Part 1 of 6

See **captodayonline.com/productguides** for an interactive version of guide

	Bio/Data Corp. **Robert F. Wheaton III** rob.wheaton@biodatacorp.com **Horsham, PA** **215-441-4000** or **800-257-3282** www.biodatacorp.com	**Chrono-log Corp.** **Kathy Jacobs** jacobs@chronolog.com **Havertown, PA** **610-853-1130** or **800-247-6665** www.chronolog.com	**Chrono-log Corp.** **Kathy Jacobs** jacobs@chronolog.com **Havertown, PA** **610-853-1130** or **800-247-6665** www.chronolog.com
Instrument name/First year sold	Platelet Aggregation Profiler PAP-8E/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	$21,990/benchtop	$10,192–$24,575/benchtop	$19,587–$37,645/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. (countries)	>500/>300 (Canada, Chile, EU, Middle East, India)	—	—
Composition of installs: Hospital lab/Reference lab/Other	85%/10%/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	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 assay agglutination, HIT/HIPA, RIPA; others	platelet agglutination with ristocetin	platelet agglutination with ristocetin
Other FDA-approved tests	platelet activation: spontaneous platelet aggregation, sticky platelet syndrome; platelet aggregation: PRP, PPP, PFP, 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	— (99 active)	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	ristocetin cofactor assay, RIPA, agglutination; open system for other Ab-Ag tests; turbidimetric, immunologic (agglutination)	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	99	4–8	2–4
Number of different assays programmed and calib. at one time	99	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	6 (up to 8 tests in throughput)/up to 8 hours	6 (24–48 tests in throughput)/5 min. minimum	6 (12–24 tests in throughput)/6 min. minimum
Design of sample-handling system	manual load	manual	manual
Operates on whole blood or spun plasma	spun plasma	spun plasma	whole blood and 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	no	no
No. of reagent containers held onboard/Reagents ready to use	2, with inserts for various sizes/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	no	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 9 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	25 µL minimum	250–500 µL	225–500 µL
Min. sample volume required for PT/PTT/Factor VIII activity	—	—	—
Types of disposables used	siliconized micro test tubes, plastic coated stir bars, pipette tips, MagnaTubes	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	yes (UPC)/—	no/no	no/no
Auto tracks product volume/Measures number of tests remaining	no/no	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 and quantitation 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	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	yes/yes	yes/no	yes/no
Multipoint calibration supported/Recommended frequency	yes/variable	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	website, email query	email query	email query
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/no	yes/no
Information that can be barcode-scanned on instrument	—	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	yes	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	1–1.5 days (at customer site or at vendor office on request)	—	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/$2,050 (cost dependent on contract)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company)	8 independently operated channels; patented electro-optical circuitry sensitive to microaggregates and compromised sample detection; up to 9 reported test results per channel	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

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

COAGULATION ANALYZERS

Part 2 of 6 See **captodayonline.com/productguides** for an interactive version of guide	**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** **John G. Chromczak** john.chromczak@us.stago.com **Parsippany, NJ** **800-222-2624** www.stago-us.com
Instrument name/First year sold	STA Compact Max/2013	STA Satellite/2010	STA-R Max/2015
List price/Model type	$150,000/benchtop	$58,935/benchtop	$241,000/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. (countries)	~1,600/~3,500 (France, Spain, UK, Germany, Denmark, others)	~700/~1,600 (France, Spain, UK, Germany, Denmark, others)	297/900 (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, alpha-2-antiplasmin, plasminogen, FVIII chromogenic	anti-FXa (UFH and LMWH), antithrombin	anti-FXa (UFH and LMWH), antithrombin, protein C, alpha-2-antiplasmin, 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	—	—	—
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	STA NeoPTimal protime reagent with ISI ~1.0, vWF:risto	—	STA NeoPTimal protime reagent with ISI ~1.0, vWF:risto
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.)	200 (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)	70/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	—	—	—
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/~262 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, LOINC codes available in STA Coag Expert	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 (Abbott, Beckman Coulter, Cerner, Inpeco, Ortho, Roche, Siemens)
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, Meditech, Sunquest, SCC, McKesson, Epic contract dependent	onboard/Cerner, Meditech, Sunquest, SCC, McKesson, Epic contract dependent	onboard/Cerner, Meditech, Sunquest, SCC, McKesson, Epic contract dependent
Interface supplied by instrument vendor	yes	yes	yes
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	no/yes	no/yes	no/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	weekly: <15 minutes; monthly: <15 minutes	weekly: <15 minutes; monthly: <15 minutes	weekly: <15 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/— (cost dependent on contract)	yes/— (cost dependent on contract)
Distinguishing features (supplied by company) *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, full complement of lupus anticoagulant testing; STA Coag Expert data manager delivers full autoverification, repeat/reflex testing, auto upload of QC to peer group	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 data manager delivers full autoverification, repeat/reflex testing, auto upload of QC to peer group

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

COAGULATION ANALYZERS

Part 3 of 6 See **captodayonline.com/productguides** for an interactive version of guide	**Diagnostica Stago** **John G. Chromczak** john.chromczak@us.stago.com **Parsippany, NJ** **800-222-2624** www.stago-us.com	**Instrumentation Laboratory** **V. Shirley** vshirley@ilww.com **Bedford, MA** **781-674-3221** www.ilus.com	**Instrumentation Laboratory** **V. Shirley** vshirley@ilww.com **Bedford, MA** **781-674-3221** www.ilus.com
Instrument name/First year sold	STart Hemostasis Analyzer/1998	ACL AcuStar/2010	ACL TOP 350/300 CTS/2012
List price/Model type	$13,079/benchtop	—/benchtop	—/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	4.7 × 16.1 × 16.5 in./12.5 lbs./1.8 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. (countries)	~850/~9,000 (France, Spain, UK, Germany, Denmark others)	5/196 (available in most countries)	1,309/3,700 (available in most countries)
Composition of installs: Hospital lab/Reference lab/Other	90%/~1%/9% (veterinary labs, pharmaceutical companies, academic research/educational labs)	100%/0/0	95%/5%/—
Targeted daily, monthly, annual test volume	daily: <20; monthly: <500; annual: <5,000	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	batch	random access	random access
Country where analyzer designed/Manufactured	France/France	U.S./U.S.	U.S./U.S.
Company manufactures instrument	yes	no	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, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C
FDA-approved chromogenic tests	—	—	anti-Xa, protein C, antithrombin, plasminogen, plasmin inhibitor
FDA-approved immunologic tests	—	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	—	—	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	mechanical clot detection, chromogenic, immunologic (micro-latex)	immunologic (chemiluminescent)	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)
Number of different measured assays onboard simultaneously	1	20	30
Number of different assays programmed and calib. at one time	20	20	500
No. of user-definable (open) channels/No. active simultaneously	4/1	0/0	250/250
Factor assays require manual manipulation or dilutions	yes (manual manipulation and dilutions)	—	—
Test throughput per hour/Assay run time	1–15 (1 test in throughput)/6–10 min. (avg. 6 min.)	60 (1 test in throughput)/30 min.	110 (1 test in throughput)/3–6 min. (avg. 4 min.)
Design of sample-handling system	semiautomated system where user manually pipettes patient sample and reagents into testing cuvette	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	no	yes, for all tests	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	—	20/yes	24/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	no/no/no	yes/yes/yes	yes/yes/yes
Reagents, consumables loaded without interrupting testing	—	yes (reagents and consumables)	yes (reagents and consumables)
Instrument uses proprietary or third-party reagents	user's option	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	18 months
Walkaway capability/Walkaway duration	no	yes/30 specimens or 280 tests	yes/40 specimens or 800 tests
Min.–max. specimen volume that can be aspirated at one time	5–100 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, stir bars, balls	cuvettes, trigger, solutions	cuvettes, clean A/B, rinse
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/no	yes/yes
Sample barcode-reading capability/Autodiscrimination	no/no	yes/yes	yes (Interleaved 2 of 5, Code 39, Code 128)/yes
Auto tracks product volume/Measures number of tests remaining	no/no	yes/yes	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	—	—	detection and quantitation for hemolysis, turbidity, icterus, lipemia
Dilutes patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/yes	yes/yes
Lag time during which hypercoagulable sample not detected	no	—	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	no/no	no/no	no/no
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/10–15 tests	—	<3 minutes/110 specimens
• PT, PTT	—	—	<6 minutes/55 specimens
• Fibrinogen	<6 minutes/5–10 tests	—	<3 minutes/60 specimens
• Factor VIII activity assay	<6 minutes/2–3 tests	—	8 minutes/38 specimens
• D-dimer	—	—	5 minutes/55 specimens
Time delay from ordering stat to aspiration of sample	—	<1 minute	none
How labs get LOINC codes for results	email query	functionality not provided	functionality not provided
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.	specimen identifier, reagent lot No.
Compatible with laboratory automation systems	no	no	no
Data-management capability/LIS or EHR systems interfaced	no/—	onboard/Meditech	onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Sunquest, Vista
Interface supplied by instrument vendor	no	contract dependent	contract dependent
Results transferred to LIS as soon as test time complete	yes	yes	yes
Bidirectional interface capability	yes (broadcast download)	yes (broadcast download and host query)	yes (broadcast download and host query)
Remote servicing provided/UPS backup power supply	no/no	no/yes	yes/yes
Instrument connections to transfer information	directly to LIS	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (IL, Beckman)	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman)
Interface standards supported	—	ASTM 1394-91	ASTM 1394-91
Information transferred to data-management software	device unique identifier, specimen ID, result	specimen ID	specimen ID
Avg. time for basic user training	1 day (at customer site)	4 days (at customer site)	9 days (5 days at customer site, 4 days at vendor office)
Approximate scheduled maintenance time	weekly: <5 minutes; monthly: <5 minutes	daily: 5 minutes; weekly: 5 minutes	daily: <5 minutes; weekly: <10 minutes
Maintenance records kept onboard	no	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)	viscosity-based, mechanical clot detection; unique ball dipsenser and pipette included; small footprint ideal as an alternate methodology for photo-optical systems	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); best-in-class reagents; 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

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

COAGULATION ANALYZERS

Part 4 of 6 See **captodayonline.com/productguides** for an interactive version of guide	**Instrumentation Laboratory** **V. Shirley** vshirley@ilww.com **Bedford, MA** **781-674-3221** www.ilus.com	**Instrumentation Laboratory** **V. Shirley** vshirley@ilww.com **Bedford, MA** **781-674-3221** www.ilus.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	ACL TOP 550 CTS/2016	ACL TOP 750 Series/2016	CoaDATA 2004 and 4004/—
List price/Model type	—/benchtop	—/floor standing	—/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 43 × 35 in./312 lbs./14 sq. ft.	29 × 60 × 35 in./356 lbs./21 sq. ft.	10 × 13 × 3.5 in./8.6 lbs./0.92 sq. ft.
No. of units in clinical use in U.S./Outside U.S. (countries)	737/3,400 (available in most countries)	737/3,200 (available in most countries)	—/>1,500 (worldwide [except U.S., Canada])
Composition of installs: Hospital lab/Reference lab/Other	85%/12%/3% (pharmaceutical or medical device labs)	85%/12%/3% (pharmaceutical or medical device labs)	—
Targeted daily, monthly, annual test volume	daily: 100–200; monthly: 3,000–6,000; annual: 36,000–72,000	daily: 200–400; monthly: 6,000–12,000; annual: 72,000–144,000	—
Operational type	random access	random access	batch
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	Germany/Germany
Company manufactures instrument	yes	yes	yes (also sold via OEM distribution, local distributors)
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	—
FDA-approved chromogenic tests	anti-Xa, protein C, antithrombin, plasminogen, plasmin inhibitor	anti-Xa, protein C, antithrombin, plasminogen, plasmin inhibitor	—
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	—
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	DOAC assays, chromogenic factor VIII	DOAC assays, 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, rivaroxaban, apixaban	—
Methodologies supported	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)	clot detection, optical; chromogenic; immunologic (immunoturbidimetric)	clot detection, mechanical and optical; photometric with mechanical stirring, turbodensitometric; chromogenic; immunologic (photometric)
Number of different measured assays onboard simultaneously	30	30	15
Number of different assays programmed and calib. at one time	500	500	15
No. of user-definable (open) channels/No. active simultaneously	250/250	250/250	—
Factor assays require manual manipulation or dilutions	—	—	yes (manual manipulation and dilutions)
Test throughput per hour/Assay run time	240 (1 test in throughput)/3–6 min. (avg. 4 min.)	360 (1 test in throughput)/3–6 min. (avg. 4 min.)	CoaDATA 2004: ~60 PT tests (1 test in throughput); CoaDATA 4004: ~120 PT tests (1 test in throughput)/—
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	semiautomated analyzer with 2 and 4 channels
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 single-use 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	40/variable (reagent specific)	60/variable (reagent specific)	4/variable (reagent specific)
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/yes	yes/yes/yes	yes/—/no
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
Maximum time same lot number of reagents can be used	18 months	18 months	—
Walkaway capability/Walkaway duration	yes/80 specimens or 800 tests	yes/120 specimens or 800 tests	no/—
Min.–max. specimen volume that can be aspirated at one time	2–250 µL	2–250 µL	50–150 µL (total volume)
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/reagent dependent
Types of disposables used	cuvettes, clean A/B, rinse	cuvettes, clean A/B, rinse	cuvettes, pipette tips, stir bars
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/yes	—/no
Accommodates most standard tube sizes/Nonstandard sizes	yes/yes	yes/yes	no/no
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/no
Auto tracks product volume/Measures number of tests remaining	yes/yes	yes/yes	no/no
Short sample detection	yes	yes	no
Clot detection as preanalytical variable in plasma sample	yes	yes	no
Auto detects adequate reagents for aspiration or analysis	yes (aspiration and analysis)	yes (aspiration and analysis)	no
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 for hemolysis, turbidity, icterus, lipemia
Dilutes patient samples onboard	yes	yes	no
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	no/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	no/no
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)	no
Autocalibration/Calibrants stored onboard	no/no	no/no	no/no
Multipoint calibration supported/Recommended frequency	yes/6 months	yes/6 months	yes/—
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/240 specimens	<3 minutes/360 specimens	—
• PT, PTT	<6 minutes/90 specimens	<6 minutes/165 specimens	—
• Fibrinogen	<3 minutes/78 specimens	<3 minutes/108 specimens	—
• Factor VIII activity assay	8 minutes/77 specimens	8 minutes/100 specimens	—
• D-dimer	5 minutes/75 specimens	5 minutes/100 specimens	—
Time delay from ordering stat to aspiration of sample	none	none	—
How labs get LOINC codes for results	functionality not provided	functionality not provided	functionality not provided
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	no/no
Information that can be barcode-scanned on instrument	specimen identifier, reagent lot No.	specimen identifier, reagent lot No.	specimen identifier, reagent lot No.
Compatible with laboratory automation systems	no	yes (HemoCell, Beckman, Siemens, Abbott, Thermo Fisher, others)	no
Data-management capability/LIS or EHR systems interfaced	onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Sunquest, Vista	onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Sunquest, Vista	no/—
Interface supplied by instrument vendor	contract dependent	contract dependent	yes (included in analyzer price)
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)	no
Remote servicing provided/UPS backup power supply	yes/yes	yes/yes	no/no
Instrument connections to transfer information	data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman)	data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system; commercial middleware (Beckman)	directly to LIS; directly to EHR
Interface standards supported	ASTM 1394-91	ASTM 1394-91	—
Information transferred to data-management software	specimen ID	specimen ID	patient ID, result
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)	1 day (at vendor office, on request)
Approximate scheduled maintenance time	daily: <5 minutes; weekly: <10 minutes	daily: <5 minutes; weekly: <10 minutes	per shift: <1 minute; daily: <1 minute; weekly: <1 minute; monthly: <3 minutes
Maintenance records kept onboard	yes	yes	no
Warranty with purchase/Annual service contract cost (24/7)	yes/— (cost dependent on contract)	yes/— (cost dependent on contract)	yes/—
Distinguishing features (supplied by company) *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	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; 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	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)

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

Part 5 of 6 See **captodayonline.com/productguides** for an interactive version of guide	**LABiTec LAbor BioMedical Technologies GmbH** **M. Schramm** info@labitec.de **Ahrensburg, Germany** **011-49-4102-47950** www.labitec.com	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com
Instrument name/First year sold	CoaLAB 1000/—	BCS XP Analyzer/2006	BFT II Analyzer/1999
List price/Model type	—/benchtop	$171,000/benchtop	$8,500/benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	19.6 × 30.7 × 23.6 in./70.5 lbs./5 sq. ft.	37 × 49 × 25 in./330 lbs./8.5 sq. ft.	3.9 × 7.9 × 11.8 in./8.4 lbs./0.65 sq. ft.
No. of units in clinical use in U.S./Outside U.S. (countries)	—/— (worldwide [except U.S., Canada])	>350/>1,000 (worldwide)	—/— (worldwide)
Composition of installs: Hospital lab/Reference lab/Other	—	—	—
Targeted daily, monthly, annual test volume	daily: 100–400; monthly: 2,000–8,000; annual: 24,000–95,000	daily: >300	daily: 1
Operational type	batch, random access	continuous random access	batch
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Company manufactures instrument	yes (also sold via OEM distribution, local distributors)	yes	yes
FDA-approved clotting-based tests	—	PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI, XII, protein C, protein S, lupus, factor V Leiden, TT, batroxobin time	PT, APTT, fibrinogen
FDA-approved chromogenic tests	—	antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin	—
FDA-approved immunologic tests	—	Innovance D-dimer, von Willebrand factor-ristocetin cofactor assay	—
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests in development or awaiting FDA 510(k) clearance	—	—	—
Methodologies supported	clot detection, mechanical and optical; photometric with mechanical stirring, turbodensitometric; chromogenic; immunologic (photometric)	clot detection, optical; chromogenic; immunologic	clot detection, mechanical and optical
Number of different measured assays onboard simultaneously	15	>100	1
Number of different assays programmed and calib. at one time	50	99	3
No. of user-definable (open) channels/No. active simultaneously	50/15	7,999/>100	—
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	120 PT tests/—	380 (1 test in throughput)/1–3 min. (avg. 5 min.)	—/5 min.
Design of sample-handling system	cuvette ring, sample cups	continuous loading uncapped primary sample tubes and cups in same rack; 10-tube position sample rack	manual
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 some tests	yes, for all tests	no
No. of reagent containers held onboard/Reagents ready to use	15/yes	90/yes	4/yes
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/no	yes/yes/yes (15°C ± 2°C)	no/no/no
Reagents, consumables loaded without interrupting testing	yes (reagents)	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)	yes (proprietary reagents, third-party reagents, user's option)
Maximum time same lot number of reagents can be used	—	1 year	1 year
Walkaway capability/Walkaway duration	yes/22 samples plus 3 stat (reagent dependent)	yes/100 specimens or up to 400 tests	no
Min.–max. specimen volume that can be aspirated at one time	2–275 µL	3 µL minimum	—
Min. sample volume required for PT/PTT/Factor VIII activity	50 µL/50 µL/assay dependent	50 µL/50 µL/5 µL (standard)	50 µL/50 µL/—
Types of disposables used	—	rotors and wash solution	cuvettes
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/no	no/no
Accommodates most standard tube sizes/Nonstandard sizes	yes/no	yes/yes	no/no
Sample barcode-reading capability/Autodiscrimination	yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no	yes/—	no/—
Auto tracks product volume/Measures number of tests remaining	yes/yes	yes/yes	no/no
Short sample detection	yes	yes	no
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)	no
Detection or quantitation for hemolysis, turbidity, icterus, lipemia	no	no	no
Dilutes patient samples onboard	yes	yes	no
Automatic rerun capability/Auto reflex testing capability	yes/no	yes/yes	no/no
Lag time during which hypercoagulable sample not detected	no	yes (PT and PTT: 7 seconds)	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	yes
Autocalibration/Calibrants stored onboard	yes/yes	yes/yes	no/yes
Multipoint calibration supported/Recommended frequency	yes/with lot change	yes/6 months, per regulatory guidelines	yes/6 months, per regulatory guidelines
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<2 minutes/120 specimens	5 minutes/380 specimens	1 minute/1 specimen
• PT, PTT	<5 minutes/71 specimens	5 minutes/325 specimens	—
• Fibrinogen	<5 minutes/50 specimens	5 minutes/315 specimens	1 minute/1 specimen
• Factor VIII activity assay	<6 minutes/—	5 minutes/280 specimens	—
• D-dimer	<6 minutes/—	5 minutes/—	—
Time delay from ordering stat to aspiration of sample	3 minutes	1 minute	—
How labs get LOINC codes for results	functionality not provided	website	website
Onboard real-time QC/Onboard software capability to review QC	yes/yes	yes/yes	no/no
Information that can be barcode-scanned on instrument	specimen identifier	operator identifier, specimen identifier, reagent lot No.	—
Compatible with laboratory automation systems	no	no	no
Data-management capability/LIS or EHR systems interfaced	onboard/—	onboard/most major vendors	no/no
Interface supplied by instrument vendor	no	contract dependent	no
Results transferred to LIS as soon as test time complete	yes	yes	no
Bidirectional interface capability	yes (host query)	yes (host query)	no
Remote servicing provided/UPS backup power supply	no/no	no/yes	no/no
Instrument connections to transfer information	data-management system, which in turn connects to LIS; directly to LIS	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)	commercial middleware (most major companies)
Interface standards supported	LAN connection provides FTP result file transfer	ASTM 1394-91, ASTM 1381, HL7	—
Information transferred to data-management software	device unique identifier, patient ID, specimen ID, result	device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks	—
Avg. time for basic user training	3 days (at customer and vendor offices)	varies at customer site, 3 days at vendor office	Siemens PEPconnect online
Approximate scheduled maintenance time	per shift: 1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: 15 minutes	daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes	daily: 1 minute
Maintenance records kept onboard	yes	no	no
Warranty with purchase/Annual service contract cost (24/7)	yes/—	yes/— (cost dependent on contract)	yes/—
Distinguishing features (supplied by company) *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	easy-to-use, standalone device with small footprint; onboard user and service software, no external PC required; optimized for small to mid-sized labs	user-definable calibration curve expiration and prewarning alerts; user-definable barcode utility enables customizable reagent protocols; user-friendly Windows 7 software	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

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

COAGULATION ANALYZERS

Part 6 of 6 See **captodayonline.com/productguides** for an interactive version of guide	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **Tarrytown, NY** **914-631-8000** siemens-healthineers.us.com
Instrument name/First year sold	Sysmex CA-600 Series Systems/2012	Sysmex CS-2500 System/2016	Sysmex CS-5100 System/2016
List price/Model type	CA-620: $42,000; CA-660: $55,000/	$155,000/benchtop	$205,000/floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	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.	50.4 × 40.6 × 45.3 in./612.9 lbs./12.8 sq. ft.
No. of units in clinical use in U.S./Outside U.S. (countries)	>2,000/>5,000 (worldwide)	>500/>2,000 (worldwide)	>100/>1,000 (worldwide)
Composition of installs: Hospital lab/Reference lab/Other	—	—	—
Targeted daily, monthly, annual test volume	daily: <25	daily: 25–300	daily: >300
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)	no (manufactured by Sysmex)	no (manufactured by Sysmex)
FDA-approved clotting-based tests	PT, APTT, fibrinogen, factors VII, VIII, protein C, TT, batroxobin time	PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI, XII, protein C, lupus, factor V Leiden, TT, batroxobin time	PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI, XII, protein C, lupus, factor V Leiden, TT, batroxobin time
FDA-approved chromogenic tests	Sysmex CA-660 only: antithrombin, protein C, Innovance heparin	antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin	antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin
FDA-approved immunologic tests	Sysmex CA-660 only: Innovance D-dimer	Innovance D-dimer	Innovance D-dimer
Other FDA-approved tests	—	—	—
User-defined tests in clinical use	—	platelet aggregation	platelet aggregation
Tests in development or awaiting FDA 510(k) clearance	—	von Willebrand factor	von Willebrand factor
Methodologies supported	clot detection, optical; chromogenic; immunologic	clot detection, optical; chromogenic; immunologic	clot detection, optical; chromogenic; immunologic
Number of different measured assays onboard simultaneously	5	60	60
Number of different assays programmed and calib. at one time	7	60	60
No. of user-definable (open) channels/No. active simultaneously	7/5	80,000/60	80,000/60
Factor assays require manual manipulation or dilutions	—	—	—
Test throughput per hour/Assay run time	60 (1 test in throughput)/1–3 min. (avg. 5 min.)	180 (2 tests in throughput)/1–10 min. (avg. 5 min.)	400 (2 tests in throughput)/1–10 min. (avg. 5 min.)
Design of sample-handling system	10-tube position sample rack	continuous loading capped and uncapped primary sample tubes and cups in same rack; 10-tube position sample rack × 5	continuous loading capped and uncapped primary sample tubes and cups in same rack; 10-tube position sample rack × 10
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	yes, for all tests	yes, for all tests
No. of reagent containers held onboard/Reagents ready to use	11/yes	40/yes	40/yes
Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard	yes/yes/no (15°C ± 2°C)	yes/yes/yes (10°C ± 2°C)	yes/yes/yes (10°C ± 2°C)
Reagents, consumables loaded without interrupting testing	no	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	1 year	1 year	1 year
Walkaway capability/Walkaway duration	yes/10 specimens or up to 50 tests	yes/50 specimens or up to 500 tests	yes/100 specimens or up to 1,000 tests
Min.–max. specimen volume that can be aspirated at one time	5 µL minimum	5 µL minimum	5 µL minimum
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 tubes, CA clean I and II	reaction tubes, CA clean I and II	reaction tubes, CA clean I and II
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/yes	yes/yes
Accommodates most standard tube sizes/Nonstandard sizes	yes/yes	yes/yes	yes/yes
Sample barcode-reading capability/Autodiscrimination	yes/—	yes/—	yes/—
Auto tracks product volume/Measures number of tests remaining	yes/no	yes/yes	yes/yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	no	yes	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	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	no/no	yes/yes	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	yes (selectable on menus)	yes (selectable on menus)
Autocalibration/Calibrants stored onboard	no/yes	no/yes	no/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	7 minutes/60 specimens	5 minutes/180 specimens	5 minutes/400 specimens
• PT, PTT	8 minutes/24 specimens	5 minutes/90 specimens	5 minutes/200 specimens
• Fibrinogen	7 minutes/60 specimens	5 minutes/180 specimens	5 minutes/201 specimens
• Factor VIII activity assay	5 minutes/—	5 minutes/—	5 minutes/—
• D-dimer	6 minutes/12 specimens	5 minutes/90 specimens	5 minutes/202 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	specimen identifier, reagent lot No.	operator identifier, specimen identifier, reagent lot No.	operator identifier, specimen identifier, reagent lot No.
Compatible with laboratory automation systems	no	no	yes (Siemens Aptio Automation)
Data-management capability/LIS or EHR systems interfaced	onboard/most major vendors	onboard/most major vendors	onboard/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	no/no	yes/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; 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-1000 protocol	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, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks	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)	varies at customer site, 3 days at vendor office	varies at customer site, 3 days at vendor office
Approximate scheduled maintenance time	daily: 8 minutes	daily: 5 minutes; weekly: 1 minute; monthly: 1 minute	daily: 5 minutes; weekly: 1 minute; monthly: 1 minute
Maintenance records kept onboard	no	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)	maximizes counter space with compact footprint in low-volume labs; increases uptime and reduces service expenses; CA-620 system for routine clotting-based testing, CA-660 system for clotting, chromogenic, and immunologic testing	confidence: simultaneous multiwavelength detection and PSI technology designed to ensure high-quality first-run results; operational efficiency: user-friendly software on Windows 7 and tilted reagent vials for efficiency; consistency: for multisite patient monitoring, with sample result traceability for in-depth audit capabilities	confidence: simultaneous multiwavelength detection and PSI technology designed to ensure high-quality first-run results; operational efficiency: user-friendly software on Windows 7, tilted reagent vials for efficiency; consistency: 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			

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