Part 1 of 8	**Bio/Data Corp.** **Mary Brown** customer.service@biodatacorp.com **Horsham, PA** **215-441-4000** or **800-257-3282** www.biodatacorp.com	**Chrono-log Corp.** **Sal Pema** sal@chronolog.com **Havertown, PA** **610-853-1130** or **800-247-6665** www.chronolog.com	**Chrono-log Corp.** **Sal Pema** sal@chronolog.com **Havertown, PA** **610-853-1130** or **800-247-6665** www.chronolog.com
Instrument name/First year sold	PAP-8E Platelet Aggregometer/2005	Optical Aggregation Systems Models 490 4+, 490 4+4/2017	Whole Blood Optical Lumi-Aggregation System 700-2, 700-4/2006
List price/Model type	$23,990/benchtop	$11,551–$27,505/benchtop	$20,410– $43,065/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	21.5–25.5 × 19.5 × 21.7 in./40 lbs./4 sq. ft.	per each 4-channel module: 8.5 × 14 × 15 in./19.3 lbs./1.5 sq. ft.	per each 2-channel module: 8.5 × 14 × 18 in./40 lbs./1.75 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	>500/>300 (worldwide)	—	—
Composition of installs: Hospital lab/Reference lab/Other	80%/15%/5% (unspecified)	—	—
Targeted daily, monthly, annual test volume	—	—	—
Operational type	batch, random access	discrete	discrete
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Company manufactures instrument	yes (also sold by möLab, Sentinel Diagnostics, Werfen, Alpha Labs, Sysmex, Analis)	yes (also sold via distribution partners)	yes (also sold via distribution partners)
FDA-approved clotting-based tests	—	—	—
FDA-approved chromogenic tests	—	—	—
FDA-approved immunologic tests	ristocetin cofactor activity, HIT/HIPA, RIPA, others	platelet agglutination with ristocetin	platelet agglutination with ristocetin
Other FDA-approved tests	routine platelet aggregation testing, platelet activation, spontaneous platelet aggregation, sticky platelets, washed platelets, others	LTA platelet aggregation, ristocetin cofactor assay	whole blood impedance platelet aggregation, LTA platelet aggregation, platelet dense granule ATP release, ristocetin cofactor assay
User-defined tests in clinical use	—	LTA platelet aggregation, ristocetin cofactor assay	whole blood impedance platelet aggregation, LTA platelet aggregation, platelet dense granule secretion, ristocetin cofactor assay
Tests in development or awaiting FDA 510(k) clearance	—	—	—
Methodologies supported	turbidimetric, immunologic (agglutination, Ab-Ag tests)	turbidimetric for measuring platelet aggregation in PRP and ristocetin cofactor assay	turbidimetric for measuring platelet aggregation in PRP and ristocetin cofactor assay, impedance for measuring platelet aggregation in whole blood
Number of different measured assays onboard simultaneously	255	4–8	2–4
Number of different assays programmed and calib. at one time	255	4–8	2–4
No. of user-definable (open) channels/No. active simultaneously	8/8	4–8/4–8	2–4/2–4
Factor assays require manual manipulation or dilutions	yes (manual manipulation and dilutions)	yes (manual dilutions)	yes (manual dilutions)
Test throughput per hour/Assay run time	80 (up to 720 samples in throughput)/6 min. average	6 (24–48 tests in throughput)/5 min. minimum	6 (12–24 tests in throughput)/6 min. minimum
Design of sample-handling system	manual	manual	manual
Operates on whole blood or spun plasma	spun plasma	spun plasma	whole blood and spun plasma
Reagent type	open reagent system (liquid, lyophilized [reconstituted manually])	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	yes, for all tests	no	no
No. of reagent containers held onboard/Reagents ready to use	none/requires operator prehandling	—/requires operator prehandling	—/requires operator prehandling
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/no/no	no/no/no	no/no/no
Reagents, consumables loaded without interrupting testing	yes (reagents and consumables)	yes (consumables)	yes (consumables)
Instrument uses proprietary or third-party reagents	user's option	proprietary reagents	proprietary reagents
Maximum time same lot number of reagents can be used	2 years	18 months–3 years	18 months–3 years
Walkaway capability/Walkaway duration	yes/8 specimens or 8 tests	yes/5 min. or 4–8 specimens or 4–8 tests	yes/6 min. or 2–4 specimens or 2–4 tests
Min.–max. specimen volume that can be aspirated at one time	—	250–500 µL	225–500 µL
Min. sample volume required for PT/PTT/Factor VIII activity	—	—	—
Types of disposables used	micro test tubes, micro stir bars, pipette tips, sample tubes, sample tube caps	cuvettes, stir bars, pipette tips	cuvettes, stir bars, disposable electrodes, pipette tips
Primary tube sampling supported/Pierces caps on primary tubes	no/no	no/no	no/no
Accommodates most standard tube sizes/Nonstandard sizes	no/no	no/no	no/no
Sample barcode-reading capability/Autodiscrimination	no/yes	no/no	no/no
Auto tracks product volume/Measures number of tests remaining	no/yes	no/no	no/no
Short sample detection	no	no	no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto detects adequate reagents for aspiration or analysis	no	no	no
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	detection for hemolysis, turbidity, icterus, lipemia	no	no
Dilutes patient samples onboard	no	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	yes/no
Lag time during which hypercoagulable sample not detected	no	no	no
User can adjust reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
User can adjust No. of reagents/Sources of reagents	yes/yes	yes/yes	yes/yes
User can adjust incubation times/Reading times	yes/yes	yes/yes	yes/yes
Read time extended for prolonged clotting times	no	yes (selectable on menus)	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	yes/no	yes/no	yes/no
Multipoint calibration supported/Recommended frequency	yes/annually	yes/annually	yes/annually
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	—	—	—
• PT, PTT	—	—	—
• Fibrinogen	—	—	—
• Factor VIII activity assay	—	—	—
• D-dimer	—	—	—
Time delay from ordering stat to aspiration of sample	—	—	—
How labs get LOINC codes for results	email query	email query	email query
Onboard real-time QC/Onboard software capability to review QC	no/yes	yes/no	yes/no
Information that can be barcode-scanned on instrument	reagent lot No.	barcode scanning not offered	barcode scanning not offered
Compatible with laboratory automation systems	no	no	no
Data-management capability/LIS or EHR systems interfaced	onboard/none	onboard/none	onboard/none
Interface supplied by instrument vendor	no	no	no
Results transferred to LIS as soon as test time complete	no	no	no
Bidirectional interface capability	no	no	no
Remote servicing provided/UPS backup power supply	no/no	no/no	no/no
Instrument connections to transfer information	—	—	—
Interface standards supported	—	—	—
Information transferred to data-management software	—	—	—
Avg. time for basic user training	1 day (at customer site or virtually)	—	1.5 days (at customer site)
Approximate scheduled maintenance time	weekly: 15 minutes; monthly: 30 minutes	preventive maintenance and calibration by clinical engineering recommended annually	preventive maintenance and calibration by clinical engineering recommended annually
Maintenance records kept onboard	no	yes	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/$2,150	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	eight independently operated channels, nine results reported per channel, standard micro volumes; preloaded routine and special test parameters, user-defined test templates and protocols, two-year warranty; includes all-in-one wireless computer, PAP-8E system software, electronic pipette, and Microsoft Office Suite	continuously monitors and regulates temperature and stirring; optical calibration can be performed by laboratory personnel using no-cost water samples; customized color-coding options	3 instruments in 1: whole blood/impedance and PRP/LTA aggregometer plus luminometer to measure platelet ATP release; continuously monitors and regulates temperature and stirring; optical calibration can be performed by laboratory personnel using no-cost water samples
Note: a dash in lieu of an answer means company did not answer question or question is not applicable			

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COAGULATION ANALYZERS

Part 2 of 8	**Diagnostica Stago** **Nichole Howard** nichole.howard@us.stago.com **Parsippany, NJ** **800-222-2624** www.stago-us.com	**Diagnostica Stago** **Nichole Howard** nichole.howard@us.stago.com **Parsippany, NJ** **800-222-2624** www.stago-us.com	**Diagnostica Stago** **Nichole Howard** nichole.howard@us.stago.com **Parsippany, NJ** **800-222-2624** www.stago-us.com
Instrument name/First year sold	STA Compact Max 3/2023	STA Satellite/2010	STA-R Max 3/2023
List price/Model type	$164,794/benchtop	$58,935/benchtop	$250,770/floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	27.75 × 38.18 × 28.73 in./309 lbs./7 sq. ft.	27.4 × 21.1 × 25.5 in./72 lbs./4 sq. ft.	49.2 × 50.3 × 32.2 in./564 lbs./26.8 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	~2,400/~4,700 (France, Spain, UK, Germany, Denmark, others)	~550/~2,100 (France, Spain, UK, Germany, Denmark, others)	~650/~3,200 (France, Spain, UK, Germany, Denmark, others)
Composition of installs: Hospital lab/Reference lab/Other	~96%/3%/1% (veterinary labs, pharmaceutical companies, academic research/educational labs)	~98%/0/2% (veterinary labs, academic research)	~90%/7%/3% (veterinary labs, pharmaceutical companies, academic research/educational labs)
Targeted daily, monthly, annual test volume	daily: >30 (moderate-volume laboratories); monthly: 900; annual: >5,000	daily: ~40; monthly: <900; annual: <13,000	daily: >100 (moderate- to high-volume laboratories); monthly: >2,500; annual: >25,000
Operational type	continuous random access	random access	continuous random access
Country where analyzer designed/Manufactured	France/France	France/France	France/France
Company manufactures instrument	yes	yes	yes
FDA-approved clotting-based tests	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT (screen and confirm)	PT, APTT, fibrinogen	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT (screen and confirm)
FDA-approved chromogenic tests	anti-FXa (UFH and LMWH), antithrombin, protein C, plasminogen, FVIII chromogenic	anti-FXa (UFH and LMWH), antithrombin	anti-FXa (UFH and LMWH), antithrombin, protein C, plasminogen, FVIII chromogenic
FDA-approved immunologic tests	D-dimer, antithrombin antigen, free protein S, total protein S, vWF antigen (all microlatex)	D-dimer	D-dimer, antithrombin antigen, free protein S, total protein S, vWF antigen (all microlatex)
Other FDA-approved tests	STA NeoPTimal protime reagent with ISI ~1.0	—	STA NeoPTimal protime reagent with ISI ~1.0
User-defined tests in clinical use	APCR, other clotting, chromogenic, and immunological tests with user-defined applications	—	APCR, other clotting, chromogenic, and immunological tests with user-defined applications
Tests in development or awaiting FDA 510(k) clearance	—	—	—
Methodologies supported	mechanical clot detection, chromogenic, immunologic (microlatex)	mechanical clot detection, chromogenic, immunologic (microlatex)	mechanical clot detection, chromogenic, immunologic (microlatex)
Number of different measured assays onboard simultaneously	80	80	200
Number of different assays programmed and calib. at one time	80	80	200
No. of user-definable (open) channels/No. active simultaneously	80/80	80/80	200/200
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	110 (2 tests in throughput)/4.6–7.3 min. (avg. 4.7 min.)	36 (3 tests in throughput for PT, APTT, fibrinogen)/4.6–7.3 min. (avg. 4.7 min.)	280 (2 tests in throughput)/4.6–7.3 min. (avg. 4.7 min.)
Design of sample-handling system	continuous loading sample drawer with continuous random access	continuous sample loading with positive sample identification, removable sample carousel for 20 primary tubes	rack with continuous specimen access
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Reagent type	self-contained single-use and multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained single-use and multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained single-use and multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	yes, for all tests	yes, for all tests	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	45/variable (reagent specific)	16/variable (reagent specific)	75/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/yes (15°–19°C)	yes/yes/yes (15°–19°C)	yes/yes/yes (15°–19°C)
Reagents, consumables loaded without interrupting testing	yes (consumables)	yes (consumables)	yes (consumables)
Instrument uses proprietary or third-party reagents	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)
Maximum time same lot number of reagents can be used	18 months	18 months	18 months
Walkaway capability/Walkaway duration	yes/96 specimens or 12 tests	yes/20 specimens or 12 tests	yes/215 specimens or 32 tests
Min.–max. specimen volume that can be aspirated at one time	5–100 µL	5–100 µL	5–100 µL
Min. sample volume required for PT/PTT/Factor VIII activity	50 µL/50 µL/50 µL	50 µL/50 µL/50 µL	50 µL/50 µL/50 µL
Types of disposables used	cuvettes, stir bars, cleaner solution	cuvettes, stir bars, cleaner solution	cuvettes, stir bars, cleaner solution
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes/yes
Accommodates most standard tube sizes/Nonstandard sizes	yes/no	yes/no	yes/no
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar)/—	yes (Interleaved 2 of 5, UPC, Codabar)/no	yes (Interleaved 2 of 5, UPC, Codabar)/—
Auto tracks product volume/Measures number of tests remaining	yes/no	yes/no	yes/no
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto detects adequate reagents for aspiration or analysis	yes (aspiration and analysis)	yes (aspiration and analysis)	yes (aspiration and analysis)
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	yes	—	yes
Dilutes patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	yes/yes
Lag time during which hypercoagulable sample not detected	no	no	no
User can adjust reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
User can adjust No. of reagents/Sources of reagents	yes/yes	yes/yes	yes/yes
User can adjust incubation times/Reading times	yes/yes	yes/yes	yes/yes
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	yes/yes	yes/yes	yes/yes
Multipoint calibration supported/Recommended frequency	yes/6 months	yes/6 months	yes/6 months
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<6 minutes/~150 specimens	<6 minutes/~50 specimens	<6 minutes/~320 specimens
• PT, PTT	<6 minutes/~100 specimens	<6 minutes/~40 specimens	<6 minutes/~280 specimens
• Fibrinogen	<6 minutes/~100 specimens	<6 minutes/~40 specimens	<6 minutes/~180 specimens
• Factor VIII activity assay	<6 minutes/~60 specimens	—	<6 minutes/~180 specimens
• D-dimer	7 minutes/~60 specimens	7 minutes/~6 specimens	7 minutes/~150 specimens
Time delay from ordering stat to aspiration of sample	<15 seconds	<15 seconds	<15 seconds
How labs get LOINC codes for results	email query, LOINC codes available in STA Coag Expert	email query	email query, LOINC codes available in STA Coag Expert
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Information that can be barcode-scanned on instrument	specimen identifier, reagent lot No., quality control ranges, calibrator values	specimen identifier, reagent lot No., quality control ranges, calibrator values	specimen identifier, reagent lot No., quality control ranges, calibrator values
Compatible with laboratory automation systems	no	no	yes (Stago, Abbott, Beckman Coulter, Cerner, Inpeco, QuidelOrtho, Roche, Siemens)
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, Meditech, Clinisys, SCC, McKesson, Epic	onboard/Cerner, Meditech, Clinisys, SCC, McKesson, Epic	onboard/Cerner, Meditech, Clinisys, SCC, McKesson, Epic
Interface supplied by instrument vendor	contract dependent	contract dependent	contract dependent
Results transferred to LIS as soon as test time complete	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (host query)	yes (broadcast download and host query)
Remote servicing provided/UPS backup power supply	yes/yes	no/yes	yes/yes
Instrument connections to transfer information	data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system	directly to LIS	data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system
Interface standards supported	ASTM 1394-91, ASTM 1381	ASTM 1394-91, ASTM 1381	ASTM 1394-91, ASTM 1381
Information transferred to data-management software	device unique identifier, patient ID, specimen ID, result, QC identifier	device unique identifier, patient ID, specimen ID, result, QC identifier	device unique identifier, patient ID, specimen ID, result, QC identifier
Avg. time for basic user training	3.5 days (at vendor office)	2.5 days (at vendor office)	3.5 days (at vendor office)
Approximate scheduled maintenance time	daily: 10 minutes; weekly: 10 minutes; monthly: none	weekly: <15 minutes; monthly: <15 minutes	daily: 10 minutes; weekly: 10 minutes; monthly: none
Maintenance records kept onboard	yes	no	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, full complement of lupus anticoagulant testing; STA Coag Expert and Coag.One data managers deliver full autoverification, repeat/reflex testing, auto upload of QC to peer group and of CPR test counts	viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, 2-mL 24-hour quality control for PT, APTT, fibrinogen; small footprint for low-throughput labs with limited space	viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, full complement of lupus anticoagulant testing; STA Coag Expert and Coag.One data managers deliver full autoverification, repeat/reflex testing, auto upload of QC to peer group and of CPR test counts

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

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Part 3 of 8	**HemoSonics LLC** **Chris Gillespie** cgillespie@hemosonics.com **Durham, NC** **919-886-9674** www.hemosonics.com	**LABiTec LAbor BioMedical Technologies GmbH** **M. Schramm** info@labitec.de **Ahrensburg, Germany** **011-49-4102-47950** www.labitec.com	**LABiTec LAbor BioMedical Technologies GmbH** **M. Schramm** info@labitec.de **Ahrensburg, Germany** **011-49-4102-47950** www.labitec.com
Instrument name/First year sold	Quantra Hemostasis Analyzer/2019	CoaDATA 2004 and 4004/—	CoaLAB 1000/—
List price/Model type	—/portable, benchtop	—/benchtop	—/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	19 × 14 × 12 in./36 lbs./1 sq. ft.	10 × 13 × 3.5 in./8.6 lbs./0.92 sq. ft.	19.6 × 30.7 × 23.6 in./70.5 lbs./5 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	>150/>150 (Europe, Japan, Hong Kong)	—/>1,500 (worldwide [except U.S., Canada])	—/— (worldwide [except U.S., Canada])
Composition of installs: Hospital lab/Reference lab/Other	35%/0/65% (point of care [operating room, ICU, stat lab, more])	—	—
Targeted daily, monthly, annual test volume	daily: 15–20; monthly: 1–200; annual: 1,200–2,400	—	daily: 100–400; monthly: 2,000–8,000; annual: 24,000–95,000
Operational type	random access, continuous random access	batch	batch, random access
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	Germany/Germany
Company manufactures instrument	yes	yes (also sold via OEM distribution, local distributors)	yes (also sold via OEM distribution, local distributors)
FDA-approved clotting-based tests	QPlus cartridge: clot time, clot time with heparinase, clot time ratio, clot stiffness, more; QStat cartridge: clot time, clot stability to lysis, clot stiffness, platelet contribution to clot stiffness, more	—	—
FDA-approved chromogenic tests	—	—	—
FDA-approved immunologic tests	—	—	—
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests in development or awaiting FDA 510(k) clearance	—	—	—
Methodologies supported	clot detection, sonic estimation of elasticity via resonance (SEER) sonorheometry	clot detection, mechanical and optical; photometric with mechanical stirring, turbodensitometric; chromogenic; immunologic (photometric)	clot detection, mechanical and optical; photometric with mechanical stirring, turbodensitometric; chromogenic; immunologic (photometric)
Number of different measured assays onboard simultaneously	QPlus cartridge: 6; QStat cartridge: 5	15	15
Number of different assays programmed and calib. at one time	no calibration required	15	50
No. of user-definable (open) channels/No. active simultaneously	—	—	50/15
Factor assays require manual manipulation or dilutions	—	yes (manual manipulation and dilutions)	—
Test throughput per hour/Assay run time	5–6 (25–36 tests in throughput)/7–60 min. (avg. 12.5 min.)	CoaDATA 2004: ~60 PT tests (1 test in throughput); CoaDATA 4004: ~120 PT tests (1 test in throughput)/—	120 PT tests/—
Design of sample-handling system	sealed room-temperature-stable cartridges accept a standard 3.2% citrate blue top tube, manually affixed to cartridge	semiautomated analyzer with 2 and 4 channels	cuvette ring, sample cups
Operates on whole blood or spun plasma	whole blood	spun plasma	spun plasma
Reagent type	self-contained single-use cartridges (lyophilized [reconstituted manually])	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	yes, for all tests	yes, for all tests	yes, for some tests
No. of reagent containers held onboard/Reagents ready to use	1 cartridge/yes	4/variable (reagent specific)	15/yes
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/no/no (20°–25°C)	yes/—/no	yes/yes/no
Reagents, consumables loaded without interrupting testing	no	yes (reagents and consumables)	yes (reagents)
Instrument uses proprietary or third-party reagents	proprietary reagents	user's option	user's option (same capabilities when third-party reagents used)
Maximum time same lot number of reagents can be used	—	—	—
Walkaway capability/Walkaway duration	yes/~12.5 min. or 1 specimen or 5–6 tests	no/—	yes/22 samples plus 3 stat (reagent dependent)
Min.–max. specimen volume that can be aspirated at one time	—	50–150 µL (total volume)	2–275 µL
Min. sample volume required for PT/PTT/Factor VIII activity	—	50 µL/50 µL/reagent dependent	50 µL/50 µL/assay dependent
Types of disposables used	single use cartridges, weekly cleaning cartridge, QC level 1 and 2	cuvettes, pipette tips, stir bars	—
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	—/no	yes/no
Accommodates most standard tube sizes/Nonstandard sizes	yes/—	no/no	yes/no
Sample barcode-reading capability/Autodiscrimination	yes/—	yes/no	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no
Auto tracks product volume/Measures number of tests remaining	—	no/no	yes/yes
Short sample detection	—	no	yes
Clot detection as preanalytical variable in plasma sample	—	no	no
Auto detects adequate reagents for aspiration or analysis	—	no	yes (aspiration and analysis)
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	no	detection for hemolysis, turbidity, icterus, lipemia	no
Dilutes patient samples onboard	no	no	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/no
Lag time during which hypercoagulable sample not detected	no	no	no
User can adjust reagent volumes/Sample volumes	no/no	yes/yes	yes/yes
User can adjust No. of reagents/Sources of reagents	—	no/no	yes/yes
User can adjust incubation times/Reading times	no/variable	yes/yes	yes/yes
Read time extended for prolonged clotting times	—	no	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	—	no/no	yes/yes
Multipoint calibration supported/Recommended frequency	no calibration required	yes/—	yes/with lot change
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	—	—	<2 minutes/120 specimens
• PT, PTT	—	—	<5 minutes/71 specimens
• Fibrinogen	fibrinogen contribution to clot stiffness: ~12.5 min./—	—	<5 minutes/50 specimens
• Factor VIII activity assay	—	—	<6 minutes/—
• D-dimer	—	—	<6 minutes/—
Time delay from ordering stat to aspiration of sample	none	—	3 minutes
How labs get LOINC codes for results	email query, included in Quantra System implementation guide, addressed during training	functionality not provided	functionality not provided
Onboard real-time QC/Onboard software capability to review QC	yes/yes	no/no	yes/yes
Information that can be barcode-scanned on instrument	operator identifier, specimen identifier, reagent lot No., lot specific QC target ranges, container ID	specimen identifier, reagent lot No.	specimen identifier
Compatible with laboratory automation systems	no	no	no
Data-management capability/LIS or EHR systems interfaced	onboard/yes	no/—	onboard/—
Interface supplied by instrument vendor	yes	yes (included in analyzer price)	no
Results transferred to LIS as soon as test time complete	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	no	yes (host query)
Remote servicing provided/UPS backup power supply	no/yes	no/no	no/no
Instrument connections to transfer information	directly to LIS; commercial middleware (RALS, Telcor, UniPOC, Cobas Infinity, DI Data Innovations)	directly to LIS; directly to EHR	data-management system, which in turn connects to LIS; directly to LIS
Interface standards supported	LIS: compliant to CLSI LIS02-A2; POC testing middleware: compliant to CLSI POCT01-A2	—	LAN connection provides FTP result file transfer
Information transferred to data-management software	device unique identifier, operator ID, patient ID, result, QC identifier, date and time of assay start, container ID, more	patient ID, result	device unique identifier, patient ID, specimen ID, result
Avg. time for basic user training	up to 14 days (at customer site)	1 day (at vendor office, on request)	3 days (at customer and vendor offices)
Approximate scheduled maintenance time	weekly: 3 minutes; monthly: 12 minutes	per shift: <1 minute; daily: <1 minute; weekly: <1 minute; monthly: <3 minutes	per shift: 1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: 15 minutes
Maintenance records kept onboard	yes	no	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/— (cost dependent on contract)	yes/—	yes/—
Distinguishing features (supplied by company)	ultrasound measure of whole blood hemostasis directly measures physical properties of a developing clot; wide range of clinical indications with simplified interpretation allows for better communication; novel technology allows for parameters not available in other systems, e.g. platelet contribution to clot	advanced coagulation diagnostics by selectable dual wavelength optics (405/750 nm) for each measuring channel; more sensitive to interferences from hemolysis, icteric, and lipemic samples; intuitive flexible user software; minimum maintenance, repair times, and costs (incl. printer)	easy-to-use, standalone device with small footprint; onboard user and service software, no external PC required; optimized for small to mid-sized labs

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

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

COAGULATION ANALYZERS

Part 4 of 8	**Siemens Healthineers** **Laura Oversmith** laura.oversmith@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com	**Siemens Healthineers** **Laura Oversmith** laura.oversmith@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com	**Siemens Healthineers** **Laura Oversmith** laura.oversmith@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com
Instrument name/First year sold	BFT II Analyzer/1999	CA-660 System/2012	CS-2500 System/2016
List price/Model type	$8,500/benchtop	$55,000/benchtop	$155,000/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	3.9 × 7.9 × 11.8 in./8.4 lbs./0.65 sq. ft.	22.5 × 19.5 × 19.5 in./94.6 lbs./3.1 sq. ft.	27 × 30.6 × 35.2 in./242.5 lbs./7.5 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	—/— (worldwide)	>2,000/>5,000 (worldwide)	>500/>2,000 (worldwide)
Composition of installs: Hospital lab/Reference lab/Other	—	—	—
Targeted daily, monthly, annual test volume	daily: 1	daily: <25	daily: 25–300
Operational type	batch	continuous random access	continuous random access
Country where analyzer designed/Manufactured	Germany/Germany	Japan/Japan	Japan/Japan
Company manufactures instrument	yes	no (manufactured by Sysmex)	no (manufactured by Sysmex)
FDA-approved clotting-based tests	PT, APTT, fibrinogen	PT, APTT, fibrinogen, factors VII and VIII, protein C, thrombin time, batroxobin time	PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI and XII, protein C, lupus screen, lupus confirm, factor V Leiden, thrombin time, batroxobin time
FDA-approved chromogenic tests	—	antithrombin, protein C, Innovance heparin	antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin, Innovance anti-Xa
FDA-approved immunologic tests	—	Innovance D-dimer	Innovance VWF activity, VWF antigen, Innovance D-dimer
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	—	—	platelet aggregation RUO, factor XIII chromogenic RUO
Tests in development or awaiting FDA 510(k) clearance	—	—	—
Methodologies supported	clot detection, mechanical and optical	clot detection, optical; turbidimetric; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; turbidimetric; chromogenic; immunologic (immunoturbidimetric)
Number of different measured assays onboard simultaneously	1	5	60
Number of different assays programmed and calib. at one time	3	7	60
No. of user-definable (open) channels/No. active simultaneously	—	7/5	80,000/60
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	—/5 min.	60 (1 test in throughput)/1–7 min. (avg. 5 min.)	180 (2 tests in throughput)/1–10 min. (avg. 5 min.)
Design of sample-handling system	manual	10-tube position sample rack	10-tube position sample rack with a maximum of 5 × racks
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Reagent type	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	no	yes, for all tests	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	4/yes	13/variable (reagent specific)	45/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	no/no/no	yes/yes/yes (15°C ± 2°C)	yes/yes/yes (10°C ± 2°C)
Reagents, consumables loaded without interrupting testing	yes (reagents and consumables)	no	yes (reagents and consumables)
Instrument uses proprietary or third-party reagents	proprietary reagents, third-party reagents, user's option	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)
Maximum time same lot number of reagents can be used	1 year	18 months	18 months
Walkaway capability/Walkaway duration	no/—	yes/10 specimens or up to 50 tests	yes/50 specimens or up to 500 tests
Min.–max. specimen volume that can be aspirated at one time	—	5–400 µL	5–500 µL
Min. sample volume required for PT/PTT/Factor VIII activity	50 µL/50 µL/—	50 µL/50 µL/5 µL (standard)	50 µL/50 µL/5 µL (standard)
Types of disposables used	cuvettes	reaction cuvettes, CA clean I and II	reaction cuvettes, CA clean I and II
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes/no	yes/yes
Accommodates most standard tube sizes/Nonstandard sizes	no/no	yes/yes	yes/yes
Sample barcode-reading capability/Autodiscrimination	no/—	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes
Auto tracks product volume/Measures number of tests remaining	no/no	yes/no	yes/yes
Short sample detection	no	yes	yes
Clot detection as preanalytical variable in plasma sample	no	no	yes
Auto detects adequate reagents for aspiration or analysis	no	yes (aspiration and analysis)	yes (aspiration and analysis)
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	no	no	detection and quantitation for hemolysis, turbidity, icterus, lipemia
Dilutes patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/yes
Lag time during which hypercoagulable sample not detected	no	yes (PT: 7 seconds; PTT: 15 seconds)	yes (PT: 7 seconds; PTT: 15 seconds)
User can adjust reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
User can adjust No. of reagents/Sources of reagents	yes/yes	yes/yes	yes/yes
User can adjust incubation times/Reading times	yes/yes	yes/yes	yes/yes
Read time extended for prolonged clotting times	yes	yes	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	no/yes	yes/yes	yes/yes
Multipoint calibration supported/Recommended frequency	yes/6 months, per regulatory guidelines	yes/6 months, per regulatory guidelines	yes/6 months, per regulatory guidelines
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	1 minute/1 specimen	<7 minutes/60 specimens	<5 minutes/180 specimens
• PT, PTT	—	<8 minutes/24 specimens	<5 minutes/90 specimens
• Fibrinogen	1 minute/1 specimen	<7 minutes/60 specimens	<5 minutes/180 specimens
• Factor VIII activity assay	—	<5 minutes/—	<5 minutes/—
• D-dimer	—	<6 minutes/12 specimens	<5 minutes/90 specimens
Time delay from ordering stat to aspiration of sample	—	<1 minute	<1 minute
How labs get LOINC codes for results	website	website	website
Onboard real-time QC/Onboard software capability to review QC	no/no	yes/yes	yes/yes
Information that can be barcode-scanned on instrument	—	specimen identifier, reagent lot No.	operator identifier, specimen identifier, reagent lot No., reagent vial ID, reagent expiry
Compatible with laboratory automation systems	no	no	no
Data-management capability/LIS or EHR systems interfaced	no/no	onboard/most major vendors	onboard/most major vendors
Interface supplied by instrument vendor	no	contract dependent	contract dependent
Results transferred to LIS as soon as test time complete	no	yes	yes
Bidirectional interface capability	no	yes (host query)	yes (host query)
Remote servicing provided/UPS backup power supply	no/no	no/yes	yes/yes
Instrument connections to transfer information	commercial middleware (most major companies)	data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies)	data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies)
Interface standards supported	—	ASTM 1394-91, ASTM 1381, HL7, CA-500 protocol, CA-1000 protocol	ASTM 1394-91, ASTM 1381, HL7, CA-1000 protocol, CA-1500 protocol
Information transferred to data-management software	—	device unique identifier, patient ID, specimen ID, result, QC identifier	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks
Avg. time for basic user training	Siemens PEPconnect online	2 days (at customer site), some self-study virtual training required	2 days (at customer site), some self-study virtual training required
Approximate scheduled maintenance time	daily: 1 minute	daily: <5 minutes	daily: <5 minutes; weekly: <10 minutes; monthly: <10 minutes
Maintenance records kept onboard	no	no	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/—	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	2-channel micro reagent volume clot-based technology; opto-mechanical detection accurate on lipemic, icteric samples; automatic INR calculation, curve storage, built-in thermal printer; effective for low-volume testing, backup to larger systems	maximizes counter space with compact footprint in low-volume labs; increases uptime and reduces service expenses; features clotting, chromogenic, and immunologic testing	simultaneous multiwavelength detection and PSI technology designed to ensure high-quality first-run results; user-friendly software on Windows 10; tilted reagent vials for efficiency; for multisite patient monitoring, with sample result traceability for in-depth audit capabilities

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

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Part 5 of 8	**Siemens Healthineers** **Laura Oversmith** laura.oversmith@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com	**Sysmex** **Krishna Ram** ram.krishna@sysmex.com **Lincolnshire, IL** **847-996-4500** www.sysmex.com/en-us	**Sysmex** **Krishna Ram** ram.krishna@sysmex.com **Lincolnshire, IL** **847-996-4500** www.sysmex.com/en-us
Instrument name/First year sold	CS-5100 System/2016	Sysmex CA-600 Series Systems: CA-620, CA-660/2012	Sysmex CS-2500 System/2016
List price/Model type	$205,000/floor standing	—/benchtop	—/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	50.4 × 40.6 × 45.3 in./612.9 lbs./12.8 sq. ft.	22.5 × 19.5 × 19.5 in./94.6 lbs./3.1 sq. ft.	27 × 30.6 × 35.2 in./242.5 lbs./7.5 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	>100/>1,000 (worldwide)	>2,000/>5,000 (worldwide)	>500/>2,000 (worldwide)
Composition of installs: Hospital lab/Reference lab/Other	—	95%/5%/—	95%/5%/—
Targeted daily, monthly, annual test volume	daily: >300	daily: <25; monthly: <750; annual: <9,000	daily: 25–300; monthly: 750-9,000; annual: 9,000-110,000
Operational type	continuous random access	continuous random access	continuous random access
Country where analyzer designed/Manufactured	Japan/Japan	Japan/Japan	Japan/Japan
Company manufactures instrument	no (manufactured by Sysmex)	yes	yes
FDA-approved clotting-based tests	PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI and XII, protein C, lupus screen, lupus confirm, factor V Leiden, thrombin time, batroxobin time	PT, APTT, fibrinogen, factor VII, factor VIII, protein C, thrombin time, reptilase time	PT, APTT, fibrinogen, thrombin time, reptilase time, factors II, V, VII, VIII, IX, X, XI, and XII, lupus screen, lupus confirm, protein C, factor V Leiden
FDA-approved chromogenic tests	antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin, Innovance anti-Xa	CA-660 only: antithrombin, protein C, anti-Xa, heparin (UFH and LMWH)	factor VIII chromogenic, antithrombin, protein C, anti-Xa, heparin (UFH and LMWH), free protein S antigen, alpha-2-antiplasmin, plasminogen
FDA-approved immunologic tests	Innovance VWF activity, VWF antigen, Innovance D-dimer	D-dimer	D-dimer, vWF activity (GP1bM), vWF antigen
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	platelet aggregation RUO, factor XIII chromogenic RUO	—	factor XIII chromogenic RUO, platelet aggregation testing RUO
Tests in development or awaiting FDA 510(k) clearance	—		
Methodologies supported	clot detection, optical; turbidimetric; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; turbidimetric; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; turbidimetric; chromogenic; immunologic (immunoturbidimetric)
Number of different measured assays onboard simultaneously	60	5	60
Number of different assays programmed and calib. at one time	60	7	60
No. of user-definable (open) channels/No. active simultaneously	80,000/60	7/5	80,000/60
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	400 (2 tests in throughput)/1–10 min. (avg. 5 min.)	60 (1 test in throughput)/1–7 min. (avg. 5 min.)	180 (2 tests in throughput)/1–10 min. (avg. 5 min.)
Design of sample-handling system	10-tube position sample rack with a maximum of 10 × racks	10-tube position sample rack	10-tube position sample rack with a maximum of 5 × racks
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Reagent type	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	yes, for all tests	no	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	45/variable (reagent specific)	13/variable (reagent specific)	45/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/yes (10°C ± 2°C)	yes/yes/yes (15°C ± 2°C)	yes/yes/yes (10°C ± 2°C)
Reagents, consumables loaded without interrupting testing	yes (reagents and consumables)	no	yes (reagents and consumables)
Instrument uses proprietary or third-party reagents	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)
Maximum time same lot number of reagents can be used	18 months	18 months	18 months
Walkaway capability/Walkaway duration	yes/100 specimens or up to 1,000 tests	yes/10 specimens or 50 tests	yes/50 specimens or up to 500 tests
Min.–max. specimen volume that can be aspirated at one time	5–500 µL	5–400 µL	5–500 µL
Min. sample volume required for PT/PTT/Factor VIII activity	50 µL/50 µL/5 µL (standard)	50 µL/50 µL/5 µL (standard)	50 µL/50 µL/5 µL (standard)
Types of disposables used	reaction cuvettes, CA clean I and II	reaction cuvettes, CA clean I, CA clean II	reaction cuvettes, CA clean I, CA clean II
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes/yes
Accommodates most standard tube sizes/Nonstandard sizes	yes/yes	yes/yes	yes/yes
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes
Auto tracks product volume/Measures number of tests remaining	yes/yes	yes/no	yes/yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	yes	no	yes
Auto detects adequate reagents for aspiration or analysis	yes (aspiration and analysis)	yes (aspiration and analysis)	yes (aspiration and analysis)
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia	no	detection and quantitation for hemolysis, turbidity, icterus, lipemia
Dilutes patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	no/no	yes/yes
Lag time during which hypercoagulable sample not detected	yes (PT: 7 seconds; PTT: 15 seconds)	yes (PT: 7 seconds; PTT: 15 seconds)	yes (PT: 7 seconds; PTT: 15 seconds)
User can adjust reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
User can adjust No. of reagents/Sources of reagents	yes/yes	yes/yes	yes/yes
User can adjust incubation times/Reading times	yes/yes	yes/yes	yes/yes
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	yes/yes	yes/yes	yes/yes
Multipoint calibration supported/Recommended frequency	yes/6 months, per regulatory guidelines	yes/6 months, per regulatory guidelines	yes/6 months, per regulatory guidelines
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<5 minutes/400 specimens	<7 minutes/60 specimens	<5 minutes/180 specimens
• PT, PTT	<5 minutes/200 specimens	<8 minutes/24 specimens	<5 minutes/90 specimens
• Fibrinogen	<5 minutes/201 specimens	<7 minutes/60 specimens	<5 minutes/180 specimens
• Factor VIII activity assay	<5 minutes/—	<5 minutes/—	<5 minutes/—
• D-dimer	<5 minutes/202 specimens	<6 minutes/12 specimens	<5 minutes/90 specimens
Time delay from ordering stat to aspiration of sample	<1 minute	<1 minute	<1 minute
How labs get LOINC codes for results	website	website	website
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Information that can be barcode-scanned on instrument	operator identifier, specimen identifier, reagent lot No., reagent vial ID, reagent expiry	specimen identifier, reagent lot No.	operator identifier, specimen identifier, reagent lot No., reagent vial ID, reagent expiry
Compatible with laboratory automation systems	yes (Siemens Aptio and FlexLab X automation)	no	no
Data-management capability/LIS or EHR systems interfaced	onboard/most major vendors	onboard; optional add-on (Bio-Rad Unity Next Peer QC)/most major vendors	onboard; optional add-on (Bio-Rad Unity Next Peer QC)/most major vendors
Interface supplied by instrument vendor	contract dependent	contract dependent	contract dependent
Results transferred to LIS as soon as test time complete	yes	yes	yes
Bidirectional interface capability	yes (host query)	yes (host query)	yes (host query)
Remote servicing provided/UPS backup power supply	yes/yes	no/yes	yes/yes
Instrument connections to transfer information	data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies)	data-management system, which in turn connects to LIS or EHR; data-management system that cannot further transmit data; directly to LIS or EHR; directly to lab automation system	data-management system, which in turn connects to LIS or EHR; data-management system that cannot further transmit data; directly to LIS or EHR; directly to lab automation system
Interface standards supported	ASTM 1394-91, ASTM 1381, HL7, CA-1000 protocol, CA-1500 protocol	ASTM 1394-91, ASTM 1381, HL7, CA-1000 protocol, CA-1500 protocol	ASTM 1394-91, ASTM 1381, HL7, CA-1000 protocol, CA-1500 protocol
Information transferred to data-management software	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks	device unique identifier, patient ID, specimen ID, result, QC identifier	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks
Avg. time for basic user training	2 days (at customer site), some self-study virtual training required	5 days (at customer site), virtual instructor-led training also available	5–10 days (at customer site), virtual instructor-led training also available
Approximate scheduled maintenance time	daily: <5 minutes; weekly: <10 minutes; monthly: <10 minutes	daily: <5 minutes	daily: <5 minutes; weekly: <10 minutes; monthly: <10 minutes
Maintenance records kept onboard	yes	no	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	simultaneous multiwavelength detection and PSI technology designed to ensure high-quality first-run results; user-friendly software on Windows 10; tilted reagent vials for efficiency; for multisite patient monitoring, with sample result traceability for in-depth audit capabilities	minimal maintenance ensures maximum uptime; easy-to-use, scalable solution for better standardization with larger Sysmex solutions for hemostasis testing	ensures quality results with customizable preanalytical checks and simultaneous multiwavelength detection technology; maximizes walkaway time with the release capacity of sample loading; minimal maintenance ensures maximum uptime
Note: a dash in lieu of an answer means company did not answer question or question is not applicable			

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COAGULATION ANALYZERS

Part 6 of 8	**Sysmex** **Krishna Ram** ram.krishna@sysmex.com **Lincolnshire, IL** **847-996-4500** www.sysmex.com/en-us	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com
Instrument name/First year sold	Sysmex CS-5100 System/2016	ACL AcuStar/2010	ACL TOP 350/2016
List price/Model type	—/floor standing	—/benchtop	—/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	50.4 × 40.6 × 45.3 in./612.9 lbs./12.8 sq. ft.	21 × 34 × 24 in./170 lbs./10 sq. ft.	29 × 32 × 33 in./200 lbs./8 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	>100/>1,000 (worldwide)	5/196 (available in most countries)	1,309/3,700 (available in most countries)
Composition of installs: Hospital lab/Reference lab/Other	95%/5%/—	100%/0/0	95%/5%/—
Targeted daily, monthly, annual test volume	daily: >300; monthly: >9,000; annual: >110,000	daily: 20–150; monthly: 600–4,500; annual: 36,000–54,000	daily: 20–150; monthly: 600–4,500; annual: 36,000–54,000
Operational type	continuous random access	random access	random access
Country where analyzer designed/Manufactured	Japan/Japan	U.S./U.S.	U.S./U.S.
Company manufactures instrument	yes	no	yes
FDA-approved clotting-based tests	PT, APTT, fibrinogen, thrombin time, reptilase time, factors II, V, VII, VIII, IX, XI, and XII, lupus screen, lupus confirm, protein C, factor V Leiden	—	PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C
FDA-approved chromogenic tests	factor VIII chromogenic, antithrombin, protein C, anti-Xa, heparin (UFH and LMWH), free protein S antigen, alpha-2-antiplasmin, plasminogen	—	anti-Xa, apixaban, protein C, antithrombin, plasminogen, plasmin inhibitor
FDA-approved immunologic tests	D-dimer, vWF activity (GP1bM), vWF antigen	HIT IgG, domain 1, anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM	high specificity D-dimer, standard D-dimer, heparin-induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	factor XIII chromogenic RUO, platelet aggregation testing RUO	—	DOAC assays, chromogenic factor VIII
Tests in development or awaiting FDA 510(k) clearance		ADAMTS13, von Willebrand factor ristocetin cofactor, von Willebrand antigen	von Willebrand factor ristocetin cofactor, dabigatran, rivaroxaban, apixaban
Methodologies supported	clot detection, optical; turbidimetric; chromogenic; immunologic (immunoturbidimetric)	immunologic (chemiluminescent)	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)
Number of different measured assays onboard simultaneously	60	20	30
Number of different assays programmed and calib. at one time	60	20	500
No. of user-definable (open) channels/No. active simultaneously	80,000/60	0/0	250/250
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	400 (2 tests in throughput)/1–10 min. (avg. 5 min.)	60 (1 test in throughput)/30 min.	110 (1 test in throughput)/3–6 min. (avg. 4 min.)
Design of sample-handling system	10-tube position sample rack, with a maximum of 10 × racks	samples loaded into carousel rack	samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Reagent type	self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained multiuse cartridges (liquid)	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	yes, for all tests	yes, for all tests	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	45/variable (reagent specific)	20/yes	24/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/yes (10°C ± 2°C)	yes/yes/yes	yes/yes/yes
Reagents, consumables loaded without interrupting testing	yes (reagents and consumables)	yes (reagents and consumables)	yes (reagents and consumables)
Instrument uses proprietary or third-party reagents	user's option (same capabilities when third-party reagents used)	proprietary reagents	user's option (same capabilities when third-party reagents used)
Maximum time same lot number of reagents can be used	18 months	6 months	—
Walkaway capability/Walkaway duration	yes/100 specimens or 1,000 tests	yes/30 specimens or 280 tests	yes/40 specimens or 800 tests
Min.–max. specimen volume that can be aspirated at one time	5–500 µL	2–250 µL	2–250 µL
Min. sample volume required for PT/PTT/Factor VIII activity	50 µL/50 µL/5 µL	50 µL/50 µL/50 µL	50 µL/50 µL/50 µL
Types of disposables used	reaction cuvettes, CA clean I, CA clean II	cuvettes, trigger, solutions	cuvettes, clean A/B, rinse
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes/yes
Accommodates most standard tube sizes/Nonstandard sizes	yes/yes	yes/no	yes/yes
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes
Auto tracks product volume/Measures number of tests remaining	yes/yes	yes/yes	yes/yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	yes	no	yes
Auto detects adequate reagents for aspiration or analysis	yes (aspiration and analysis)	yes (aspiration and analysis)	yes (aspiration and analysis)
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia	—	detection and quantitation for hemolysis, turbidity, icterus, lipemia
Dilutes patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	yes/yes
Lag time during which hypercoagulable sample not detected	yes (PT: 7 seconds; PTT: 15 seconds)	—	no
User can adjust reagent volumes/Sample volumes	yes/yes	no/no	yes/yes
User can adjust No. of reagents/Sources of reagents	yes/yes	no/no	yes/yes
User can adjust incubation times/Reading times	yes/yes	no/no	yes/yes
Read time extended for prolonged clotting times	yes (selectable on menus)	no	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	yes/yes	no/no	no/no
Multipoint calibration supported/Recommended frequency	yes/6 months, per regulatory guidelines	yes/6 months	yes/per lab's quality management system rules
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<5 minutes/400 specimens	—	<3 minutes/110 specimens
• PT, PTT	<5 minutes/200 specimens	—	<6 minutes/55 specimens
• Fibrinogen	<5 minutes/201 specimens	—	<3 minutes/60 specimens
• Factor VIII activity assay	<5 minutes/—	—	8 minutes/38 specimens
• D-dimer	<5 minutes/202 specimens	—	5 minutes/55 specimens
Time delay from ordering stat to aspiration of sample	<1 minute	<1 minute	none
How labs get LOINC codes for results	website	functionality not provided	functionality not provided
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Information that can be barcode-scanned on instrument	operator identifier, specimen identifier, reagent lot No., reagent vial ID, reagent expiry	specimen identifier, reagent lot No.	specimen identifier, reagent lot No., International Sensitivity Index
Compatible with laboratory automation systems	yes (Siemens Aptio Automation, Inpeco Automation)	no	no
Data-management capability/LIS or EHR systems interfaced	optional add-on (Bio-Rad Unity Next Peer QC)/most major vendors	onboard/Meditech	onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, others
Interface supplied by instrument vendor	contract dependent	contract dependent	contract dependent
Results transferred to LIS as soon as test time complete	yes	yes	yes
Bidirectional interface capability	yes (host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Remote servicing provided/UPS backup power supply	yes/yes	no/yes	yes/yes
Instrument connections to transfer information	data-management system, which in turn connects to LIS or EHR; data-management system that cannot further transmit data; directly to LIS or EHR; directly to lab automation system	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Werfen, Beckman Coulter)	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman Coulter)
Interface standards supported	ASTM 1394-91, ASTM 1381, HL7, CA-1000 protocol, CA-1500 protocol	ASTM 1394-91	ASTM 1394-91
Information transferred to data-management software	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks	specimen ID	specimen ID
Avg. time for basic user training	5–10 days (at customer site), virtual instructor-led training also available	4 days (at customer site)	9 days (5 days at customer site, 4 days at vendor office)
Approximate scheduled maintenance time	daily: <5 minutes; weekly: <10 minutes; monthly: <10 minutes	daily: 5 minutes; weekly: 5 minutes	daily: <5 minutes; weekly: <10 minutes
Maintenance records kept onboard	yes	yes	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	ensures quality results with customizable preanalytical checks and simultaneous multiwavelength detection technology; maximizes walkaway time with the release capacity of sample loading; minimal maintenance ensures maximum uptime	on-demand HIT IgG testing with results available in 30 minutes; uses sensitive chemiluminescent technology, improving sensitivity; reagents are ready to use with onboard stability up to 12 weeks	FDA 510(k) approved; improves patient care, lab efficiencies, and costs; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); liquid format for PT/APTT (10-day onboard stability), high specificity D-dimer, on-demand HIT testing

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

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Part 7 of 8	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com
Instrument name/First year sold	ACL TOP 370/2024	ACL TOP 550 CTS/2016	ACL TOP 570/2024
List price/Model type	—/benchtop	—/benchtop	—/floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 39 × 32 in./244 lbs./8.67 sq. ft.	29 × 43 × 35 in./312 lbs./14 sq. ft.	29 × 50 × 32 in./326 lbs./11.11 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	—	737/3,400 (available in most countries)	—
Composition of installs: Hospital lab/Reference lab/Other	—	85%/12%/3% (pharmaceutical or medical device labs)	—
Targeted daily, monthly, annual test volume	daily: 20–150; monthly: 600–4,500; annual: 36,000–54,000	daily: 100–200; monthly: 3,000–6,000; annual: 36,000–72,000	daily: 100–200; monthly: 3,000–6,000; annual: 36,000–72,000
Operational type	random access	random access	random access
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Company manufactures instrument	yes	yes	yes
FDA-approved clotting-based tests	PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C	PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C	PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C
FDA-approved chromogenic tests	anti-Xa, apixaban, rivaroxaban, protein C, antithrombin, plasminogen, plasmin inhibitor, chromogenic factor IX	anti-Xa, apixaban, protein C, antithrombin, plasminogen, plasmin inhibitor	anti-Xa, apixaban, rivaroxaban, protein C, antithrombin, plasminogen, plasmin inhibitor, chromogenic factor IX
FDA-approved immunologic tests	high specificity D-dimer, standard D-dimer, heparin-induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine	high specificity D-dimer, standard D-dimer, heparin-induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine	high specificity D-dimer, standard D-dimer, heparin-induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	chromogenic factor VIII	DOAC assays, chromogenic factor VIII	chromogenic factor VIII
Tests in development or awaiting FDA 510(k) clearance	von Willebrand factor ristocetin cofactor, dabigatran, chromogenic factor VIII	von Willebrand factor ristocetin cofactor, dabigatran, rivaroxaban, apixaban	von Willebrand factor ristocetin cofactor, dabigatran, chromogenic factor VIII
Methodologies supported	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)
Number of different measured assays onboard simultaneously	18	30	24
Number of different assays programmed and calib. at one time	500	500	500
No. of user-definable (open) channels/No. active simultaneously	250/250	250/250	250/250
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	110 (1 test in throughput)/3–6 min. (avg. 4 min.)	240 (1 test in throughput)/3–6 min. (avg. 4 min.)	240 (1 test in throughput)/3–6 min. (avg. 4 min.)
Design of sample-handling system	samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification	samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification	samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Reagent type	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	yes, for all tests	yes, for all tests	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	26/variable (reagent specific)	40/variable (reagent specific)	40/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/yes (15°C)	yes/yes/yes	yes/yes/yes (15°C)
Reagents, consumables loaded without interrupting testing	yes (reagents and consumables)	yes (reagents and consumables)	yes (reagents and consumables)
Instrument uses proprietary or third-party reagents	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)
Maximum time same lot number of reagents can be used	—	—	—
Walkaway capability/Walkaway duration	yes/40 specimens or 800 tests	yes/80 specimens or 800 tests	yes/80 specimens or 800 tests
Min.–max. specimen volume that can be aspirated at one time	2–250 µL	2–250 µL	2–250 µL
Min. sample volume required for PT/PTT/Factor VIII activity	50 µL/50 µL/50 µL	50 µL/50 µL/50 µL	50 µL/50 µL/50 µL
Types of disposables used	cuvettes, clean A/B, rinse	cuvettes, clean A/B, rinse	cuvettes, clean A/B, rinse
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/yes	yes/yes
Accommodates most standard tube sizes/Nonstandard sizes	yes/yes (16 × 100 mm)	yes/yes	yes/yes (16 × 100 mm)
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes
Auto tracks product volume/Measures number of tests remaining	yes/yes	yes/yes	yes/yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	yes	yes	yes
Auto detects adequate reagents for aspiration or analysis	yes (aspiration and analysis)	yes (aspiration and analysis)	yes (aspiration and analysis)
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia
Dilutes patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	yes/yes
Lag time during which hypercoagulable sample not detected	no	no	no
User can adjust reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
User can adjust No. of reagents/Sources of reagents	yes/yes	yes/yes	yes/yes
User can adjust incubation times/Reading times	yes/yes	yes/yes	yes/yes
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	yes/yes	no/no	yes/yes
Multipoint calibration supported/Recommended frequency	yes/per lab's quality management system rules	yes/per lab's quality management system rules	yes/per lab's quality management system rules
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/110 specimens	<3 minutes/240 specimens	<3 minutes/240 specimens
• PT, PTT	<6 minutes/55 specimens	<6 minutes/90 specimens	<6 minutes/90 specimens
• Fibrinogen	<3 minutes/60 specimens	<3 minutes/78 specimens	<3 minutes/78 specimens
• Factor VIII activity assay	8 minutes/38 specimens	8 minutes/77 specimens	8 minutes/77 specimens
• D-dimer	5 minutes/55 specimens	5 minutes/75 specimens	5 minutes/75 specimens
Time delay from ordering stat to aspiration of sample	none	none	none
How labs get LOINC codes for results	website, package insert, email query	functionality not provided	website, package insert, email query
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Information that can be barcode-scanned on instrument	specimen identifier, reagent lot No., assigned values, International Sensitivity Index	specimen identifier, reagent lot No., International Sensitivity Index	specimen identifier, reagent lot No., assigned values, International Sensitivity Index
Compatible with laboratory automation systems	no	no	no
Data-management capability/LIS or EHR systems interfaced	onboard, optional add-on (HemoHub Intelligent Data Manager)/ Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Clinisys, Vista	onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Clinisys, Vista	onboard, optional add-on (HemoHub Intelligent Data Manager)/ Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Clinisys, Vista
Interface supplied by instrument vendor	contract dependent	contract dependent	contract dependent
Results transferred to LIS as soon as test time complete	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Remote servicing provided/UPS backup power supply	yes/yes	yes/yes	yes/yes
Instrument connections to transfer information	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman Coulter)	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman Coulter)	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman Coulter)
Interface standards supported	ASTM 1394-91	ASTM 1394-91	ASTM 1394-91
Information transferred to data-management software	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, reagent traceability, calibrators and control traceability	specimen ID	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, reagent traceability, calibrators and control traceability
Avg. time for basic user training	9 days (5 days at customer site, 4 days at vendor office)	14 days (10 days at customer site, 4 days at vendor office)	9 days (5 days at customer site, 4 days at vendor office)
Approximate scheduled maintenance time	daily: <5 minutes; weekly: <10 minutes	daily: 5 minutes; weekly: 10 minutes	daily: 5 minutes; weekly: 10 minutes
Maintenance records kept onboard	yes	yes	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	FDA 510(k) approved; improves patient care, lab efficiencies, and costs; liquid format for PT/APTT; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); offers performance verification studies, supporting accreditation requirements	FDA 510(k) approved; improves patient care, lab efficiencies, and costs; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); liquid format for PT/APTT (10-day onboard stability), high specificity D-dimer, on-demand HIT testing	FDA 510(k) approved; improves patient care, lab efficiencies, and costs; liquid format for PT/APTT; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); offers performance verification studies, supporting accreditation requirements

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

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Part 8 of 8	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com	**Werfen** **Annie Lopatin** alopatin@werfen.com **Bedford, MA** **800-955-9525** www.werfen.com
Instrument name/First year sold	ACL TOP 750 Series/2016	ACL TOP 770/770s/2024	ACL TOP 770 LAS/2024
List price/Model type	—/floor standing	—/floor standing	—/floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 60 × 35 in./356 lbs./21 sq. ft.	29 × 65 × 31 in./388 lbs./13.99 sq. ft.	64 × 76 × 31 in./400 lbs./16.36 sq. ft.
No. of units in clinical use in U.S./Outside U.S.	737/3,200 (available in most countries)	—	—
Composition of installs: Hospital lab/Reference lab/Other	85%/12%/3% (pharmaceutical or medical device labs)	—	—
Targeted daily, monthly, annual test volume	daily: 200–400; monthly: 6,000–12,000; annual: 72,000–144,000	daily: 200–400; monthly: 6,000–12,000; annual: 72,000–144,000	daily: 200–400; monthly: 6,000–12,000; annual: 72,000–144,000
Operational type	random access	random access	random access
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Company manufactures instrument	yes	yes	yes
FDA-approved clotting-based tests	PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C	PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C	PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C
FDA-approved chromogenic tests	anti-Xa, apixaban, protein C, antithrombin, plasminogen, plasmin inhibitor	anti-Xa, apixaban, rivaroxaban, protein C, antithrombin, plasminogen, plasmin inhibitor, chromogenic factor IX	anti-Xa, apixaban, rivaroxaban, protein C, antithrombin, plasminogen, plasmin inhibitor, chromogenic factor IX
FDA-approved immunologic tests	high specificity D-dimer, standard D-dimer, heparin-induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine	high specificity D-dimer, standard D-dimer, heparin-induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine	high specificity D-dimer, standard D-dimer, heparin-induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	DOAC assays, chromogenic factor VIII	chromogenic factor VIII	chromogenic factor VIII
Tests in development or awaiting FDA 510(k) clearance	von Willebrand factor ristocetin cofactor, dabigatran, rivaroxaban, apixaban	von Willebrand factor ristocetin cofactor, dabigatran, chromogenic factor VIII	von Willebrand factor ristocetin cofactor, dabigatran, chromogenic factor VIII
Methodologies supported	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)
Number of different measured assays onboard simultaneously	30	36	36
Number of different assays programmed and calib. at one time	500	500	500
No. of user-definable (open) channels/No. active simultaneously	250/250	250/250	250/250
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	360 (1 test in throughput)/3–6 min. (avg. 4 min.)	360 (1 test in throughput)/3–6 min. (avg. 4 min.)	220 (1 test in throughput)/dependent on laboratory automation system track manufacturer
Design of sample-handling system	samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification	samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification	samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Reagent type	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])	self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually])
Reagent barcode-reading capability	yes, for all tests	yes, for all tests	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	60/variable (reagent specific)	60/variable (reagent specific)	60/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/yes	yes/yes/yes (15°C)	yes/yes/yes (15°C)
Reagents, consumables loaded without interrupting testing	yes (reagents and consumables)	yes (reagents and consumables)	yes (reagents and consumables)
Instrument uses proprietary or third-party reagents	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)	user's option (same capabilities when third-party reagents used)
Maximum time same lot number of reagents can be used	—	—	—
Walkaway capability/Walkaway duration	yes/120 specimens or 800 tests	yes/120 specimens or 800 tests	yes/90 specimens or 800 tests
Min.–max. specimen volume that can be aspirated at one time	2–250 µL	2–250 µL	2–250 µL
Min. sample volume required for PT/PTT/Factor VIII activity	50 µL/50 µL/50 µL	50 µL/50 µL/50 µL	50 µL/50 µL/50 µL
Types of disposables used	cuvettes, clean A/B, rinse	cuvettes, clean A/B, rinse	cuvettes, clean A/B, rinse
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/yes	yes/yes
Accommodates most standard tube sizes/Nonstandard sizes	yes/yes	yes/yes (16 × 100 mm)	yes/yes (16 × 100 mm)
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes
Auto tracks product volume/Measures number of tests remaining	yes/yes	yes/yes	yes/yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	yes	yes	yes
Auto detects adequate reagents for aspiration or analysis	yes (aspiration and analysis)	yes (aspiration and analysis)	yes (aspiration and analysis)
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia	detection and quantitation for hemolysis, turbidity, icterus, lipemia
Dilutes patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	yes/yes
Lag time during which hypercoagulable sample not detected	no	no	no
User can adjust reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
User can adjust No. of reagents/Sources of reagents	yes/yes	yes/yes	yes/yes
User can adjust incubation times/Reading times	yes/yes	yes/yes	yes/yes
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	no/no	yes/yes	yes/yes
Multipoint calibration supported/Recommended frequency	yes/per lab's quality management system rules	yes/per lab's quality management system rules	yes/per lab's quality management system rules
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/360 specimens	<3 minutes/360 specimens	<3 minutes/360 specimens
• PT, PTT	<6 minutes/165 specimens	<6 minutes/165 specimens	<6 minutes/165 specimens
• Fibrinogen	<3 minutes/108 specimens	<3 minutes/108 specimens	<3 minutes/108 specimens
• Factor VIII activity assay	8 minutes/100 specimens	8 minutes/100 specimens	8 minutes/100 specimens
• D-dimer	5 minutes/100 specimens	5 minutes/100 specimens	5 minutes/100 specimens
Time delay from ordering stat to aspiration of sample	none	none	none
How labs get LOINC codes for results	functionality not provided	website, package insert, email query	website, package insert, email query
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	yes/yes
Information that can be barcode-scanned on instrument	specimen identifier, reagent lot No., International Sensitivity Index	specimen identifier, reagent lot No., assigned values, International Sensitivity Index	specimen identifier, reagent lot No., assigned values, International Sensitivity Index
Compatible with laboratory automation systems	yes (Werfen, Beckman, Siemens, Abbott, Thermo Fisher, others)	no	yes (Werfen, Beckman, Siemens, Abbott, Thermo Fisher, others)
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Clinisys, Vista	onboard, optional add-on (HemoHub Intelligent Data Manager)/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, others	onboard, optional add-on (HemoHub Intelligent Data Manager)/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, others
Interface supplied by instrument vendor	contract dependent	contract dependent	contract dependent
Results transferred to LIS as soon as test time complete	yes	yes	yes
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (broadcast download and host query)
Remote servicing provided/UPS backup power supply	yes/yes	yes/yes	yes/yes
Instrument connections to transfer information	data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system; commercial middleware (Beckman Coulter)	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman Coulter)	data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system; commercial middleware (Beckman Coulter)
Interface standards supported	ASTM 1394-91	ASTM 1394-91	ASTM 1394-91
Information transferred to data-management software	specimen ID	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, reagent traceability, calibrators and control traceability	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, reagent traceability, calibrators and control traceability
Avg. time for basic user training	14 days (10 days at customer site, 4 days at vendor office)	14 days (10 days at customer site, 4 days at vendor office)	14 days (10 days at customer site, 4 days at vendor office)
Approximate scheduled maintenance time	daily: <5 minutes; weekly: <10 minutes	daily: 5 minutes; weekly: 10 minutes	daily: 5 minutes; weekly: 10 minutes
Maintenance records kept onboard	yes	yes	yes
Warranty with purchase/Annual service contract cost (24/7)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	FDA 510(k) approved; improves patient care, lab efficiencies, and costs; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); liquid format for PT/APTT (10-day onboard stability), high specificity D-dimer, on-demand HIT testing	FDA 510(k) approved; improves patient care, lab efficiencies, and costs; liquid format for PT/APTT; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); offers performance verification studies, supporting accreditation requirements	FDA 510(k) approved; improves patient care, lab efficiencies, and costs; liquid format for PT/APTT; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); offers performance verification studies, supporting accreditation requirements
Note: a dash in lieu of an answer means company did not answer question or question is not applicable			

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