AUTOMATED MOLECULAR PLATFORMS

Part 1 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**Abbott Laboratories, Abbott Molecular Division** **Vladimir Nozinic** vladimir.nozinic@abbott.com **1350 East Touhy Ave., Suite 300W, Des Plaines, IL 60018** **224-361-7338** www.abbottmolecular.com	**Agilent Technologies** contact_us@agilent.com **5301 Stevens Creek Blvd., Santa Clara, CA 95051** **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 BTU per hour
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 hours; m2000rt: 8 hours	4 weeks/destination included/Agilent/2 hours
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/3 days/yes	on site/1–5/2–3 hours/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, IDH2/CMV, CT, CTNG, EBV, HBV, HCV, HCV GT, HR HPV, HIV-1, HIV qual, VZV, parvo B19, 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 minutes for intial setup (24 samples)	no/5–30 minutes
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 1-D or 2-D	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 polymerase chain reaction	no
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 minutes/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 batch 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 (assay and run-size dependent)/30 minutes	yes/5–30 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/864	yes/112
Time between start and initial result/Instrument automatic shutdown	for a CT-NG batch of 48 samples: 4 hours, 41 minutes/yes	15 minutes/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 hours; m2000rt: 3.3 hours	preventive maintenance and extended warranty/—/—
Turnaround time for problem solving by phone/Email/Field service	time to answer <30 seconds/24-hour 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	22/based on contract/M–F, 8 AM–5 PM, extended hours 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 minutes; weekly: 45 minutes; monthly: 15 minutes/yes	yearly: 0–5 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	1/1	—
Downtime for preventive maintenance/Spare parts on site	4–12 hours/yes	4 hours/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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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, etc.
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 minutes	—/<1 hour 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 1-D or 2-D	—/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, etc.
Amplification reagents or methods supported	FISH	—
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 minutes	—/1 hour
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	3:45–4 hours/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 hours	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 minutes; bi-weekly: 25 minutes; monthly: 56 minutes; 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 hours 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) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	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 hours; broad spectrum of 70 assays; built-in replicate testing on each BioFilmChip microarray ensures assay result integrity and accuracy; easy and automated result interpretation

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Name of instrument	INFINITI PLUS Analyzer	BD Viper LT
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/analytical
First year sold in U.S./Sold internationally/Installed	2011/2011/2011	2014/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	26 × 44 × 24/7.3/—	46 × 51 × 36/12.75/65
Supplied with UPS/BTU	no/—	no/up to 3,000 (1,000 when idle)
Physical contamination control features	no aspiration tubing, disposable tips	closed system
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/1 µL	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/110 V and 220 V, 50–60 Hz	yes/100V–240 V, 50–60 Hz
Labor and parts warranties/Advanced operator training	1 year/no	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	1 week/—/AGI/1–2 days	2–3 weeks/origin/BD service engineer/<2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/1/2.5 days/yes	off site/2–4/2 days/no
Test menu	>70 tests on women's health, infectious diseases, pharmacogenomics, oncology, and genetic disorders	chlamydia trachomatis, neisseria gonorrhoeae
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/29	2/3
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, etc.	U.S. CT-GC/Exus CT-GC, HPV
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	HPV/1
Research-use-only assays/Tests in development	65/5	0/HPV for U.S. market
Open-channel capabilities/Start-up and preparation time	yes/20 minutes	no/<10 minutes
Model type of sample-handling system/Maximum sample load capacity	—/48	Hamilton pipettor/120
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	1 µL/no/—	2 mL/no/swabs: 2 mL; urine: 2–3 mL; liquid-based cytology: 2.2 mL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	<400 µL/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/—	4 mL tubes/—/—
Sample barcode languages/Sample types available in open mode	—	—/swabs, urine, liquid-based cytology
Clot detection/Open extraction platform/Sample types (open extraction)	—/yes/variable, assay dependent: blood, buccal, saliva, tissue, vaginal swabs, liquid cytology media, culture, sputum, stool, etc.	no/no/none
Amplification reagents or methods supported	—	SDA, PCR
No. of different assays onboard at once/Programmed or calibrated at once	4/70	2/2
Tests per container set/Multiple reagent configurations supported	48/—	2/no
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	yes/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	yes/liquid and dry
Reagent reconstitution required/Chemical contamination control	no/—	no/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	no/no	no/yes
Same capabilities when third-party reagent used/Lot sequestering available	no/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	—	—
Storage temp. requirement for amplification reagents/Extraction reagents	-20°C/—	room temperature/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	-20°C/—	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	12 months/24 months	6 months/18 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	yes/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/no	—
Multiple calibrant lots stored for same assay/Required calibration frequency	—	—
Length of assay calibration/Typical calibration frequency	—	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/no	no/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/—/—	yes/—/—
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	1/2/3/4
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	5 hours/15 minutes	30 samples/<5 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/504	yes/480
Time between start and initial result/Instrument automatic shutdown	3 hours/no	~3 hours/—
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/built-in waste tray, solid state waste products	—/yes/—
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	annual/—/—	multiyear/—/—
Turnaround time for problem solving by phone/Email/Field service	24 hours/24 hours/48 hours	<1 day/<2 days/variable
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/24–48 hours/6 AM–6 PM (PDT)	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes (within 24 hours)/no/yes	—/yes/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 min.; weekly: 10 min.; monthly: 20 min.; yearly: 45 min./no	—
Preventive maintenance per year for sample extraction/Amplification detection	—/1	—
Downtime for preventive maintenance/Spare parts on site	1 day/no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	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) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	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	automated, integrated molecular testing, tabletop analyzer, BD SurePath and Hologic Thin Prep compatible

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AUTOMATED MOLECULAR PLATFORMS

Part 4 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**BD Diagnostic Systems** **William Hardy** william_hardy@bd.com **7 Loveton Circle, Sparks, MD 21152** **410-316-4237** moleculardiagnostics.bd.com	**BD Diagnostic Systems** **William Hardy** william_hardy@bd.com **7 Loveton Circle, Sparks, MD 21152** **410-316-4237** 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/.63/quiet
Supplied with UPS/BTU	yes/—	no/—
Physical contamination control features	unitized reagent strip, dedicated pipette tips, microfluidic PCR cartridge with microvalves, pipettor flight path avoids crossing strips or tubes	—
List price/Price for sample extraction and amplification detection modules	—	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/specimen dependent (as low as 10–15 µL)	straight purchase, reagent rental, lease/72 tests per month
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC, ~50–60 Hz, 10 A	no/120 V
Labor and parts warranties/Advanced operator training	1 year (≤3 year contracts optional)/yes	1 year/no
Delivery time/Delivery charges/Installer/Time to install on site	90 day, or less from contract/—/BD/1.5 days	2 weeks/none for instrumentation/BD field applications/4 hours
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/flexible/1 day/yes	on site/6/4 hours/no
Test menu	GBS, MRSA XT, C. difficile, StaphSR, enteric bacterial panel, extended bacterial panel, enteric parasite panel, CT-GC-TV, vaginal panel; open system general-purpose reagents for user-defined protocols: DNA and RNA extraction kits and generic DNA master mix with and without internal process control	Candida species (six different), Gardnerella vaginalis, trichomonas vaginalis
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	3/3
Tests available on instrument in U.S./Outside U.S.	GBS, MRSA, C. difficile, StaphSR, enteric bacterial, extended bacterial panel, enteric parasite, CT-GC-TV, vaginal panel, CRE RUO/—	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 minute per specimen	no/immediate
Model type of sample-handling system/Maximum sample load capacity	fully automated, integrated extraction and amplification detection/24	swab, tube, and cap/6
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	specimen dependent (as low as 10–15 µL)/yes/volumes range up to 750 µL	—/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	50–200 µL/specimen dependent/no	—/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	uses standard 4 mL tube format/yes/—	5 mL/no/no
Sample barcode languages/Sample types available in open mode	Codabar codes 39, Interleaved 2 of 5, EAN, UCC code 128, 2-D capability/—	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/yes/swab, swab in transport medium, urine, plasma, CSF, stool	no/no/—
Amplification reagents or methods supported	real-time PCR for most probe types, melt analysis	—
No. of different assays onboard at once/Programmed or calibrated at once	designed for multiple assays up to 24 samples/significant number	3/3
Tests per container set/Multiple reagent configurations supported	unitized reagent strips, one test per strip, 24 strips per kit/yes	24 or 120/—
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	yes/yes/yes	no/no/no
Monitors expiration date/Auto lot recognition or calibration	yes/yes	no/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid and dry	no/dry
Reagent reconstitution required/Chemical contamination control	no/no (system has a closed-unit test format disposable)	no/—
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/no	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes (with user-supplied primers and probes in open-system format)/on terms	no/no
Closed-vial stability for amplification reagents/Extraction reagents	12 months/12 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Minimum/Maximum reagent shelf-life guarantee	3 months/12–24 months	6 months/14 months
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	no/no
Assay calibrations required by end user/Calibrants can be stored onboard	—/no	no/no
Multiple calibrant lots stored for same assay/Required calibration frequency	yes/determined and validated by user	no/factory calibrated only
Length of assay calibration/Typical calibration frequency	determined and validated by user/determined and validated by user	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	no/no	no/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	no/none/—	no/—/no
Total number of controls per batch for 24 tests/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 hours; 24 samples in 2 hours/~1 min. per sample	30 minutes/3 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/self-contained in unitized reagent strip	no/—
Time between start and initial result/Instrument automatic shutdown	1–12 samples in <1.5 hours; 24 samples in 2 hours/automatic move to standby	45 minutes/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/biohazardous waste	no/no/biohazardous waste
Windows technology/Mouse or touchscreen/Modular add-on capability	no/mouse/no	no/—/no
Service contracts available/Mean time between failures/To repair failures	5 and 7 days per week/180 days/<24 hours from field service visit	repair by replacement (normally ships same day of call to tech service)/—/single swap option within 24 hours
Turnaround time for problem solving by phone/Email/Field service	<1 hour after hours/same day (next day after hours)/next business day	immediate during business hours; 1 hour nonbusiness/immediately/as needed
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/next business day/24 hours, 7 days	—
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	—/no/yes	no/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	weekly: 10 minutes/—	daily: <5 minutes/no
Preventive maintenance per year for sample extraction/Amplification detection	1/1 (for total system)	—
Downtime for preventive maintenance/Spare parts on site	4 hours/no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	—	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	no/no
• Priority processing	no	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/—	no/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	no/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	—	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	—	no/no
• QC results transferred automatically to LIS/Data-management capability	—	no/no
• Interfaces operational in active user sites	yes	no
• Rules-based control subsystem/Process control via control subsystem	—	no/no
• LIS operates simultaneously with assays running	—	no
• Uses LOINC to transmit orders and results/Unidirectional interface capability	—	no/no
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	—	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	no/no/no
• Can print, archive, transmit data	yes	no
Distinguishing features (supplied by company)	next-generation platform for molecular testing, automating cell lysis, nucleic acid extraction, PCR setup, amplification, and detection	simultaneous detection/differentiation of the three organisms that cause up to 90 percent of vaginal infections in 1 swab; quick turnaround time (45 minutes for 6 samples or 18 results); simultaneously detects mixed infections caused by 3 organisms; objective, visual results

**for calibration and controls*

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

AUTOMATED MOLECULAR PLATFORMS

Part 5 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**BD Diagnostic Systems** **William Hardy** william_hardy@bd.com **7 Loveton Circle, Sparks, MD 21152** **410-316-4237** moleculardiagnostics.bd.com	**Biocartis US** **Vishal Sikri** customerserviceUS@biocartis.com **2500 Harborside Plaza 5, Ste. 2547, Jersey City, NJ 07311** **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 hour	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 hours
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/1/2 hours/no
Test menu	chlamydia, gonorrhea, HSV-1, HSV-2, trichomonas	EGFR, KRAS, NRAS, NRAS-BRAF, BRAF, ctKRAS, ctNRAS-BRAF, ctBRAF
No. of tests for which analyzer has FDA-cleared applications/CE mark	—	0/5
Tests available on instrument in U.S./Outside U.S.	5/5	EGFR, KRAS, NRAS-BRAF, BRAF, ctKRAS, ctNRAS-BRAF, ctBRAF/EGFR, KRAS, 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, KRAS, NRAS-BRAF, BRAF, ctKRAS, ctNRAS-BRAF, ctBRAF/MSI, ctEGFR
Open-channel capabilities/Start-up and preparation time	no/10 minutes	no/<2 minutes
Model type of sample-handling system/Maximum sample load capacity	sample rack/96	—/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 1-D or 2-D	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, and 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, 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 minutes/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 hours, 5 minutes/10 minutes	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/768	no/—
Time between start and initial result/Instrument automatic shutdown	3 hours, 15 minutes/no	BRAF: min. 90 minutes; EGFR: max. 145 minutes/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 hours/280 days/24 hours	yearly/>18 months/depot replacement model 1–3 days
Turnaround time for problem solving by phone/Email/Field service	real time/—/24 hours	1 day/1 day/3 days
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	>30/24 hours/24 hours, 7 days	—/—/8 hours, 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 minutes/no	monthly: <1 minute; yearly: 10 minutes/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 hours/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• 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)	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 mins for tissue or plasma; extensive menu for oncology; low running costs

**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 6 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**BioFire Diagnostics** **Wade Stevenson** wade.stevenson@biofiredx.com **515 Colorow Way, Salt Lake City, UT 84108** **801-736-6354** www.biofiredx.com	**BioFire Diagnostics** **Wade Stevenson** wade.stevenson@biofiredx.com **515 Colorow Way, Salt Lake City, UT 84108** **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	4/4	4/4
Tests available on instrument in U.S./Outside U.S.	4/4	4/4
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—
Research-use-only assays/Tests in development	—/lower respiratory tract panel	—/lower respiratory tract panel
Open-channel capabilities/Start-up and preparation time	—/2 minutes	—/2 minutes
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 1-D or 2-D	—/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: 20; blood culture ID panel: 27; gastrointestinal panel: 22; meningitis-encephalitis panel: 14/—	respiratory panel: 20; 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	room temperature/room temperature	room temperature/room temperature
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	—/12 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 hour/—	~1 hour/—
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 hours/within 24 hours/—	within 24 hours/within 24 hours/—
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) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	user-friendly multiplex PCR; fully automated; sample to result in about 1 hour; 2 minutes 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

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Part 7 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**bioMérieux** **Anne Beall** anne.beall@biomerieux.com **100 Rodolphe St., Durham, NC 27712** **919-479-3630** www.biomerieux-usa.com	**bioMérieux** **Anne Beall** anne.beall@biomerieux.com **100 Rodolphe St., Durham, NC 27712** **919-479-3630** www.biomerieux-usa.com
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/between 67 and 75	20.9 × 39.4 × 25.6/3.7/between 67 and 75
Supplied with UPS/BTU	no/1,400 per hour maximum (less in standby)	no/341 per hour 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 hours	30 days/destination and origin, price varies/field service engineer/5 hours
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site and off site/1 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	HPV, KPC (U.S.)/—
Open-channel capabilities/Start-up and preparation time	yes/15–20 minutes	yes/10–15 minutes
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 1-D or 2-D	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/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	—/RTI
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	—	24 tests: downstream assay dependent/—/—/—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	48/15–20 minutes	—
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/576	no/—
Time between start and initial result/Instrument automatic shutdown	45 minutes/no	45 minutes/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/yes
Service contracts available/Mean time between failures/To repair failures	7 days full service, preventive maintenance/extraction: >100 days/3.5 hours	7 days full service, preventive maintenance/extraction: 328 days/3.5 hours
Turnaround time for problem solving by phone/Email/Field service	immediate (30 min. after hours)/<24 hours/within 2 hours after scheduling	immediate (30 min. after hours)/<24 hours/within 2 hours after scheduling
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	32/within 24 hours/24–7 phone support, 12–7 PM on-site support	32/within 24 hours/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 minutes; weekly: 10 minutes; monthly: 10 minutes; yearly: performed by FSE/no	daily: 5 minutes; weekly: 10 minutes; 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 hours/no	3 hours/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	data retrieval
• 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	yes/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 three internal controls per sample for downstream molecular testing applications	varies sample and elution volumes from sample to sample in the same run; entire extraction process in a single sample compartment, minimizing potential sample loss and cross-contamination; doesn't use multiple racks of pipette tips or processing plates, thus reducing plastics waste

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AUTOMATED MOLECULAR PLATFORMS

Part 8 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**Cepheid** **Glen Tinevez** MarCommGroup@cepheid.com **904 Caribbean Ave., Sunnyvale, CA 94089** **888-336-2743** www.cepheid.com	**Cepheid** **Glen Tinevez** MarCommGroup@cepheid.com **904 Caribbean Ave., Sunnyvale, CA 94089** **888-336-2743** www.cepheid.com
Name of instrument	GeneXpert 1, GeneXpert 2, GeneXpert 4, GeneXpert 16	GeneXpert Infinity-48s, Infinity-80
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2006 (2011 for GX 2)/2006/2006	2012/2012/2012
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	GeneXpert 1: 4 × 12 × 11.70; GeneXpert 2: 6.35 × 12 × 11.70; GeneXpert 4: 11 × 12 × 11.70; GeneXpert 16: 22.75 × 25.80 × 13.25/2.625/—	79.1 × 105.2 × 34.6 (48); 78.5 × 85 × 34.6 (48s); 78.5 × 108 × 35 (80)/25.25/—
Supplied with UPS/BTU	yes/—	yes/—
Physical contamination control features	closed-cartridge technology	closed-cartridge technology
List price/Price for sample extraction and amplification detection modules	$24,900–$174,400/—	$199,000–$530,000/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–120 VAC, 50–60 Hz	yes/100–120 VAC, 50–60 Hz (48); 200–240 VAC, 50–60 Hz (48s, 80)
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	less than 1 week/FOB origin/company/<1 day	2–4 weeks/FOB origin/company/<1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1 or more/<1 day/no	on site/1 or more/1–3 days/no
Test menu	Xpert: 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 minute	—/<1 minute
Model type of sample-handling system/Maximum sample load capacity	cartridge based/up to 16, based on number of installed modules	cartridge based/2,300 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 1-D or 2-D	—/yes/yes	—/yes/yes
Sample barcode languages/Sample types available in open mode	all common/no restrictions	all common/no restrictions
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/no restrictions	no/no/no restrictions
Amplification reagents or methods supported	—	—
No. of different assays onboard at once/Programmed or calibrated at once	full menu/full menu	full menu/full menu
Tests per container set/Multiple reagent configurations supported	single-use cartridges/reagents contained in cartridge	single-use cartridges/reagents contained in cartridge
Reagent container placed directly on system/Onboard test auto inventory	yes/yes	yes/yes
Determines reagent volume in container/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 minutes–2 hours, depending on test/no	35 minutes–2 hours, depending on test/no
Startup programmable/Remote system monitoring/Waste required for disposables	—/—/disposable cartridges	yes/no/disposable cartridges
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/yes	yes/mouse and touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	full service, labor and parts/—/24–48 hours	5 days (standard) or 6 days (preferred) labor and parts/—/24–48 hours
Turnaround time for problem solving by phone/Email/Field service	yes/yes/yes	yes/yes/yes
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	14/within 24 hours/24–7 or M–F, 5 AM–5 PM	14/within 24 hours/8 AM–7 PM, M–F; Saturday with preferred
Guaranteed response time/Modem servicing 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 minutes; weekly: 5 minutes; monthly: based on system configuration; yearly: up to 30 minutes (based on number of modules)/yes	daily: 5 minutes; weekly: 10 minutes; monthly: based on system configuration; yearly: 30–60 minutes (based on number of modules)/yes
Preventive maintenance per year for sample extraction/Amplification detection	—	—
Downtime for preventive maintenance/Spare parts on site	6–8 hours per year/no	6–8 hours per year/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	yes	yes
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/yes
• Priority processing	yes	yes
• Supports accession No. redundancy/Specimen carrier and level identification	yes/yes	yes/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/yes	yes/yes
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	yes/yes/yes	yes/yes/—
• Sample storage and retrieval software supports CLSI standards	yes	yes
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/TCP-IP	yes/TCP-IP
• QC results transferred automatically to LIS/Data-management capability	yes/yes	yes/yes
• Interfaces operational in active user sites	yes	yes
• Rules-based control subsystem/Process control via control subsystem	yes/yes	yes/yes
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	yes/yes	yes/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/yes	yes/yes
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	yes/yes/yes	yes/yes/yes
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	fully integrated real-time PCR system; automated and integrated steps for PCR-based DNA testing: sample preparation and DNA amplification and detection; simplifies hands-on preparation; provides PCR test results from raw sample in ~1 hour; variety of configurations to meet broad range of demands	fully automated, robotic, real-time PCR system integrates all steps required for PCR-based DNA testing: sample preparation and DNA amplification and detection; cartridge handling; fully integrated; built-in smart technology: fluid master scheduler prioritizes test runs; reduces hands-on labor

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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	no/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 hour	yes/—
Physical contamination control features	disc sealers	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; 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	as scheduled/none/DiaSorin Molecular/1 hour	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/flexible/<1 day/yes	on site/1–3/1 day for operational training/yes
Test menu	Simplexa assays: HSV 1&2 for CSF and genital swabs, Group A Strep, Flu A/B & RSV, Flu A/B & RSV Direct, Influenza A H1N1, C. difficile Direct, C. difficile Universal Direct, Bordetella Universal Direct, Dengue, CMV, EBV	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	7/11	Zika EUA/>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	1/4	—/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/2–3 minutes	yes/~1 minute per sample
Model type of sample-handling system/Maximum sample load capacity	—/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 1-D or 2-D	—/yes/yes	6.0 mL, 13 x 100 mm; 4.0 mL, 13 x 75 mm; 3.0 mL, 13 x 75 mm/yes/yes
Sample barcode languages/Sample types available in open mode	most 1-D and 2-D symbologies/user defined, including NPS, stool, serum, whole blood, plasma, urine, CSF, throat 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/no/—	yes/yes/whole blood, plasma, serum, CSF, urine, stool, nasal, and urogenital swabs
Amplification reagents or methods supported	yes	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	up to 96 wells/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	no/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/disc sealers	no/yes
Onboard test auto inventory/Capable of inventory monitoring by barcode	—	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	up to 18 months/—	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/no	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 hours/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 module: 2–3 minutes/yes	no/<2 minutes/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	0–3/0–3/0–3/0–3	operator defined and validated
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	yes/15–30 minutes	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 hour/no	2–2.5 hours/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 hour on site	1–5 years/—/—
Turnaround time for problem solving by phone/Email/Field service	<1 hour during business hours/<1 hour during business hours/within 24 hours	<3 hours, same day (after hours)/<3 hours, same day (after hours)/24-hour response
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	50/within 48 hours/M–F, 7 AM–5 PM	—/next day/24 hours, 7 days
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes, M–F/no/no	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 minute; weekly: 5 minutes; monthly: 5–15 minutes; yearly: ~1 hour/no	daily: empty waste container; weekly: <10 minutes; monthly: <5 minutes/—
Preventive maintenance per year for sample extraction/Amplification detection	—/2	1/1 for combined platform
Downtime for preventive maintenance/Spare parts on site	~1 hour/—	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
• 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; scalable and flexible system for qualitative and quantitative assays with small footprint; multiple assays can be performed at one time in approximately 1 hour	open, fully integrated, automated; DNA/RNA specimen with universal extraction and independently controlled real-time PCR system; walkaway system fully automates specimen results; flexible system adapts to lab workflows operating in multiple modes: extraction/PCR, extraction only, PCR only; 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

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AUTOMATED MOLECULAR PLATFORMS

Part 10 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**GenMark Diagnostics** info@genmarkdx.com **5964 La Place Court, Carlsbad, CA 92008** **800-eSensor (800-373-6767)** www.genmarkdx.com	**GenMark Diagnostics** info@genmarkdx.com **5964 La Place Court, Carlsbad, CA 92008** **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/—	$47,250–$84,250/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/—	straight purchase, reagent rental, lease/1+
Co. performs installation, operation, and performance qualifications/Electrical 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 hour
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/2–3/~3 hours/yes	on site/up to 3/1–3 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	—	—
Research-use-only assays/Tests in development	—/gastrointestinal pathogen panel (GI); central nervous system panel (CNS); HCV genotyping panel (HCVg)	HCVg Direct Test, 2C19 Genotyping Test/—
Open-channel capabilities/Start-up and preparation time	no/<2 minutes	no/<5 minutes
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-hour shift
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	assay dependent; RP: 200 µL; BCID: 50 µL/no/—	varies by test/yes/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/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, 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 minutes per sample)	up to 3.5 hours/up to 2.5 hours
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—	no/—
Time between start and initial result/Instrument automatic shutdown	<2 hours (assay dependent)/no	30 minutes/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, 5 AM–8 PM PT: ≤1 hour; weekends on call/same as phone/within 48 hours	M–F, 5 AM–8 PM PT: ≤1 hour; weekends on call/same as phone/within 48 hours
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	9/—/24 hours–7 days	6/24 hours–7 days/24 hours–7 days
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	no/no/yes	yes (within 48 hours)/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 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	instrument maintenance every 6 months	—
Downtime for preventive maintenance/Spare parts on site	~2 hours/no	60 minutes/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	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	no/no	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*	bidirectional LIS with rules-based autovalidation of results; modular and scalable "True Sample-to-Answer Solution"; easy-to-use with least hands-on time and processing steps	complete benchtop system for multiplex molecular testing; touchscreen user interface; customizable reports; no routine maintenance or calibration

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Name of instrument	Great Basin PA500 Benchtop Analyzer	Tigris DTS System
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S	U.S./U.S./U.S., U.K.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2012/2012/2012	2004/2005/2004
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	17.2 × 6.3 × 21.4/.94/—	72 × 69 × 36/17.25/compliant with EN 61010-1
Supplied with UPS/BTU	no/—	yes/2,637
Physical contamination control features	closed-cartridge technology	closed system, liquid level sensing, pressure-dispense verification, onboard deactivation, deep-well reaction tube, single sample aspiration and dispense, penetrable cap
List price/Price for sample extraction and amplification detection modules	instrument placed at no cost/—	—
Purchase options/Minimum test volume requirements	—/no	straight purchase, reagent rental, lease/variable
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/input 100–240 V ~1.0 A, 50/60 Hz	yes/220 V
Labor and parts warranties/Advanced operator training	—	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	overnight/none/Great Basin/30 minutes	<1 week/variable at origin and destination/Hologic/2–3 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1–3/2 hours/yes	on and off site/2/4 days/yes
Test menu	toxigenic C. difficile, group B strep, shiga toxin direct, staph ID/R blood culture panel, Bordetella direct, stool bacterial pathogens panel	CT-GC, CT, GC, HPV, trich, HPV genotyping
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.	4/4	CT-GC, CT, GC, HPV, trich, HPV genotyping/CT-GC, CT, GC, HPV, trich, HPV genotyping
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 (CT/NG, SA nasal screen, stool parasites panel, candida blood infections panel)	—
Open-channel capabilities/Start-up and preparation time	no/~2 minutes	yes/~30 minutes
Model type of sample-handling system/Maximum sample load capacity	closed-cartridge technology/1 per analyzer	onboard automated pipettor/180
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	50–250 µL, depending on test/no/—	400 µL/no/no
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	800 µL/no/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/yes	various/yes (automated onboard scanner to maintain positive sample ID)/no
Sample barcode languages/Sample types available in open mode	code 128/—	Interleaved 2 of 5, Codabar codes 39 and 128/—
Clot detection/Open extraction platform/Sample types (open extraction)	—	yes/no/—
Amplification reagents or methods supported	HDA, PCR	transcription-mediated amplification
No. of different assays onboard at once/Programmed or calibrated at once	1/1	4/4
Tests per container set/Multiple reagent configurations supported	single-use cartridge with reagents onboard/—	100 or 250/yes
Reagent container placed directly on system/Onboard test auto inventory	yes/—	yes/yes
Determines reagent volume in container/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/closed-cartridge technology	yes/yes
Onboard test auto inventory/Capable of inventory monitoring by barcode	—	yes/yes
System is open to homebrew/General-purpose reagents allowed	no/no	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	no/—	no/yes
Closed-vial stability for amplification reagents/Extraction reagents	6 months/6 months	assay dependent/assay dependent
Storage temp. requirement for amplification reagents/Extraction reagents	refrigeration/room temperature	refrigeration/refrigeration
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	room temperature/room temperature
Minimum/Maximum reagent shelf-life guarantee	—/6 months	—/up to 2 years after manufacture date
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/—	—/yes
Assay calibrations required by end user/Calibrants can be stored onboard	no/—	—/no
Multiple calibrant lots stored for same assay/Required calibration frequency	—	no/assay dependent (done per worklist)
Length of assay calibration/Typical calibration frequency	—	—/assay dependent (done per worklist)
Onboard real-time QC/Supports multiple QC lot numbers per assay	yes/—	—
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	—/1 minute/yes	no/—/—
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	4/4/4/4 (4 controls for up to 250 tests)
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	—	up to 180 samples/<19 seconds per sample
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/—	yes/480 (1.2 tips per sample)
Time between start and initial result/Instrument automatic shutdown	~90 minutes/—	3.5 hours/no
Startup programmable/Remote system monitoring/Waste required for disposables	—/—/disposable single-use cartridge	no/yes/plastics and cardboard
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse and touchscreen/yes	yes/mouse and touchscreen/no
Service contracts available/Mean time between failures/To repair failures	support is included with no service contracts/—/—	premiere and standard/—/—
Turnaround time for problem solving by phone/Email/Field service	6 AM–6 PM, M–F (holidays and weekends on call)/6 AM–6 PM, M–F (holidays and weekends on call)/24 hours	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/—/6 AM–6 PM MT	—/—/premiere: 24 hours, 7 days; standard: M–F, 8 AM–5 PM PST
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	no/yes/yes	yes (<24 hours)/yes/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	weekly: ~5 minutes/no	daily: 15 minutes; weekly: 5 minutes; monthly: 3 hours/yes
Preventive maintenance per year for sample extraction/Amplification detection	—	2/2
Downtime for preventive maintenance/Spare parts on site	—/no	1 day/yes
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	—/yes	no/yes
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	—	no/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	—	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	—	no/no/—
• Sample storage and retrieval software supports CLSI standards	—	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—	yes/LIS1-A and LIS2-A2 (ASTM), custom flat file LIS formats
• QC results transferred automatically to LIS/Data-management capability	—	yes/yes
• Interfaces operational in active user sites	—	yes
• Rules-based control subsystem/Process control via control subsystem	—	yes/yes
• LIS operates simultaneously with assays running	—	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	—	no/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	—	yes/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—	yes/yes/no
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	placed at no cost; uses proprietary low-cost cartridges to provide an easy-to-use, cost-effective, sample-to-result system capable of performing low-plex, multiplex, and direct from specimen molecular diagnostic testing; closed system to fully process, analyze, and report findings from reagents fully contained within these single-use cartridges and is capable of running all current and future planned tests and panels; future enhancement to deliver test results directly to the hospital information systems, which will further the efficiency and functionality of this versatile system	totally integrated platform; high-throughput CT/GC, HPV, and trich platform; flexible worklist size from 1 to 246 patient samples; sample positive ID for confidence in results; scalable for menu expansion and lab growth; built-in process controls to minimize crossover contamination

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Name of instrument	Panther System	HTG EdgeSeq Processor
Country where designed/Manufactured/Reagents manufactured	U.S./Switzerland/U.S.	U.S./U.S./U.S.
Instrument FDA cleared or approved/Platform	yes/preanalytical and analytical	no (CE-IVD approved)/analytical
First year sold in U.S./Sold internationally/Installed	2012/2010/2010	2014/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	69 × 48 × 32/10.6/<55	17 × 36 × 24/6/<65
Supplied with UPS/BTU	yes/1,878 per hour	no/—
Physical contamination control features	closed system, liquid level sensing, pressure-dispense verification, onboard deactivation, deep-well reaction tube, single sample aspiration and dispense, penetrable cap	self-contained waste capture
List price/Price for sample extraction and amplification detection modules	—	$125,000/—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental, lease/variable	straight purchase, lease/8 samples
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 V +/– 10%	yes/120–240 V
Labor and parts warranties/Advanced operator training	1 year/yes	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	~1 week/variable at origin and destination/Hologic/1–2 days	1–4 days/$800 destination/HTG/2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on and off site/2/3 days/yes	on site/2–3/2 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	HTG EdgeSeq: Immuno-Oncology assay, Oncology Biomarker panel, Lymphoma panel, miRNA Whole Transcriptome assay, PATH assay, DLBCL Cell of Origin assay (RUO), DLBCL Cell of Origin assay (CE-IVD), ALK*Plus* EU assay (CE-IVD)
No. of tests for which analyzer has FDA-cleared applications/CE mark	7/12	—/2
Tests available on instrument in U.S./Outside U.S.	CT-GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HSV 1&2/ CT-GC, CT, GC, HPV, HPV genotyping, trich, HIV-1 viral load, HCV viral load, HBV viral load, M. gen, HSV 1&2, Zika (CE)	7/7
Tests not available in U.S. but submitted to FDA/Available in other countries only	HBV viral load/CT, GC, M. gen	—/HTG EdgeSeq DLBCL Cell of Origin assay, ALK*Plus* EU assay
Research-use-only assays/Tests in development	—/HBV viral load, BV-CV, M. gen	7/5
Open-channel capabilities/Start-up and preparation time	yes/<15 minutes	no/<30 minutes
Model type of sample-handling system/Maximum sample load capacity	automated onboard/120	manual (lysis only prep)/96
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	400 µL/no/—	single 5-micron FFPE section, 15 µL serum or plasma, PAXGene 32 µL, ≥2,000 cells, extracted RNA/yes (assay and tissue dependent)/assay and tissue dependent
Minimum dead volume/Pediatric sample volume/Primary tube sampling	250 µL/no/yes	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	various/yes (automated onboard scanner to maintain positive sample ID)/no	uses 96-well microtiter plate/no/yes
Sample barcode languages/Sample types available in open mode	Codabar codes 39 and 128, Interleaved 2 of 5, JAN13, code 93, UPC, NW7/—	—/assay and tissue dependent
Clot detection/Open extraction platform/Sample types (open extraction)	yes/no/—	no/no/assay and tissue dependent
Amplification reagents or methods supported	transcription-mediated amplification	—
No. of different assays onboard at once/Programmed or calibrated at once	4/4	1/8
Tests per container set/Multiple reagent configurations supported	100 or 250/yes	up to 8, 24, or 96/yes
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/yes/yes
Monitors expiration date/Auto lot recognition or calibration	yes/yes	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid	no/liquid
Reagent reconstitution required/Chemical contamination control	yes/yes	no/onboard waste capture
Onboard test auto inventory/Capable of inventory monitoring by barcode	yes/yes	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	—	no/yes
Closed-vial stability for amplification reagents/Extraction reagents	assay dependent/assay dependent	—
Storage temp. requirement for amplification reagents/Extraction reagents	refrigeration/refrigeration	—
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	—
Minimum/Maximum reagent shelf-life guarantee	—/up to 2 years	reagent dependent/12 months
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/—	no/—
Assay calibrations required by end user/Calibrants can be stored onboard	yes/yes	—
Multiple calibrant lots stored for same assay/Required calibration frequency	no/24 hours	no/at install
Length of assay calibration/Typical calibration frequency	24 hours/24 hours	—
Onboard real-time QC/Supports multiple QC lot numbers per assay	—/yes	no/yes
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/<15 minutes/yes	no/—/no
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	2/2/2/2	user determined
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	up to 120 samples/<15 seconds per sample	up to 96 samples/30 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/576 (2.2 tips per sample)	yes/386
Time between start and initial result/Instrument automatic shutdown	2.7–3.5 hours/no	~20 hours/no
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/plastics and cardboard	no/no/plastic, contained liquid
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/yes	yes/mouse/yes
Service contracts available/Mean time between failures/To repair failures	standard and premiere/—/—	yearly (parts and labor)/—/2–3 days
Turnaround time for problem solving by phone/Email/Field service	—	<1 hour/<1 hour/24–72 hours
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/24 hours/premiere: 24 hours, 7 days; standard: M–F, 8 AM–5 PM PST	—/24–72 hours/M–F, 10 hours
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes/yes/yes	no/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no	no/yes/yes
Average maintenance time for lab personnel/Onboard maintenance records	weekly: <5 minutes; monthly: <45 minutes/yes	daily: 10 minutes; weekly: 90 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	2/2	—
Downtime for preventive maintenance/Spare parts on site	<1 day/yes	8 hours/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	yes
• Data retrieval or Internet connectivity	yes	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	yes/yes	yes/no
• Priority processing	yes	no
• Supports accession No. redundancy/Specimen carrier and level identification	yes/—	yes/no
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/no	yes/no
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/—/—	no/no/no
• Sample storage and retrieval software supports CLSI standards	no	—
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/LIS1-A and LIS2-A2 (ASTM)	no/—
• QC results transferred automatically to LIS/Data-management capability	yes/yes	no/yes
• Interfaces operational in active user sites	yes	—
• Rules-based control subsystem/Process control via control subsystem	yes/yes	—
• LIS operates simultaneously with assays running	yes	no
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	no/—
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/—	no/no
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	—/yes/—	—
• Can print, archive, transmit data	yes	yes
Distinguishing features (supplied by company) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	random and continuous access, fully automated; scheduled/automated maintenance for rapid startup; lean, out-of-the-box workflow; no return visits required for up to 120 samples/day; eliminates constraints of batching; runs multiple assays from a single sample loaded onboard; true positive sample ID; sample-to-result automation; consolidated testing on a single platform; small footprint, highest throughput per sq. ft.	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

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Part 13 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**Luminex Corp.** **Christine Valle** cvalle@luminexcorp.com **12212 Technology Blvd., Austin, TX 78727** **512-219-8020** www.luminexcorp.com	**Luminex Corp.** **Christine Valle** cvalle@luminexcorp.com **12212 Technology Blvd., Austin, TX 78727** **512-219-8020** www.luminexcorp.com
Name of instrument	ARIES System	VERIGENE 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	yes/preanalytical and analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2015/2016/2015	2011/2011/2011
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	38 × 61 × 100 cm/2.5/negligible	18.7 × 7.6 × 22.9/1.88/—
Supplied with UPS/BTU	yes/2,730	no/—
Physical contamination control features	—	—
List price/Price for sample extraction and amplification detection modules	$95,000/—	$20,000 per box/reader: $20,000; processor SP: $20,000
Purchase options/Minimum test volume requirements	straight purchase, reagent rental/200 µL	straight purchase, reagent rental, lease/100 µL
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/120 V	yes/100–240 VAC, 50/60 Hz
Labor and parts warranties/Advanced operator training	—/no	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	2–3 days/per agreement/Luminex/6 hours	variable by customer preference/variable by order size/Luminex/1 day
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/11/1–2 days/yes	on site/1 or more/1–2 days/yes
Test menu	ARIES Bordetella assay, ARIES C. Difficile assay, ARIES Flu A/B & RSV assay, ARIES GBS assay, ARIES HSV 1&2 assay, ASR Primers	Gram-positive blood culture, Gram-negative blood culture, C. difficile, enteric pathogens, respiratory pathogens flex
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/6	6/6
Tests available on instrument in U.S./Outside U.S.	ARIES Bordetella assay, ARIES C. difficile assay, ARIES GBS assay, ARIES HSV 1&2 assay, ARIES Flu A/B & RSV 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	6/6
Tests not available in U.S. but submitted to FDA/Available in other countries only	none/none	0/0
Research-use-only assays/Tests in development	Atopobium vaginae, Fusobacterium, Gardnerella vaginalis, group A strep, adenovirus, enterovirus, varicella zoster virus (VZV), Trichomonas vaginalis, Candida albicans, Candida glabrata/>8	0/2
Open-channel capabilities/Start-up and preparation time	yes/<2 minutes per sample	no/<5 minutes per test
Model type of sample-handling system/Maximum sample load capacity	cartridge based/400 µL	—/2 mL
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	200 µL/yes (200 µL–400 µL input)/—	100 µL/no/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—	—/same as adult/—
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/no	—/standard barcodes/—
Sample barcode languages/Sample types available in open mode	—	—
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/dependent on assay	—/no/ positive blood culture broth, fresh liquid or soft stool, liquid or soft stool in Cary-Blair, NPS in viral or universal transport medium
Amplification reagents or methods supported	real-time PCR	onboard
No. of different assays onboard at once/Programmed or calibrated at once	up to 12/up to 12	single test protocol at a time per Processor SP/single test protocol at a time per Processor SP
Tests per container set/Multiple reagent configurations supported	24/—	1/no
Reagent container placed directly on system/Onboard test auto inventory	yes/no	yes/yes
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/yes	yes/no
Auto detection of adequate reagent or specimen/Reagents available	no/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	yes/yes
System is open to homebrew/General-purpose reagents allowed	yes/yes	no/no
Same capabilities when third-party reagent used/Lot sequestering available	yes/no	no/no
Closed-vial stability for amplification reagents/Extraction reagents	9 months, planned to 18 months/9 months, planned to 18 months	6 months/6 months
Storage temp. requirement for amplification reagents/Extraction reagents	room temperature/room temperature	≤-20°C/2°–30°C
Shipment temp. requirement for amplification reagents/Extraction reagents	refrigeration/refrigeration	dry ice/ambient
Minimum/Maximum reagent shelf-life guarantee	9 months, planned to 18 months/9 months, planned to 18 months	—/6 months
Autocalibration or autocalibration alert/Multipoint calibration supported	yes/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/no
Auto shutdown*/Instrument warm-up time/Onboard software reviews QC	yes/5 minutes for initialization/yes	yes/<1 minute/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	internal sample processing control (SPC) in each cartridge	—
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	2 hours per run, batched 12 samples per run/<2 minutes per sample	scalable/<5 minutes per test
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/tips not stored on instrument	yes/—
Time between start and initial result/Instrument automatic shutdown	2 hours/yes	2–2.5 hours/yes
Startup programmable/Remote system monitoring/Waste required for disposables	yes/yes/biohazard disposal	no/no/biohazardous waste
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/touchscreen/no	no/touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	Bronze, Silver, Gold, Gold+, Platinum, Diamond/26 weeks/4.8 hours	flexible; 2–5 years/—/—
Turnaround time for problem solving by phone/Email/Field service	1 hour/1 hour/—	24–7 accessible tech support/24–7 accessible tech support/1–4 days
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	23/varies per contract: next business day to second business day/M–F, 8 AM–6 PM	6/2–4 days/24–7 accessible
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes, per service contract/no/no	no/no/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/—	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	daily: 5 minutes; monthly: 15 minutes/no	daily: <5 minutes; weekly: <5 minutes; monthly: <20 minutes; yearly <10 hours/yes
Preventive maintenance per year for sample extraction/Amplification detection	1/1	yes/yes
Downtime for preventive maintenance/Spare parts on site	4 hours/no	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	—
• 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	yes/no	yes/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	yes/—	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	yes
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/HL7, CSV	yes/—
• 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/no	yes/—
• LIS operates simultaneously with assays running	yes	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/no	yes/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) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	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	superior cost-effective multiplexing technology relative to competitors

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Name of instrument	Illumipro-10	QIAsymphony RGQ
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	Switzerland, Germany, U.K./Switzerland/Germany
Instrument FDA cleared or approved/Platform	yes/analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2010/2010/2010	2008/2007/2007
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	8.3 × 11.5 × 3.7/.66/—	QIAsymphony SP: 128 × 103 × 73 cm; QIAsymphony AS: 59 × 103 × 73 cm; QIAsymphony SP/AS (integrated operation): 185 × 103 × 73 cm; Rotor-Gene Q: 28.6 × 37 × 42 (depth without cables) 53.8 (depth with door open) cm/—/—
Supplied with UPS/BTU	no/—	no/—
Physical contamination control features	closed test devices	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	$8,300/amplification: $8,300	—
Purchase options/Minimum test volume requirements	straight purchase, reagent rental/100 µL	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	yes/100–240 VAC, 50–60 Hz	yes/110V–230 V
Labor and parts warranties/Advanced operator training	1 year/no	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	1 business day/based on location/Meridian Bioscience (optional)/1 day	4 weeks/—/Qiagen service engineers/1–2 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/no limit/2 hours/no	on and off site/4/2 days/yes
Test menu	C. difficile, group B strep, group A strep, Mycoplasma pneumoniae, Bordetella pertussis, HSV 1/2	open platform
No. of tests for which analyzer has FDA-cleared applications/CE mark	5/C. difficile, group A strep, group B strep, Mycoplasma pneumoniae, Bordetella pertussis, HSV 1/2, Chlamydia trachomatis, Neisseria gonorrhea, Malaria	5/15
Tests available on instrument in U.S./Outside U.S.	C. difficile, group A strep, group B strep, Mycoplasma pneumoniae, Bordetella pertussis, HSV 1/2/Chlamydia trachomatis, Neisseria gonorrhea	CMV/HBV, HCV, CMV, EBV, BKV, CT/NG, parvo, malaria
Tests not available in U.S. but submitted to FDA/Available in other countries only	none/Malaria	MRSA/HIV, HCV, HBV, C. difficile, MRSA, VanR, GBS, CMV, EBV, BKV, VZV, HSV 1/2, RespiFast, CT-NG
Research-use-only assays/Tests in development	Malaria, CMV, Kingella, Babesia/—	—/multiple
Open-channel capabilities/Start-up and preparation time	no/2 minutes hands-on time per sample, 12 minutes total	yes/15 minutes
Model type of sample-handling system/Maximum sample load capacity	—/10 per Illumipro module	QIAsymphony SP/96
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	100 µL/no/—	200 µL/yes/400 µL, 500 µL, 800 µL, 4 mL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/100 µL/no	100 µL/200 µL/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/no	1.5–15 mL/yes/no
Sample barcode languages/Sample types available in open mode	Codabar codes 39, 93-93i, 128-IBT, UPC-EAN-ISBN, 128-UCC EAN 128, Interleaved 2 of 5	diverse, e.g. Codabar codes 39 and 128/plasma, blood, stool, urine, FFPE, respiratory, CSF, swabs, LBC, transport media
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—	yes/yes/plasma, blood, stool, urine, FFPE, respiratory, CSF, swabs, LBC, transport media
Amplification reagents or methods supported	loop-mediated isothermal amplification	yes
No. of different assays onboard at once/Programmed or calibrated at once	5/5	4/4
Tests per container set/Multiple reagent configurations supported	50/no	—/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/liquid and dry	yes/yes
Auto detection of adequate reagent or specimen/Reagents available	yes/closed test device system with internal control	yes/liquid
Reagent reconstitution required/Chemical contamination control	no/no	no/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	yes/yes
System is open to homebrew/General-purpose reagents allowed	no/no	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	no/no	yes/yes
Closed-vial stability for amplification reagents/Extraction reagents	18 months/—	minimum 1 year/minimum 1year
Storage temp. requirement for amplification reagents/Extraction reagents	2°–27°C/—	refrigerator/room temperature
Shipment temp. requirement for amplification reagents/Extraction reagents	room temperature/—	cool packs/room temperature
Minimum/Maximum reagent shelf-life guarantee	2 months/18 months	9 months/2 years
Autocalibration or autocalibration alert/Multipoint calibration supported	—/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/none, monthly optic verification	—
Length of assay calibration/Typical calibration frequency	2 minutes for optic verification/2 minutes	—/assay dependent
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	yes/5 minutes/no	no/none/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	controls run with each kit lot or shipment	assay dependent
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	10 samples per batch per module/2 minutes per sample	80 percent of run time/30 minutes
Uses disposable pipette tips/Maximum number of pipette tips stored	no/200 batches per 1,000 samples	yes/sufficient for 96 samples
Time between start and initial result/Instrument automatic shutdown	40 minutes/yes	typically 6–7 hours for 96 samples/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/—	yes/no/separate liquid, plastic, and tip waste
Windows technology/Mouse or touchscreen/Modular add-on capability	no/—/yes	yes/mouse and touchscreen/yes
Service contracts available/Mean time between failures/To repair failures	3-year extended warranty/—/24 hours	24 hours, 48 hours, and 5 days/—/—
Turnaround time for problem solving by phone/Email/Field service	10 minutes/10 minutes/none	yes/yes/yes
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/—/M–F, 8 AM–6 PM EST	75/contract dependent/24 hours, 7 days per week
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	24-hour replacement shipment/no/yes	yes/yes/yes
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/yes	no/no/yes
Average maintenance time for lab personnel/Onboard maintenance records	daily: 1 minute; monthly: 2 minutes/no	daily: 10 minutes; weekly: 30 minutes; monthly: 30 minutes/yes
Preventive maintenance per year for sample extraction/Amplification detection	—	1/1
Downtime for preventive maintenance/Spare parts on site	none/no	4 hours/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	no	no
• Data retrieval or Internet connectivity	no	yes
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/yes	yes/yes
• Priority processing	no	yes
• Supports accession No. redundancy/Specimen carrier and level identification	yes/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	yes/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/—	yes/QIAlink and HL7
• QC results transferred automatically to LIS/Data-management capability	no/yes	yes/yes
• Interfaces operational in active user sites	no	yes
• Rules-based control subsystem/Process control via control subsystem	no/no	no/yes
• LIS operates simultaneously with assays running	no	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/no	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	no/no/no	yes/yes/yes
• Can print, archive, transmit data	no	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*	loop-mediated isothermal amplification technology eliminates need for thermal cycling equipment; no extensive purification or extraction required; results in less than 1 hour	runs FDA-cleared 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

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Name of instrument	Solana	cobas 6800/8800 system
Country where designed/Manufactured/Reagents manufactured	U.S./U.S./U.S.	Switzerland/Switzerland/U.S.
Instrument FDA cleared or approved/Platform	yes/analytical	yes/preanalytical and analytical
First year sold in U.S./Sold internationally/Installed	2015/2016/2015	2016/2014/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	5.9 × 9.4 × 9.4/1/none	cobas 6800: 85 × 51 × 115/40.7/<65; cobas 8800: 85 × 51 × 169/59.9/<65
Supplied with UPS/BTU	yes/—	yes/cobas 6800: 7,507 kJ/h; cobas 8800: 13,649 kJ/h
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
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, lease/none	straight purchase, reagent rental, lease/—
Co. performs installation, operation, and performance qualifications/Electrical requirements	no/100–240 VAC, 47–63 Hz, 1.5–0.7 amps	yes/200–240 VAC, 50 or 60 Hz
Labor and parts warranties/Advanced operator training	—/no	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	2-day shipping/—/Quidel FAS/—	<30 days/—/Roche/<5 days
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/1/1 day/yes	on and off site/2/4 days/yes
Test menu	group A strep, strep complete, trichomonas, HSV 1+2/VZV, influenza A+B, C. difficile	HIV-1, HCV, HBV, CMV, MPX, WNV
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	HIV-1, HCV, HBV, CMV, MPX, WNV/HIV-1, HCV, HBV, CMV, CT/NG, HPV, HIV-1/2 qual., MPX, WNV
Tests not available in U.S. but submitted to FDA/Available in other countries only	1/0	additional menu in development/CT/NG, HPV, HIV-1/2 qual
Research-use-only assays/Tests in development	1/3	—/CT/NG, HPV, HIV-1/2 qual., TV (Trichomonas vaginalis) and MG (Mycoplasma genitalium), omni channel for lab-developed testing
Open-channel capabilities/Start-up and preparation time	no/2 minutes	no/~30 minutes
Model type of sample-handling system/Maximum sample load capacity	none/12	integrated system/350 with continuous loading
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	varies by analyte/no/—	HBV/HIV: 350 µL; HCV: 650 µL; CMV: 500 µL/yes/—
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no	150 µL/—/yes
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/yes/yes	height: 75–100 mm, outside diameter: 12.5–16 mm/1–23 characters, ASCII codes 32–126 in the barcode/no
Sample barcode languages/Sample types available in open mode	code 128, EAN-13, data matrix/—	Codabar, codes 39, 128, 93, EAN-8, EAN-13 incl. JAN code, Interleaved 2 of 5/—
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—	yes/no/—
Amplification reagents or methods supported	helicase dependent amplification	real-time PCR
No. of different assays onboard at once/Programmed or calibrated at once	12/12	12, for up to 1,152 tests/ 12, for up to 1,152 tests (no user calibration requirements)
Tests per container set/Multiple reagent configurations supported	12/—	96 tests/cassette for HIV-1, HBV, HCV, CMV/—
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/yes/yes	yes/no/no
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	yes/liquid
Reagent reconstitution required/Chemical contamination control	yes/—	no/AmpErase
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no	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/yes	no/yes
Closed-vial stability for amplification reagents/Extraction reagents	varies by analyte, up to 12 months/varies by analyte, up to 12 months	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	2°–8°C/2°–8°C	room temperature or with cool packs/room temperature or with cool packs
Minimum/Maximum reagent shelf-life guarantee	12 months/18 months	3 months/18 months
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/instrument calibrates each time it is turned on	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/—/yes	yes/—/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	—	3 for quantitative virology assays for all
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	—	cobas 6800: 8 hours for 384 tests; cobas 8800: 4 hours for 960 tests in 8 hours/ cobas 6800: <30 minutes; cobas 8800: <1 hour
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/—	yes/768
Time between start and initial result/Instrument automatic shutdown	varies by analyte/yes	<3.5 hours/yes
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/biohazard	yes/yes/onboard solid and liquid waste containers
Windows technology/Mouse or touchscreen/Modular add-on capability	no/touchscreen/no	yes/touchscreen/no
Service contracts available/Mean time between failures/To repair failures	replacement and repairs as long as customer is actively running the assay/—/—	phone support 24/7, 5-day and 7-day premium 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	—/—/8	175/24 hours/24 hours, 7 days based on contract
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	no/no/yes	24 hours/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: 10 minutes/no	weekly: ~45 minutes (15 minutes hands on)
Preventive maintenance per year for sample extraction/Amplification detection	—	2/2
Downtime for preventive maintenance/Spare parts on site	—/no	~4 hours/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	no/no	yes/yes
• Priority processing	no	yes
• Supports accession No. redundancy/Specimen carrier and level identification	no/no	yes/yes
• Unique barcode per container/Multistop routing (1 tube to many workstations)	no/no	yes/yes
• Specimen scheduling/Routes test to workstation/Automatic reflex, repeat, dilutions	no/no/no	no/yes/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/—	yes/Roche middleware solutions
• QC results transferred automatically to LIS/Data-management capability	no/yes	no/yes
• Interfaces operational in active user sites	no	yes
• Rules-based control subsystem/Process control via control subsystem	no/no	no/no
• LIS operates simultaneously with assays running	yes	yes
• Uses LOINC to transmit orders and results/Unidirectional interface capability	no/yes	yes/yes
• Results immediately transmitted to LIS/Interface available to auto specimen-handling system	yes/no	no/yes
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/yes	yes/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*	utilizes helicase dependent amplification, ensuring fast time to result relative to assay sensitivity; 12 test throughput allows for high demand; detects four channels per well, allowing for multiplexing capabilities	unmatched operational efficiency: refrigerated reagent storage, 350 samples onboard, up to 960 results in 8 hours; 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

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

AUTOMATED MOLECULAR PLATFORMS

Part 16 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**Roche Diagnostics** **Keith Obye** keith.obye@roche.com **9115 Hague Rd., Indianapolis, IN 46250** **317-521-4033** www.usdiagnostics.roche.com	**Roche Diagnostics** **David Gayes** david.gayes@roche.com **9115 Hague Rd., Indianapolis, IN 46250** **317-521-3569** www.usdiagnostics.roche.com
Name of instrument	cobas AmpliPrep/cobas TaqMan/cobas TaqMan 48	cobas Liat Analyzer
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	2007/2005/2007	2014/—/2014
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	AmpliPrep†: 37 × 65 × 29/13.1/—; TaqMan†: 37 × 45 × 30/9.4/—; TaqMan 48†: 20 × 18 × 30/3.8/—	7.5 × 4.5 × 9.5/<1/52 maximum
Supplied with UPS/BTU	yes/AmpliPrep†: 4904.6 per hour; TaqMan†: 3412 per hour; TaqMan 48†: 2049.1 per hour	no/440
Physical contamination control features	closed tube processing with dedicated consumables and pipette tips, more	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/100–125 VAC, 50–60 Hz +/–2 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	up to 30 days/—/Roche/1 day	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 hour/no
Test menu	see "Tests available on instrument in U.S./Outside U.S."	influenza A/B, strep A, influenza A/B & RSV
No. of tests for which analyzer has FDA-cleared applications/CE mark	7/11	3/3
Tests available on instrument in U.S./Outside U.S.	HIV-1 v2.0 (IVD), HBV v2 (IVD), HCV v2 (IVD), CMV (IVD), High Pure HBV (IVD), High Pure HCV v2 (IVD)/HIV-1 v2.0 (CE-IVD), HIV v2 qual (CE-IVD), HBV v2 (CE-IVD), HCV v2 qual (CE-IVD), HCV v2 quant (CE-IVD), CMV (CE-IVD), High Pure HIV v2 (CE-IVD), High Pure HBV (CE-IVD), High Pure HCV (CE-IVD), MTB qual (CE-IVD), CT qual (CE-IVD)	influenza A/B, strep A, influenza A/B & RSV/—
Tests not available in U.S. but submitted to FDA/Available in other countries only	—	—
Research-use-only assays/Tests in development	HIV-1 qual/—	—
Open-channel capabilities/Start-up and preparation time	yes/20 minutes for 24 samples	no/<2 minutes
Model type of sample-handling system/Maximum sample load capacity	cobas AmpliPrep: sample extraction††/cobas AmpliPrep: 72 samples, continuous load††	—/1 sample run at a time
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	HIV: 1.0 mL; HCV: 650 µL; HBV: 650 µL; CMV: 500 µL/yes (TNAI kit)/ 250 µL, 325 µL, 650 µL, 1 mL with TNAI	200 mL of UTM 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 1-D or 2-D	11 × 66 mm, 11 × 92 mm, 13 × 65 mm, 13 × 75 mm, 13 × 90 mm, 13 × 100 mm, 15 × 75 mm, 15 × 92 mm, 16 × 92 mm, 16 × 100 mm††/yes/no	—/yes/yes
Sample barcode languages/Sample types available in open mode	code 2 of 5 interleaved, code 39 (3 of 9 interleaved), Codabar, code 128/serum, plasma	Codabar, codes 39, 93, 128, 128-A, 128-B, GS1 Databar-14/—
Clot detection/Open extraction platform/Sample types (open extraction)	yes/yes/serum, plasma	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	4/4 (no calibration required)	1/3
Tests per container set/Multiple reagent configurations supported	HIV: 48; HBV, CMV, HCV; v2: 72/yes	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/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/amperase enzyme incorporated into all assays	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	no/yes	no/no
Closed-vial stability for amplification reagents/Extraction reagents	18 months/18 months	—
Storage temp. requirement for amplification reagents/Extraction reagents	2°–8°C/2°–8°C	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/0°–30°C
Minimum/Maximum reagent shelf-life guarantee	3 months/18 months	3 months/18 months for influenza A/B and influenza A/B & RSV, 16 months for strep A
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes	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 user calibration required	no/—
Length of assay calibration/Typical calibration frequency	no user calibration required/no user calibration required	—
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/<5 minutes sample extraction, <3 minutes amplification detection/yes	yes/—/yes
Total number of controls per batch for 24 tests/48 tests/72 tests/96 tests	3/6/9/12	1/1/1/1
Walkaway capacity/Tech hands-on time (both for batch of 96 samples)	72 samples/47 minutes	1 sample/1 sample
Uses disposable pipette tips/Maximum number of pipette tips stored	yes/72	no/—
Time between start and initial result/Instrument automatic shutdown	3.5 hours/no	20 minutes for influenza A/B and influenza A/B & RSV, 15 minutes for strep A/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/yes/onboard waste container	no/no/—
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	phone: weekdays 24–7; weekend 24–7 at premium/AmpliPrep: 135 days; TaqMan: 211 days; TaqMan 48: 336 days/<2.5 hours	per terms of contract/data not available/data not available
Turnaround time for problem solving by phone/Email/Field service	—	immediate/24 hours/—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	175/24 hours/24–7	—/—/24–7
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	yes (24 hours)/yes/no	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	daily: 15 minutes; weekly: 30 minutes; yearly: 20 minutes/yes	—/no
Preventive maintenance per year for sample extraction/Amplification detection	2 (AmpliPrep)††/1 (TaqMan, TaqMan 48)	—
Downtime for preventive maintenance/Spare parts on site	2–4 hours/yes	—/no
Software and LIS interface:		
• Patient demographics and insurance data available via rules-based architecture	yes	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	no/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	yes/yes/no	no/no/no
• Sample storage and retrieval software supports CLSI standards	no	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	yes/ethernet direct or middleware supported	yes/direct connectivity using HL7, drivers available for IT1000 and RALS
• 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/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	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)	parallel processing allows for multiple asays to be run simultaneously; physical and chemical contamination control; fully automated, continuous-load IVD platform features sample-in and results-out capability	the only real-time PCR platform that is CLIA waived for influenza A/B, strep A and RSV testing in 20 minutes or less; whether results are positive or negative, no confirmation is required at the time of visit; definitive results with no need for interpretation
**for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	*† does not include measurements for companion cobas p 630 preanalytical instrument* *†† with the cobas p 630 preanalytical instrument*	

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Part 17 of 18 See **captodayonline.com/productguides** for an interactive version of guide	**Roche Diagnostics** **Lynda Denney** lynda.denney@roche.com **9115 Hague Rd., Indianapolis, IN 46250** **317-521-4335** www.usdiagnostics.roche.com	**Thermo Fisher Scientific** customerservice@lifetech.com **5791 Van Allen Way, Carlsbad, CA 92008** **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 cm × 53 cm × 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	influenza A/B, RSV + hMPV, C. difficile
No. of tests for which analyzer has FDA-cleared applications/CE mark	8/—	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/—	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 V/II	measures nucleic acid signals from DNA or reverse-transcribed RNA/—
Open-channel capabilities/Start-up and preparation time	yes/30 minutes	yes/<5 minutes
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 1-D or 2-D	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	1/1	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/yes, 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 minutes	run dependent/<1 hour
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 hours; 96 CT-NG results in <4 hours/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 business hours or 7 days per week/sample: >100 days; amplification: >300 days/<4 hours	service and compliance plans, extended warranty/—/—
Turnaround time for problem solving by phone/Email/Field service	15 minutes/15 minutes/varies	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	250/24 hours/24 hours, 7 days	—/—/M–F, 8 AM–5 PM
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	24 hours/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 minutes; weekly: <5 minutes/yes	—
Preventive maintenance per year for sample extraction/Amplification detection	2/1	—/twice per year
Downtime for preventive maintenance/Spare parts on site	4 hours/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) **for calibration and controls* *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	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

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Name of instrument	7500 Fast Dx Real-Time PCR Instrument
Country where designed/Manufactured/Reagents manufactured	U.S./Singapore/—
Instrument FDA cleared or approved/Platform	yes/analytical
First year sold in U.S./Sold internationally/Installed	2008/2010/2009
Dimensions in inches (H × W × D)/Footprint in square feet/Noise generated in dB	19.29 × 13.99 × 17.72/1.8/—
Supplied with UPS/BTU	no/maximum output: 3241.5 per hour (950 W)
Physical contamination control features	no
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
Labor and parts warranties/Advanced operator training	1 year/yes
Delivery time/Delivery charges/Installer/Time to install on site	—/—/certified applied biosystems field service agent/—
Training location/No. of techs that can receive initial training/ Length of training/Retraining at company facility	on site/based on customer requirements/—/yes
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
No. of tests for which analyzer has FDA-cleared applications/CE mark	—
Tests available on instrument in U.S./Outside U.S.	—
Tests not available in U.S. but submitted to FDA/Available in other countries only	—
Research-use-only assays/Tests in development	—
Open-channel capabilities/Start-up and preparation time	yes/<5 minutes
Model type of sample-handling system/Maximum sample load capacity	—/96
Minimum specimen volume/Sample volume flexibility/Other sample volumes available	10 µL (reaction volume)/yes, reaction volumes 10–30 µL/10–30 µL
Minimum dead volume/Pediatric sample volume/Primary tube sampling	—/—/no
Sample tube sizes/Sample barcode reading/Autodiscrimination in 1-D or 2-D	—/no/no
Sample barcode languages/Sample types available in open mode	—/nucleic acid signals from reverse-transcribed RNA
Clot detection/Open extraction platform/Sample types (open extraction)	no/no/—
Amplification reagents or methods supported	nucleic acid signals from reverse-transcribed RNA
No. of different assays onboard at once/Programmed or calibrated at once	dependent on real-time PCR reaction plate setup/—
Tests per container set/Multiple reagent configurations supported	—
Reagent container placed directly on system/Onboard test auto inventory	no/no
Determines reagent volume in container/Reagent barcode reading/Reagents barcoded	no/no/no
Monitors expiration date/Auto lot recognition or calibration	no/no
Auto detection of adequate reagent or specimen/Reagents available	yes/liquid
Reagent reconstitution required/Chemical contamination control	yes/no
Onboard test auto inventory/Capable of inventory monitoring by barcode	no/no
System is open to homebrew/General-purpose reagents allowed	yes/yes
Same capabilities when third-party reagent used/Lot sequestering available	yes/no
Closed-vial stability for amplification reagents/Extraction reagents	—
Storage temp. requirement for amplification reagents/Extraction reagents	—
Shipment temp. requirement for amplification reagents/Extraction reagents	—
Minimum/Maximum reagent shelf-life guarantee	—
Autocalibration or autocalibration alert/Multipoint calibration supported	no/yes
Assay calibrations required by end user/Calibrants can be stored onboard	yes/no
Multiple calibrant lots stored for same assay/Required calibration frequency	no/6 months or after service repair
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
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 minutes to >2 hours/<1 hour
Uses disposable pipette tips/Maximum number of pipette tips stored	no/—
Time between start and initial result/Instrument automatic shutdown	assay run-mode dependent/no
Startup programmable/Remote system monitoring/Waste required for disposables	no/no/none
Windows technology/Mouse or touchscreen/Modular add-on capability	yes/mouse/no
Service contracts available/Mean time between failures/To repair failures	service plans, compliance services, extended warranty/—/—
Turnaround time for problem solving by phone/Email/Field service	—
No. of U.S. field reps/Service engineer on-site response time/Hours and days available	—/—/M–F, 8 AM–5 PM
Guaranteed response time/Modem servicing avail./System diagnose own malfunctions	—/—/no
Order parts via modem/Onboard error codes/Maintenance training demo module	no/yes/no
Average maintenance time for lab personnel/Onboard maintenance records	—
Preventive maintenance per year for sample extraction/Amplification detection	—/twice per year
Downtime for preventive maintenance/Spare parts on site	yes/no
Software and LIS interface:	
• Patient demographics and insurance data available via rules-based architecture	no
• Data retrieval or Internet connectivity	no
• Online real-time help, QC, stats, and management reports/Evaluates results validity	no/no
• Priority processing	no
• Supports accession No. redundancy/Specimen carrier and level identification	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
• Sample storage and retrieval software supports CLSI standards	no
• LIS(s) interfaced live with lab automation systems/How LIS(s) interfaced with LAS	no/—
• QC results transferred automatically to LIS/Data-management capability	no/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
• Stores QC lot files/Worklist edit capability/Viewable PCR graphs	no/yes/yes
• Can print, archive, transmit data	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*	96-well format eases plate setup; tube strips capped immediately after pipetting each sample; runs in <40 minutes; standard-length real-time PCR assays without changing thermal cycling parameters; 5-color variable excitation enables multiplex assays; security, auditing, and e-signatures allow full control over thermal cycling protocols

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