOLECULAR PLATFORMS

Part 13 of 17

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	Luminex Corp. **Christine Valle** cvalle@luminexcorp.com **Austin, TX** **512-219-8020** www.luminexcorp.com	**Meridian Bioscience** **Julie Clark** julie.clark@meridianbioscience.com **Cincinnati, OH** **513-271-3700** www.meridianbioscience.com
Name of instrument	VERIGENE System	Alethia (formerly Illumipro)
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2011/2011/2011	2010/2010/2010
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	18.7 × 7.6 × 22.9/1.88/—	8.3 × 11.5 × 3.7/0.66/—
Supplied with UPS/BTU	no/—	no/—
Physical contamination control features	—	closed system amplification
List price/Price for sample extraction and amplification detection modules	$20,000 per box/reader: $20,000; processor SP: $20,000	$8,300/amplification: $8,300
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/100 µL	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC, 50/60 Hz	yes/100–240 VAC, 50–60 Hz
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	variable by customer preference/variable by order size/Luminex/1 day	1 business day/based on location/Meridian Bioscience (optional)/1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1 or more/1–2 days/yes	on site/no limit/2 hrs./no
Test menu	Gram-positive blood culture, Gram-negative blood culture, C. difficile, enteric pathogens, respiratory pathogens flex	C. difficile, Chlamydia, Gonorrhea, group B strep, group A strep, Mycoplasma Direct, Pertussis, Malaria, Malaria Plus, HSV 1/2
No. of tests for which analyzer has FDA-cleared applications/CE mark	6/6	6/10
Tests available on instrument in U.S./Outside U.S.	6/6	C. difficile, group A strep, group B strep, Mycoplasma Direct, Pertussis, HSV 1/2/ C. difficile, Chlamydia, Gonorrhea, group A strep, group B strep, HSV 1/2, Mycoplasma Direct, Pertussis, Malaria, Malaria Plus
Tests not available in U.S. but submitted to FDA/Available in other countries only	0/0	CMV/Chlamydia, Gonorrhea, Malaria, Malaria Plus
Research-use-only assays/Tests in development	0/2	Malaria, Malaria Plus/—
Open-channel capabilities/Start-up and preparation time	no/<5 min. per test	no/2 min. hands-on time per sample
Model type of sample-handling system/Maximum sample load capacity	—/2 mL	—/10
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	100 µL/no/—	100 µL/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/same as adult/—	—/100 µL/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/standard barcodes/—	—/yes/no
Sample barcode languages/Sample types available in open mode	—	Codabar codes 39, 93-93i, 128-IBT, UPC-EAN-ISBN, 128-USS EAN 128, Interleaved 2 of 5
Clot detection/Open extraction platform/Sample types (open extraction)	—/no/ positive blood culture broth, fresh liquid or soft stool, liquid or soft stool in Cary-Blair, NPS in viral or universal transport medium	no/no/—
Amplification reagents or methods supported	onboard	loop-mediated isothermal amplification
No. of different assays onboard at once/Programmed or calibrated at once	single test protocol at a time per Processor SP/single test protocol at a time per Processor SP	10/10
Tests per container set/Multiple reagent configurations supported	1/no	25–50/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	no/no/no
Monitors expiration date/Auto lot recognition or calibration	yes/no	no/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	no/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/—	no/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	6 months/6 months	18 months/—
Storage temp. requirement for amplification reagents/Extraction reagents	≤-20°C/2°–30°C	2°–30°C/—
Shipment temp. requirement for amplification reagents/Extraction reagents	dry ice/ambient	2°–30°C/—
Minimum/Maximum reagent shelf-life guarantee	—/6 months	2 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/no	no/no
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	no/—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/<1 min./yes	yes/amplification detection: 5 min./no
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	controls run with each kit lot or shipment
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	scalable/<5 min. per test	10 samples per batch per module/2 min. per sample
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/—	no/—
Time between start and initial result/Instrument automatic shutdown	2–2.5 hrs./yes	40 min./yes
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/biohazardous waste	no/no/biohazardous waste
Windows technology/Mouse or touchscreen/Modular add-on capability	no/touchscreen/yes	no/—/no
Service contracts available/Mean time between failures/To repair failures	flexible; 2–5 years/—/—	3-year extended warranty/—/1 business day
Turnaround time for problem solving by phone/Email/Field service	24–7 accessible tech support/24–7 accessible tech support/1–4 days	10 min./10 min./—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	6/2–4 days/24–7	none/—/M–F, 8 AM–6 PM EST; weekends, 8 AM–5 PM EST
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	no/no/yes	1 business day replacement shipment/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: <5 min.; weekly: <5 min.; monthly: <20 min.; yearly <10 hrs./yes	daily: 1 min.; monthly: 2 min./no
Preventive maintenance per year for sample extraction/Amplification detection	yes/yes	no/no
Downtime for preventive maintenance/Spare parts on site	—/no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	—	no
• Data retrieval or Internet connectivity	yes	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/yes
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	yes	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/—	yes/HL7 via LIS Connect module
• QC results transferred automatically to LIS/Data-management capability	no/yes	no/no
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/—	no/no
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	yes/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/no/no	no/no/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	superior cost-effective multiplexing technology relative to competitors	loop-mediated isothermal amplification technology eliminates need for thermal cycling equipment; no extensive purification or extraction required; results in less than 1 hr.

**for calibration and controls*

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

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Part 14 of 17

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	QIAGEN **Germantown, MD** **240-686-7430** www.qiagen.com	**Quidel** **Aimee O'Connell** aimee.oconnell@quidel.com **San Diego, CA** **858-431-5855** www.quidel.com
Name of instrument	QIAsymphony SP/AS and RGQ MDx	Solana
Country where designed/Manufactured/Reagents manufactured	Switzerland, Germany, U.K./Switzerland, Malaysia/Germany	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2012/2007/2007	2015/2016/2015
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	QIAsymphony SP: 128 × 103 × 73 cm; QIAsymphony AS: 59 × 103 × 73 cm; QIAsymphony SP/AS (integrated operation): 185 × 103 × 73 cm; Rotor-Gene Q MDx: 28.6 × 37 × 42 (depth without cables) 53.8 (depth with door open) cm/—/—	5.9 × 9.4 × 9.4/1/none
Supplied with UPS/BTU	no/—	yes/—
Physical contamination control features	disposable filter tips, tip guards, magnetic head guards, moving UV lamp, drawer concept, protocol design (strategy around liquid transfer)	—
List price/Price for sample extraction and amplification detection modules	—	$8,000 for unit only/$8,000 for amplification detection module
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, lease/none
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/110 V–230 V	no/100–240 VAC, 47–63 Hz, 1.5–0.7 amps
Labor and parts warranties/Advanced operator training	1 year/yes	—/no
Delivery time/Delivery charges/Installer/Time to install on site	4 weeks/—/Qiagen service engineers/1–2 days	2-day shipping/—/Quidel FAS/—
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/4/2 days/yes	on site/1/1 day/yes
Test menu	open platform	group A strep, group B strep, strep complete, trichomonas, HSV 1+2/VZV, influenza A+B, C. difficile, RSV + hMPV, bordetella
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/15	9/9
Tests available on instrument in U.S./Outside U.S.	CMV/HBV, HCV, CMV, EBV, BKV, CT-NG, parvo, malaria	9/9
Tests not available in U.S. but submitted to FDA/Available in other countries only	—/HIV, HCV, HBV, CMV, EBV, BKV, VZV, HSV 1/2, CT-NG, T. vaginalis, HHV6, JCV, HAdV	0/0
Research-use-only assays/Tests in development	—/multiple	0/3
Open-channel capabilities/Start-up and preparation time	yes/15 min.	no/2 min.
Model type of sample-handling system/Maximum sample load capacity	QIAsymphony SP/96	none/12
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	200 µL/yes/400 µL, 500 µL, 800 µL, 4 mL	varies by analyte/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	100 µL/200 µL/yes	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	1.5–15 mL/yes/no	—/yes/yes
Sample barcode languages/Sample types available in open mode	diverse, e.g. Codabar codes 39 and 128/plasma, blood, stool, urine, FFPE, respiratory, CSF, swabs, LBC, transport media	code 128, EAN-13, data matrix/—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/plasma, blood, stool, urine, FFPE, respiratory, CSF, swabs, LBC, transport media	no/no/—
Amplification reagents or methods supported	real-time PCR	helicase dependent amplification
No. of different assays onboard at once/Programmed or calibrated at once	4/4	12/12
Tests per container set/Multiple reagent configurations supported	—/yes	12/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	no/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	no/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	no/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/no	yes/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes	no/yes
Closed-vial stability for amplification reagents/Extraction reagents	minimum 1 year/minimum 1year	varies by analyte, up to 12 months/varies by analyte, up to 12 months
Storage temp. requirement for amplification reagents/Extraction reagents	refrigerator/room temperature	2°–8°C/2°–8°C
Shipment temp. requirement for amplification reagents/Extraction reagents	cool packs/room temperature	2°–8°C/2°–8°C
Minimum/Maximum reagent shelf-life guarantee	9 months/2 years	12 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/yes	yes/no
Assay calibrations required by end user/Calibrants can be stored onboard	no/yes	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	—	no/instrument calibrates each time it is turned on
Length of assay calibration/Typical calibration frequency	—/assay dependent	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	no/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	no/—/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	assay dependent	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	80 percent of run time/30 min.	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/sufficient for 96 samples	yes/—
Time between start and initial result/Instrument automatic shutdown	typically 6–7 hrs. for 96 samples/no	varies by analyte/yes
Startup programmable/Remote system monitoring/Waste required for disposables	yes/no/separate liquid, plastic, and tip waste	no/yes/biohazard
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/yes	no/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	24 hrs., 48 hrs., and 5 days/—/—	replacement and repairs as long as customer is actively running the assay/—/—
Turnaround time for problem solving by phone/Email/Field service	yes/yes/yes	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	75/contract dependent/24–7	—/—/8
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes/yes/yes	no/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/no/yes	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 10 min.; weekly: 30 min.; monthly: 30 min./yes	daily: 10 min./no
Preventive maintenance per year for sample extraction/Amplification detection	1/1	—
Downtime for preventive maintenance/Spare parts on site	4 hrs./no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/no
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	—/yes	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/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	yes/QIAlink and HL7	yes/—
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/yes
• Interfaces operational in active user sites	yes	no
• Rules-based control subsystem/Process control via control subsystem	no/yes	no/no
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	no/yes/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	runs FDA-cleared and -approved content from sample to result as well as being a flexible, convenient system for independent modular operation; process security, user safety, and ease of use make this an ideal investment for a molecular diagnostic laboratory	utilizes helicase dependent amplification, ensuring fast time to result relative to assay sensitivity; 12 test throughput allows for high demand; detects 4 channels per well, allowing for multiplexing capabilities

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AUTOMATED MOLECULAR PLATFORMS

Part 15 of 17

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	Roche Diagnostics **Keith Obye** keith.obye@roche.com **Indianapolis, IN** **317-521-2000** usdiagnostics.roche.com	**Roche Diagnostics** **David Gayes** david.gayes@roche.com **Indianapolis, IN** **317-521-3569** usdiagnostics.roche.com
Name of instrument	cobas 6800/8800 system	cobas Liat PCR system
Country where designed/Manufactured/Reagents manufactured	Switzerland/Switzerland/U.S.	U.S./U.S., Switzerland/U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2016/2014/2014	2014/2017/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	cobas 6800: 85 × 51 × 115/40.7/<65; cobas 8800: 85 × 51 × 169/59.9/<65	7.5 × 4.5 × 9.5/<1/52 maximum
Supplied with UPS/BTU	yes/cobas 6800: 7,507 kJ/h; cobas 8800: 13,649 kJ/h	no/440
Physical contamination control features	airlock doors with HEPA filtration, pipette tips with filter technology, dedicated tips for each sample transfer and for transfer of extracted nucleic acid, stainless steel needle pipetting transfers for reagents, automatic heat sealing of amplification plate	all reagents are in self-contained assay tube requiring only the patient sample to be added
List price/Price for sample extraction and amplification detection modules	—	$25,000/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/none
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/200–240 VAC, 50 or 60 Hz	no/standard AC/DC outlet
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	<30 days/—/Roche/<5 days	1–2 days/origin/customer/out of box in several minutes
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/4 days/yes	on and off site/to be determined/<1 hr./no
Test menu	HIV-1, HCV, HBV, CMV, MPX, WNV, Zika, DPX, CT-NG, Babesia for IND	influenza A/B, strep A, influenza A/B & RSV
No. of tests for which analyzer has FDA-cleared applications/CE mark	10/12	3/4
Tests available on instrument in U.S./Outside U.S.	HIV-1, HCV, HBV, CMV, MPX, WNV, Zika, DPX, CT-NG/HIV-1, HCV, HBV, CMV, CT-NG, HPV, HIV-1/2 qual., MPX, WNV	influenza A/B, strep A, influenza A/B & RSV/influenza A/B, strep A, influenza A/B & RSV, C. diff.
Tests not available in U.S. but submitted to FDA/Available in other countries only	additional menu in development/HPV, HIV-1/2 qual.	—
Research-use-only assays/Tests in development	—/HPV, HIV-1/2 qual., EBV, BK, TV (Trichomonas vaginalis) and MG (Mycoplasma genitalium), omni channel for lab-developed testing	—
Open-channel capabilities/Start-up and preparation time	no/~30 min.	no/<2 min.
Model type of sample-handling system/Maximum sample load capacity	integrated system/350 with continuous loading	—/1 sample run at a time
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	HBV/HIV: 350 µL; HCV: 650 µL; CMV: 500 µL/yes/—	200 mL of UTM or Liquid Aries into assay/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	150 µL/—/yes	—/same as standard/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	height: 75–100 mm, outside diameter: 12.5–16 mm/1–23 characters, ASCII codes 32–126 in the barcode/no	—/yes/yes
Sample barcode languages/Sample types available in open mode	Codabar, codes 39, 128, 93, EAN-8, EAN-13 incl. JAN code, Interleaved 2 of 5/—	Codabar, codes 39, 93, 128, 128-A, 128-B, GS1 Databar-14/—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/—	no/no/—
Amplification reagents or methods supported	real-time PCR	real-time PCR
No. of different assays onboard at once/Programmed or calibrated at once	12, for up to 1,152 tests/12, for up to 1,152 tests (no user calibration requirements)	1/3
Tests per container set/Multiple reagent configurations supported	96 tests/cassette for HIV-1, HBV, HCV, CMV; 480 tests for CT-NG/—	20/no
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/no/no	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/AmpErase	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	yes/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/no
Same capabilities when third-party reagent used/Lot sequestering available	no/yes	no/no
Closed-vial stability for amplification reagents/Extraction reagents	up to 18 months/up to 18 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	2°–8°C/2°–8°C	2°–8°C/2°–8°C
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature or with cool packs/room temperature or with cool packs	0°–30°C for influenza A/B & RSV, strep A; 0°–15°C for influenza A/B/ 0°–30°C for influenza A/B & RSV, strep A; 0°–15°C for influenza A/B
Minimum/Maximum reagent shelf-life guarantee	3 months/18 months	3 months/18 months for influenza A/B; 15 months for strep A; 12 months for influenza A/B & RSV (all from date of manufacture)
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/no	yes/no
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	no/—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	yes/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/—/yes	yes/—/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	3 for quantitative virology assays, 2 for qualitative assays	1/1/1/1
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	cobas 6800: 8 hrs. for 384 tests; cobas 8800: 4 hrs. for 960 tests in 8 hrs./ cobas 6800: <30 min.; cobas 8800: <1 hr.	1 sample/1 min.
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/768	no/—
Time between start and initial result/Instrument automatic shutdown	<3.5 hrs./yes	20 min. for influenza A/B and influenza A/B & RSV, 15 min. for strep A/no
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/onboard solid and liquid waste containers	no/no/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/no	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	phone support 24–7, 5-day and 7-day premium service contracts/—/—	per terms of contract/data not available/data not available
Turnaround time for problem solving by phone/Email/Field service	—	immediate/24 hrs./—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	175/24 hrs./24–7, based on contract	—/—/24–7
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	24 hrs./yes/yes	no/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	weekly: ~45 min. (15 min. hands on)/yes	—/no
Preventive maintenance per year for sample extraction/Amplification detection	2/2	—
Downtime for preventive maintenance/Spare parts on site	~4 hrs./yes	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	no/yes
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/yes	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/yes/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	yes	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/Roche middleware solutions	yes/direct connectivity using HL7, drivers available for IT1000 and RALS
• QC results transferred automatically to LIS/Data-management capability	no/yes	yes/yes
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/no	no/no
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	yes/yes	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	no/yes	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	yes/no/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	unmatched operational efficiency: refrigerated reagent storage, 350 samples onboard, up to 960 results in 8 hrs.; contamination control with physical design separating system from lab environment and chemical control via amperase; no reagent preparation, no calibration, no daily maintenance for CLIA moderately complex designation	the only real-time PCR platform that is CLIA waived for influenza A/B, influenza A/B & RSV, and strep A, delivering all results in 20 min. or less; confirmation of negative test results is not required; definitive and actionable results with no need for interpretation

*for calibration and controls

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Part 16 of 17

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	Roche Diagnostics **Michael Ferranto** michael.ferranto@roche.com **Indianapolis, IN** **317-425-6533** usdiagnostics.roche.com	**Thermo Fisher Scientific** customerservice@lifetech.com **Carlsbad, CA** **800-955-6288** www.lifetechnologies.com
Name of instrument	cobas 4800 system	QuantStudio Dx Real-Time PCR Instrument
Country where designed/Manufactured/Reagents manufactured	Switzerland/Switzerland/U.S.	U.S./Singapore/U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2011/2009/2011	2012/2012/2012
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	cobas x 480: 35.6 × 65.55 × 30.5/19.6/<65; cobas z 480: 19.6 × 22.6 × 23.1/19.6/<65	75 × 53 × 70 cm/4/—
Supplied with UPS/BTU	yes/1,300 W	no/—
Physical contamination control features	Core Tip technology to reduce cross-contamination	imaging through sealed reaction plate
List price/Price for sample extraction and amplification detection modules	—	$79,900/amplification: $79,900
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/10 µL
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/cobas x 480: line voltage 115–230 VAC, line frequency 50 or 60 Hz; cobas z 480 analyzer: 200–240 VAC, line frequency 50 or 60 Hz	yes/100–240 VAC at 50 or 60 Hz
Labor and parts warranties/Advanced operator training	labor: 1 year; parts: covered by service contract/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	2–4 weeks/—/Roche service engineer/5 days	—/—/certified applied biosystems service engineer/—
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/4 days/yes	on site/based on customer requirements/based on customer requirements/yes
Test menu	CT-NG, HSV 1/2, HPV, MRSA/MSSA, C. diff., BRAF V600 mutation, EGFR mutation, KRAS mutation, factor II, factor V	influenza A/B, RSV + hMPV, C. difficile
No. of tests for which analyzer has FDA-cleared applications/CE mark	10/16	3/3
Tests available on instrument in U.S./Outside U.S.	CT-NG, HSV 1/2, HPV, MRSA/MSSA, C. diff., BRAF V600 mutation, EGFR mutation, KRAS mutation, factor II, factor V/—	3/3
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	HSV 1+2, VZV/—
Research-use-only assays/Tests in development	cobas PIK3CA/factor II, factor V	measures nucleic acid signals from DNA or reverse-transcribed RNA/—
Open-channel capabilities/Start-up and preparation time	yes/30 min.	yes/<5 min.
Model type of sample-handling system/Maximum sample load capacity	cobas x 480 instrument/96 (2 control samples plus up to 94 others)	—/96 (Dx mode), 96, 384, TaqMan Array Card (test development mode)
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	1 mL/—/—	10 µL (reaction volume)/yes, 10–30 µL reaction volume/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	1 mL/—/yes	—
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	13 mL (16–16.5 mm) and PreservCyt vials, MSwabs, cobas PCR media tubes/yes/no	—
Sample barcode languages/Sample types available in open mode	Codabar (without check sum), code 39 (without check sum), code 128, subset B and C (without check sum)/swab, urine, liquid-based cytology, FFPE tissue	—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/no	—/—/DNA or reverse-transcribed RNA
Amplification reagents or methods supported	real-time PCR	qPCR
No. of different assays onboard at once/Programmed or calibrated at once	mixed batch: 3 (MRSA/MSSA, C. diff., HSV 1/2); HPV, CT-NG run individually/1	depends on customer requirement/depends on customer requirement
Tests per container set/Multiple reagent configurations supported	CT-NG and HPV: 240 and 960 test kits; HSV 1/2, MRSA/SA, C. diff.: 80 and 240 test kits; oncology: 24 test kits/CT-NG and HPV: runs of 24, 48, 72, 96; HSV 1/2, MRSA/SA, C. diff.: mixed run of 8 or more; oncology: average runs of 3 or more	—
Reagent container placed directly on system/Onboard test auto inventory	yes/no	no/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	no/no/no
Monitors expiration date/Auto lot recognition or calibration	yes/no	no/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/AmpErase enzyme	no/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	yes/yes	yes/no
Closed-vial stability for amplification reagents/Extraction reagents	12–18 months/12–18 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	2°–8°C/2°–25°C	—
Shipment temp. requirement for amplification reagents/Extraction reagents	cool packs/cool packs	—
Minimum/Maximum reagent shelf-life guarantee	3 months/—	—
Autocalibration or autocalibration alert/Multipoint calibration supported	no/—	no/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	yes/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/—	no/3 months
Length of assay calibration/Typical calibration frequency	—	<1 day/—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/yes	yes/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/yes	no/yes/—
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	24, 42, 72, and 96: 2 controls (1 positive, 1 negative)	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	~90 percent of run time/40 min.	run dependent/<1 hr.
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/960	no/—
Time between start and initial result/Instrument automatic shutdown	assay dependent, 8 HSV results in <3 hrs.; 96 CT-NG results in <4 hrs./no	run dependent/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/plastic tips, liquid	no/yes/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/no	yes/mouse/no
Service contracts available/Mean time between failures/To repair failures	M–F bus. hrs. or 7 days per week/sample: >100 days; amplification: >300 days/<4 hrs.	service and compliance plans, extended warranty/—/—
Turnaround time for problem solving by phone/Email/Field service	15 min./15 min./varies	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	250/24 hrs./24–7	—/—/M–F, 8 AM–5 PM
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	24 hrs./yes/yes	—/no/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 2–7 min.; weekly: <5 min./yes	—
Preventive maintenance per year for sample extraction/Amplification detection	2/1	—/twice per year
Downtime for preventive maintenance/Spare parts on site	4 hrs./no	<1 day/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	no	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/no	no/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	no/yes	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/no/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	—	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/ASTM, HL7	no/—
• QC results transferred automatically to LIS/Data-management capability	no/yes	no/no
• Interfaces operational in active user sites	yes	no
• Rules-based control subsystem/Process control via control subsystem	no/no	no/no
• LIS operates simultaneously with assays running	yes	no
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/no
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/no	yes/yes/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	uses CORE Tip technology with TADM software and anti-droplet control along with AmpErase to reduce potential contamination; has minimal hands-on workflow and maintenance with no bleaching	can be operated using Dx software with the approved test menu or with test development software for assay develop.; interchangeable thermal blocks provide flexibility during assay develop., enabling 96-well standard, 96-well fast, 384-well, and TaqMan Array Card formats; decoupled excitation and emission filters for more color options; instrument-to-instrument normalization ensures consistent performance; security, auditing, and e-signature controls allow efficient management and traceability for run protocols executed by many users

**for calibration and controls*

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AUTOMATED MOLECULAR PLATFORMS

Part 17 of 17

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	Thermo Fisher Scientific customerservice@lifetech.com **Carlsbad, CA** **800-955-6288** www.lifetechnologies.com	**Vela Diagnostics** **Sandra Nielsen** infousa@veladx.com **Fairfield, NJ** **973-758-5341** www.veladx.com
Name of instrument	7500 Fast Dx Real-Time PCR Instrument	Vela GB Analyzer
Country where designed/Manufactured/Reagents manufactured	U.S./Singapore/—	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2008/2010/2009	2012/2012/2012
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	19.29 × 13.99 × 17.72/1.8/—	17.2 × 6.3 × 21.4/—/—
Supplied with UPS/BTU	no/maximum output: 3241.5 per hr. (950 W)	no/—
Physical contamination control features	no	closed cartridge technology
List price/Price for sample extraction and amplification detection modules	$65,900/amplification: $65,900	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/10 µL	—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC at 50 or 60 Hz and 15 A circuit	yes/100–240 V, ~50–60 Hz
Labor and parts warranties/Advanced operator training	1 year/yes	—/yes
Delivery time/Delivery charges/Installer/Time to install on site	—/—/certified applied biosystems field service agent/—	overnight/—/Vela Diagnostics/1 hr.
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/based on customer requirements/—/yes	on and off site/1–3/2 hrs./yes
Test menu	measures nucleic acid signals from reverse-transcribed RNA, CDC rRT-PCR flu panel (CDC 510[k] K080570), CDC DENV-1–4, MRSA/SA ELITe MGB, Quidel Pro hMPV+ assay, NAi ProsVue PSA assay	Vela Great Basin Stool Bacterial Pathogens Panel, Vela Great Basin Bordetella Direct Test, Vela Great Basin Group B Streptococcus Test, Vela Great Basin Shiga Toxin Direct Test, Vela Great Basin Staph ID/R Blood Culture Panel, Vela Great Basin Toxigenic C. difficile Test
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	6/6
Tests available on instrument in U.S./Outside U.S.	—	6/6
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	0/0
Research-use-only assays/Tests in development	—	0/4
Open-channel capabilities/Start-up and preparation time	yes/<5 min.	no/2 min.
Model type of sample-handling system/Maximum sample load capacity	—/96	manual/1
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	10 µL (reaction volume)/yes, reaction volumes 10–30 µL/10–30 µL	50–250 µL depending on assay/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1D or 2D	—/no/no	—/yes/yes
Sample barcode languages/Sample types available in open mode	—/nucleic acid signals from reverse-transcribed RNA	code 128/—
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—	—/no/—
Amplification reagents or methods supported	nucleic acid signals from reverse-transcribed RNA	HDA/PCR
No. of different assays onboard at once/Programmed or calibrated at once	dependent on real-time PCR reaction plate setup/—	1/1
Tests per container set/Multiple reagent configurations supported	—	10/yes
Reagent container placed directly on system/Onboard test auto inventory	no/no	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	no/no/no	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	no/no	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	yes/no	no/closed cartridge technology
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	—
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/no	no/—
Closed-vial stability for amplification reagents/Extraction reagents	—	6 months/6 months
Storage temp. requirement for amplification reagents/Extraction reagents	—	refrigeration/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	—	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	—	—/6 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	yes/—
Assay calibrations required by end user/Calibrants can be stored onboard	yes/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/6 months or after service repair	no/—
Length of assay calibration/Typical calibration frequency	<1 day/6 months	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/no	—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/yes	—/sample extraction: 1 min./yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	end user and assay dependent	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	40 min. to >2 hrs./<1 hr.	—
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	yes/—
Time between start and initial result/Instrument automatic shutdown	assay run-mode dependent/no	~90 min./no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/none	no/yes/disposable single-use cartridge
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/no	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	service plans, compliance services, extended warranty/—/—	full service contracts/—/—
Turnaround time for problem solving by phone/Email/Field service	—	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/—/M–F, 8 AM–5 PM	4/—/7 AM–6 PM MT
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	—/—/no	no/yes/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	—	weekly: 5 min./no
Preventive maintenance per year for sample extraction/Amplification detection	—/twice per year	—
Downtime for preventive maintenance/Spare parts on site	yes/no	—/no
Software and LIS interface:		
• 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	no/yes
• Priority processing	no	yes
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	—
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	—/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	no	—
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—	no/—
• QC results transferred automatically to LIS/Data-management capability	no/no	no/—
• Interfaces operational in active user sites	no	—
• Rules-based control subsystem/Process control via control subsystem	no/no	—
• LIS operates simultaneously with assays running	no	—
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/no	—
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	no/no	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/yes	—/no/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company)	96-well format eases plate setup; tube strips capped immediately after pipetting each sample; runs in <40 min.; standard-length real-time PCR assays without changing thermal cycling parameters; 5-color variable excitation enables multiplex assays; security, auditing, and e-signatures allow full control over thermal cycling protocols	simple workflow: less than 2 min. hands-on time with no walkaway points; sample-to-result: on-demand, closed system simplicity so all shifts can run and report results; fast results: definitive results in ~90 min. and no batching to delay results

**for calibration and controls*

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