Part 1 of 8

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	Bio/Data Corp. **Robert F. Wheaton III** rob.wheaton@biodatacorp.com **155 Gibraltar Rd., Horsham, PA 19044** **215-441-4000** or **800-257-3282** www.biodatacorp.com	**Chrono-log Corp.** **Kathy Jacobs** jacobs@chronolog.com **2 West Park Rd., Havertown, PA 19083** **610-853-1130** or **800-247-6665** www.chronolog.com	**Chrono-log Corp.** **Kathy Jacobs** jacobs@chronolog.com **2 West Park Rd., Havertown, PA 19083** **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
Number of units installed in U.S./Outside U.S.	401/267	—	160/205
Number of contracts signed between 1/1/17 and 11/15/17	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	batch, random access	batch, random access	batch, random access
Reagent type	open reagent system (liquid, lyophilized, reconstituted manually)	open reagent system (lyophilized, reconstituted manually)	open reagent system, assay kits, reference plasmas, controls (lyophilized, reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	whole blood, spun plasma
Sample handling system	electronic pipette with presets and memory	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	21.5 × 27.5 × 21.7 in/40 lbs/4 sq ft	for each 4-channel module: 8.5 × 14 × 15 in/19.3 lbs/1.5 sq ft	8.5 × 14.0 × 18.0 in/40 lbs/M700-2: 1.75 sq ft; M700-4: 3.5 sq ft
FDA-cleared clotting-based tests	—	—	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	ristocetin cofactor assay, RIPA, agglutination; open system for other AB-AG tests	—	—
Other FDA-cleared tests	platelet aggregation: PRP, PPP, PFP, WBC, washed platelets, platelet activation, spontaneous aggregation, veterinary applications	LTA aggregation, ristocetin cofactor assay	platelet-dense granule secretion, whole blood impedance aggregation, LTA aggregation, ristocetin cofactor assay
User-defined tests in clinical use	>99 active	LTA aggregation, ristocetin cofactor assay	platelet-dense granule secretion, whole blood impedance aggregation, LTA aggregation with all standard reagents, ristocetin cofactor assay
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	proprietary	—	—
Methodologies supported	turbidimetric	turbidimetric; LTA aggreg., ristocetin cofactor assay	turbidimetric, platelet dense granule secretion, whole blood impedance aggreg., LTA aggreg., ristocetin cofactor assay
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/—
Number of different measured assays onboard simultaneously	—	4–8	2–4
Number of different assays programmed and calib. at one time	—	4–8	4–8
Number of user-definable (open) channels	8	4–8	2–4
Of those defined, number active simultaneously	8	4–8	2–4
Factor assays require manual manipulation or dilutions	yes (von Willebrand factor)	—	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	2, with inserts for various sizes/varies/no	—/—/no	no/—/no
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when third-party reagent used	no	yes	no
Maximum time same lot number of reagents can be used	1 year, extended periods may be available for projects	12–30 months	12–30 months
Walkaway capacity: Number of specimens/Number of tests	8/9	4–8/4–8	2–4/4–8
Minimum sample volume aspirated precisely at one time	25 µL	250 µL	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	—	—	225 µL PRP-lumi aggregation 450 µL; 450 µL whole blood-lumi aggregation 450 µL/25 µL ristocetin cofactor 50 µL
Disposables used/Price of each	siliconized microtubes: 100 @ $36.25; plastic-coated microstir bars: 50 @ $21; pipette tips: 960 @ $48; MagneTubes: 50 @ $49	cuvettes: 144 @ $45; stir bars: 144 @ $35; pipette tips: $85, $67, and $73	cuvettes: 144 @ $34; stir bars: 144 @ $30; impedance probes: 25 @ $130; pipette tips: 1,000 @ $73, $55, and $60
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	no/no	no/no
Sample/Reagent barcode reading capability	yes/yes	no/no	no/no
Onboard test automatic inventory	no	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	no	no	no
Hemolysis/Turbidity detection-quantitation	no/no	no/—	no/no
Dilution of 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	—	—	—
Read time extended for prolonged clotting times	—	yes	yes
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incubation times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes	yes/—
Auto shutdown/Auto startup programmable	yes/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	—	—	—
• PT, PTT	—	—	—
• Fibrinogen	—	—	—
• Factor VIII activity assay	—	—	—
Time delay from ordering stat to aspiration of sample	—	—	—
Automatic transfer of QC results to LIS	no	no	no
Data-management capability	onboard (includes QC: L-J plots, Westgard multirules for low-volume tests)	onboard	onboard
Interface supplied by instrument vendor	—	yes	yes
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	no	no	no
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	email query	email query	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	weekly: 15 minutes; monthly: 30 minutes	30 minutes when optical calibration required	30 minutes when optical calibration required
Onboard maintenance records	no	yes	yes
Training provided with purchase	1.5 days on site; at vendor offices on special request	—	1.5 days on site
Approximate number of training hours needed per tech	4–6	—	8
List price	$21,990	M490 4+: $11,800; M490 4+4: $20,700	M700-2: $19,500; M700-4: $32,000
Annual service contract cost (24/7)/Warranty with purchase	$2,050 (during business hours)/2 yrs, includes in-lab PC service	M490 4+: $1,804; M490 4+4: $3,008 for 3 years/1 year	M700-2: $1,804; M700-4: $3,008 for 3 years/1 year
Distinguishing features (supplied by company)	patented electro-optical circuitry sensitive to microaggregates; 2-yr warranty on entire system, incl. 2-yr in-lab service and repair of PC so patient information never leaves; TeleCheck calibration verification service performed in lab with telephone guidance	continuously monitors temperature and stirring with warning messages; optical calibration by laboratory personnel; Windows-based software provides customized color-coding options	tests platelet aggregation; measures ATP release in 4 samples simultaneously using whole blood, PRP, washed, or gel-filtered platelets; continuously monitors temp. and stirring speed; optical calibration by lab personnel; dedicated software packages calculate amplitude, slope, lag time, and more

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

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Instrument name/First year sold	STA Compact Max/2013	STA Satellite/2010	STA-R Max/2015
Number of units installed in U.S./Outside U.S.	~800/~3,400	>500/1,250	~150/~1,200
Number of contracts signed between 1/1/17 and 11/15/17	—	—	—
Country where analyzer designed/Manufactured	France/France	France/France	France/France
Operational type	continuous random access	random access	continuous random access
Reagent type	open reagent system	open reagent system	open reagent system, complete line of routine and specialty assays
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	continuous load sample drawer	carousel	rack with continuous specimen access
Model type	benchtop	benchtop	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
FDA-cleared 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-cleared chromogenic tests	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin	heparin (UFH and LMWH), AT	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin
FDA-cleared immunologic tests	D-dimer, VWF, total and free protein S, AT antigen	D-dimer	D-dimer, VWF, total and free protein S, AT antigen
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	APCR, other clotting chromogenic and immunological tests with user-defined applications
Tests submitted for 510(k) clearance	NeoPTimal ISI ~1.0 rabbit brain extract PT reagent, apixaban calibrators and controls for use with STA Liquid Anti-Xa	—	NeoPTimal ISI ~1.0 rabbit brain extract PT reagent, apixaban calibrators and controls for use with STA Liquid Anti-Xa
Tests in development but not yet submitted	ristocetin cofactor assay	—	ristocetin cofactor assay
Methodologies supported	exclusive mechanical clot detection, chromogenic, immunologic	exclusive mechanical clot detection, chromogenic, immunologic	exclusive mechanical clot detection, chromogenic, immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	80	80	200
Number of different assays programmed and calib. at one time	80	80	200
Number of user-definable (open) channels	80	80	200
Of those defined, number active simultaneously	80	80	200
Factor assays require manual manipulation or dilutions	no	—	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	45/varies/yes (15°–19°C)	16/varies/yes (15°–19°C)	70/varies/yes (15°–19°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	consumables: yes; reagents: no	consumables: yes; reagents: no	consumables: yes; reagents: no
Same capabilities when third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	18 months	18 months	18 months
Walkaway capacity: Number of specimens/Number of tests	96/12	20/12 per specimen	215/32
Minimum sample volume aspirated precisely at one time	5 µL	5 µL	5 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/5 µL	50 µL/—	50 µL/5 µL
Disposables used/Price of each	cuvettes, cleaner solution/varies	cuvettes, cleaner solution/varies	cuvettes, cleaner solution/varies
Supports direct-from-track sampling	no	no	yes (Beckman Coulter, Siemens, Roche, Abbott, Ortho, Labotix, Inpeco)
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes/yes
Sample/Reagent barcode reading capability	yes/yes	yes/yes	yes/yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	no/yes	no/yes	no/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no (not necessary)/no (not necessary)	no (not necessary)/no (not necessary)	no/no (not necessary for mechanical detection technology)
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/no	yes/yes
Lag time during which hypercoagulable sample not detected	no	no	no
Read time extended for prolonged clotting times	yes	yes	yes (selectable on menus)
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incubation times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	no (not necessary)/no (not necessary)	no (not necessary)/no (not necessary)	no (not necessary)/no (not necessary)
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<6 minutes/~150 specimens	<6 minutes/~50 specimens	<6 minutes/~300 specimens
• PT, PTT	<6 minutes/~100 specimens	<6 minutes/~40 specimens	<6 minutes/~200 specimens
• Fibrinogen	<6 minutes/~100 specimens	<6 minutes/~40 specimens	<6 minutes/~180 specimens
• Factor VIII activity assay	<6 minutes/~50 specimens	—	<6 minutes/~180 specimens
Time delay from ordering stat to aspiration of sample	<15 seconds	<15 seconds	<15 seconds
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots, Westgard rules)	onboard (includes QC: L-J plots)	onboard (includes QC: L-J plots, Westgard rules)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	all major LIS vendors	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (broadcast download, host query)	yes (host query)	yes (broadcast download, host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	yes	no	yes
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	yes (Beckman Coulter, Siemens, Roche, Abbott, Ortho, Labotix, Inpeco)
Modem servicing	yes	no	yes
Time required for maintenance by lab personnel	weekly: <20 minutes; monthly: 30 minutes	weekly: <20 minutes; monthly: 30 minutes	weekly: <20 minutes; monthly: <30 minutes
Onboard maintenance records	yes	yes	yes
Training provided with purchase	3.5 days at Stago headquarters	2.5 days at Stago headquarters	3.5 days at Stago headquarters
Approximate number of training hours needed per tech	24	12	24
List price	$150,000	$55,000	$241,000
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—/1 year	—/1 year
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; integrated STA Coag Expert (enhanced software) delivers full autoverification, repeat/reflex testing, expert rules to simplify complex factor assays and LA tests, comprehensive patient/QC management; online, customizable Quality Control peer program; standardized with all STA analyzers	viscosity-based, mechanical clot detection; integrated STA Coag Expert (enhanced software) delivers full autoverification, repeat/reflex testing, expert rules to simplify complex factor assays and LA tests, comprehensive patient/QC management; online, customizable Quality Control peer program; standardized with all STA analyzers	viscosity-based, mechanical clot detection; integrated STA Coag Expert (enhanced software) delivers full autoverification, repeat/reflex testing, expert rules to simplify complex factor assays and LA tests, comprehensive patient/QC management; online, customizable Quality Control peer program; standardized with all STA analyzers

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	Diagnostica Stago **Paul Riley, PhD, MBA** paul.riley@us.stago.com **5 Century Drive, Parsippany, NJ 07054** **973-671-1200 ext. 4238** www.stago-us.com	**Diagnostica Stago** **Nichole Howard** nichole.howard@us.stago.com **5 Century Drive, Parsippany, NJ 07054** **800-222-2624** www.stago-us.com	**Helena Laboratories** **David Pearman** dpearman@helena.com **1530 Lindbergh Drive, Beaumont, TX 77704** **409-842-3714 ext. 265** www.helena.com
Instrument name/First year sold	Calibrated Automated Thrombogram/2006	STart Hemostasis Analyzer/1998	AggRAM/2005
Number of units installed in U.S./Outside U.S.	100/~200	>700/>9,000	100+/500+
Number of contracts signed between 1/1/17 and 11/15/17	—	—	8
Country where analyzer designed/Manufactured	Finland/China	France/France	U.S./U.S.
Operational type	batch, discrete	batch	batch, random access
Reagent type	self-contained single-use and multiuse cartridges, packages, slides; open reagent system (lyophilized, reconstituted manually)	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma, platelet rich plasma
Sample handling system	96-well plate pipetted manually, inserted into instrument where the last reagent is automatically dispensed	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	34 × 42 × 42 cm/30 lbs/2 sq ft	4.7 × 16.1 × 16.5 in/12.5 lbs/1.8 sq ft	6 × 10 × 17 in/15 lbs/—
FDA-cleared clotting-based tests	—	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVV (screen and confirm)	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	—	—	ristocetin cofactor and platelet aggregation
User-defined tests in clinical use	—	—	ristocetin cofactor, platelet aggregation (ADP, EPI, COL, ristocetin, arachidonic acid)
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	thrombin generation in platelet poor (PPP) and platelet rich plasma (PRP) samples	—	lumi, chromogenics, HIT
Methodologies supported	quartz-halogen, fluorescence-based detection of thrombin generation	exclusive mechanical clot detection	ristocetin cofactor, platelet aggregation
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	16	1	4–8
Number of different assays programmed and calib. at one time	16	20	4–8
Number of user-definable (open) channels	16	4	12
Of those defined, number active simultaneously	16	1	4–8
Factor assays require manual manipulation or dilutions	—	yes	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	—/16/no	2/varies/no	—/—/no
Multiple reagent configurations supported	yes	yes	no
Reagents, consumables loaded without interrupting testing	no	no	no
Same capabilities when third-party reagent used	yes	yes	—
Maximum time same lot number of reagents can be used	~12 months	18 months	12 months
Walkaway capacity: Number of specimens/Number of tests	16/16	no (semiautomated)	no
Minimum sample volume aspirated precisely at one time	—	—	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	—	50 µL/50 µL	platelet aggregation: 225 µL PRP; ristocetin cofactor: 50 µL/ platelet aggregation: 225 µL PRP; ristocetin cofactor: 50 µL
Disposables used/Price of each	—	cuvettes, balls/varies	cuvettes: 200 @ $55.65; pipette tips: 1,000 @ $82; stir bars: 30 @ $62.25
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	no/—	no/—
Sample/Reagent barcode reading capability	no/no	no/no	no/no
Onboard test automatic inventory	no	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/—	no/no
Clot detection as preanalytical variable in plasma sample	no	no	—
Auto. detects adequate reagents for aspiration and analysis	no	no	no
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for internal calibration technology)	no/no (not necessary)	no/no
Dilution of patient samples onboard	no	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/—	no/no
Lag time during which hypercoagulable sample not detected	no	yes (selectable on menus)	—
Read time extended for prolonged clotting times	—	—	—
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/—	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incubation times/Reading times	yes/yes	no/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/no	—	no/yes
Auto shutdown/Auto startup programmable	no/no	—	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	—	<6 minutes/up to 120 specimens	—
• PT, PTT	—	—	—
• Fibrinogen	—	<6 minutes/up to 120 specimens	—
• Factor VIII activity assay	—	<6 minutes/up to 60 specimens	—
Time delay from ordering stat to aspiration of sample	—	—	—
Automatic transfer of QC results to LIS	no	no	yes
Data-management capability	onboard	no	onboard (includes QC: L-J plots, Westgard multirules)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	no (unidirectional only)	no
Results transferred to LIS as soon as test time complete	no	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	—
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: 15 minutes	weekly: <5 minutes; monthly: <5 minutes	daily: 15 minutes; weekly: 15 minutes; monthly: 1 hour
Onboard maintenance records	no	no	yes
Training provided with purchase	1 day on site	1 day on site	2 days on site
Approximate number of training hours needed per tech	5	1	4–8
List price	$45,000	$12,000	$15,744
Annual service contract cost (24/7)/Warranty with purchase	$2,900/1 year	—/1 year	$1,984/1 year
Distinguishing features (supplied by company)	software automatically calculates all thrombin generation parameters; sample-specific calibrator corrects for plasma color, turbidity, inner filter effect, substrate depletion	viscosity-based detection system; ideal for low-volume testing or backup for optical system; programmable and preprogrammed assays with curve storage plus four independently timed measurement wells	specialized coagulation instrument intended for platelet aggregation and ristocetin cofactor

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

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	Helena Laboratories **David Pearman** dpearman@helena.com **1530 Lindbergh Drive, Beaumont, TX 77704** **409-842-3714 ext. 265** www.helena.com	**Instrumentation Laboratory** **Venita Shirley** vshirley@ilww.com **180 Hartwell Rd., Bedford, MA 01730** **800-955-9525** www.instrumentationlaboratory.com	**Instrumentation Laboratory** **Venita Shirley** vshirley@ilww.com **180 Hartwell Rd., Bedford, MA 01730** **800-955-9525** www.instrumentationlaboratory.com
Instrument name/First year sold	Cascade M-4/1992	ACL TOP 750/700 Series/2004	ACL TOP 550/500 CTS/2008
Number of units installed in U.S./Outside U.S.	200+/40	4,000+/8,000+ (all ACL models combined)	4,000+/8,000+ (all ACL models combined)
Number of contracts signed between 1/1/17 and 11/15/17	5	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	random access	continuous random access	continuous random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	racks, continuous loading of primary tubes	racks, continuous loading of primary tubes
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	8 × 15 × 13 in/25 lbs/1.4 sq ft	29 × 60 × 35 in/331 lbs/21 sq ft	29 × 43 × 35 in/312 lbs/14 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVVT), APCR-V, proteins C and S, FVIII (with VWF)	PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVVT), APCR-V, proteins C and S, FVIII (with VWF)
FDA-cleared chromogenic tests	—	anti-Xa, protein C, AT, plasminogen, plasmin inhibitor	anti-Xa, protein C, AT, plasminogen, plasmin inhibitor
FDA-cleared immunologic tests	—	D-Dimer, D-Dimer HS, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine, heparin-induced thrombocytopenia	D-Dimer, D-Dimer HS, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine, heparin-induced thrombocytopenia
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	DRVVT	VWF (RCo), direct oral anticoagulants (dabigatran, rivaroxaban, apixaban)	VWF (RCo), direct oral anticoagulants (dabigatran, rivaroxaban, apixaban)
Methodologies supported	clot detection, optical; turbidimetric	LED optical detection: clotting, chromogenic, and immunologic	LED optical detection: clotting, chromogenic, and immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	4	500	500
Number of different assays programmed and calib. at one time	4	500	500
Number of user-definable (open) channels	4	250	250
Of those defined, number active simultaneously	2	30	30
Factor assays require manual manipulation or dilutions	yes	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	0/—/no	60/varies/yes	40/varies/yes
Multiple reagent configurations supported	no	yes	yes
Reagents, consumables loaded without interrupting testing	no	yes	yes
Same capabilities when third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	12 months	18 months	18 months
Walkaway capacity: Number of specimens/Number of tests	no	120/800	80/800
Minimum sample volume aspirated precisely at one time	manual, 50 µL	4 µL	4 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted)	50 µL/25 µL	50 µL/25 µL
Disposables used/Price of each	cuvettes: 500 @ $54; pipette tips: 1,000 @ $82	cuvettes/varies	cuvettes/varies
Supports direct-from-track sampling	no	yes (model available)	no
Primary tube sampling supported/Pierces caps on primary tubes	no/—	yes/yes (optional)	yes/yes
Sample/Reagent barcode reading capability	no/no	yes/yes	yes/yes
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	—	optional	optional
Auto. detects adequate reagents for aspiration and analysis	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	optional/optional	optional/optional
Dilution of 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	yes (PT: 4 seconds; PTT: 14 seconds)	no	no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes	yes
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incubation times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	not needed/not needed	not needed/not needed
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	3 minutes/140 specimens	<3 minutes/360 specimens	<3 minutes/240 specimens
• PT, PTT	7 minutes/80 specimens	<6 minutes/165 specimens	<6 minutes/90 specimens
• Fibrinogen	3 minutes/160 specimens	<3 minutes/108 specimens	<3 minutes/78 specimens
• Factor VIII activity assay	7 minutes/80 specimens	8 minutes/100 specimens	8 minutes/77 specimens
Time delay from ordering stat to aspiration of sample	—	0 seconds	0 seconds
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	no	yes	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	most major vendors	most major vendors
Bidirectional interface capability	no	yes (broadcast download and host query)	yes (broadcast download and host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	yes	no
Modem servicing	no	in development	in development
Time required for maintenance by lab personnel	daily: 10 minutes; weekly: 10 minutes; monthly: 30 minutes	daily: <10 minutes; weekly: 10 minutes; monthly: none	daily: <10 minutes; weekly: 10 minutes; monthly: none
Onboard maintenance records	no	yes	yes
Training provided with purchase	1 day on site	4 days at vendor offices	4 days at vendor offices
Approximate number of training hours needed per tech	2	24–40	24–40
List price	$10,115	—	—
Annual service contract cost (24/7)/Warranty with purchase	$1,291/1 year	—/1 year	—/1 year
Distinguishing features (supplied by company)	four-channel manual analyzer, QC program onboard, singles or duplicates	complete standardization solution; on-demand HIT testing; detects underfilled samples; 671-nm LED detection minimizes interferences from HIL, samples with HIL levels exceeding assay threshold are flagged; complete HemosIL assay menu, including D-Dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH	complete standardization solution; on-demand HIT testing; detects underfilled samples; 671-nm LED detection minimizes interferences from HIL, samples with HIL levels exceeding assay threshold are flagged; complete HemosIL assay menu, including D-Dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH

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COAGULATION ANALYZERS

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	Instrumentation Laboratory **Venita Shirley** vshirley@ilww.com **180 Hartwell Rd., Bedford, MA 01730** **800-955-9525** www.instrumentationlaboratory.com	**Instrumentation Laboratory** **Venita Shirley** vshirley@ilww.com **180 Hartwell Rd., Bedford, MA 01730** **800-955-9525** www.instrumentationlaboratory.com	**Instrumentation Laboratory** **Venita Shirley** vshirley@ilww.com **180 Hartwell Rd., Bedford, MA 01730** **800-955-9525** www.instrumentationlaboratory.com
Instrument name/First year sold	ACL TOP 350/300 CTS/2012	ACL ELITE Series/2006	ACL AcuStar/2010
Number of units installed in U.S./Outside U.S.	4,000+/8,000+ (all ACL models combined)	4,000+/8,000+ (all ACL models combined)	4,000+/8,000+ (all ACL models combined)
Number of contracts signed between 1/1/17 and 11/15/17	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	continuous random access	modified random access	random access
Reagent type	open reagent system	open reagent system	multiuse reagent cartridges (liquid)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	racks, continuous loading of primary tubes	tray, primary tubes	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 32 × 33 in/200 lbs/8 sq ft	24 × 37 × 24 in/139 lbs/6 sq ft	21 × 34 × 24 in/170 lbs/15 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, factors, FVIII (with VWF)	PT, APTT, fibrinogen, TT, factors	—
FDA-cleared chromogenic tests	anti-Xa, AT	anti-Xa	—
FDA-cleared immunologic tests	Domain 1, D-Dimer, D-Dimer HS, heparin-induced thrombocytopenia	D-Dimer, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine	Domain 1, HIT IgG, anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	VWF (RCo), direct oral anticoagulants (dabigatran, rivaroxaban, apixaban)	—	VWF (RCo), VWF (Ag.), HIT total ab
Methodologies supported	LED optical detection: clotting, chromogenic, and immunologic	clot detection, LED optical (nephelometric), chromogenic, immunologic	immunologic (chemiluminescent)
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	500	22	20
Number of different assays programmed and calib. at one time	500	300	20
Number of user-definable (open) channels	250	100	0
Of those defined, number active simultaneously	30	20	—
Factor assays require manual manipulation or dilutions	no	no	—
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	24/varies/yes	22/varies/yes	20/varies/yes (4°C)
Multiple reagent configurations supported	yes	yes	no
Reagents, consumables loaded without interrupting testing	yes	yes	no
Same capabilities when third-party reagent used	yes	yes	no
Maximum time same lot number of reagents can be used	18 months	18 months	—
Walkaway capacity: Number of specimens/Number of tests	40/800	40/260	30/280
Minimum sample volume aspirated precisely at one time	4 µL	5 µL	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/—	60 µL/18 µL	—
Disposables used/Price of each	cuvettes/varies	cuvettes/varies	cuvettes/varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes/no
Sample/Reagent barcode reading capability	yes/yes	yes/yes	yes/yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	optional	no	yes
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	optional/optional	no/no	no/no
Dilution of 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	yes (PT and PTT: 3 seconds)	—
Read time extended for prolonged clotting times	yes	yes	—
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	no/no
• No. and sources of reagent	yes	yes	no
• Incubation times/Reading times	yes/yes	yes/yes	no/no
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	not needed/not needed	not needed/not needed	not needed/not needed
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/110 specimens	4 minutes/175 specimens	—
• PT, PTT	<6 minutes/55 specimens	8 minutes/270 specimens	—
• Fibrinogen	<6 minutes/60 specimens	4 minutes/175 specimens	—
• Factor VIII activity assay	<11 minutes/38 specimens	8 minutes/125 specimens	—
Time delay from ordering stat to aspiration of sample	0 seconds	15 seconds	<1 minute
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	yes	yes	onboard (includes QC: L-J plots and Westgard multirules)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major vendors	most major vendors	—
Bidirectional interface capability	yes (broadcast download and host query)	yes (broadcast download and host query)	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	in development	no	no
Time required for maintenance by lab personnel	daily: <10 minutes; weekly: 10 minutes; monthly: none	daily: <5 minutes; weekly: 10 minutes; monthly: 5 minutes	daily: 5 minutes; weekly: 5 minutes
Onboard maintenance records	yes	yes	no
Training provided with purchase	4 days at vendor offices	4 days at vendor offices	—
Approximate number of training hours needed per tech	24–40	24	6 on site
List price	—	—	—
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	various options available/1 year	—
Distinguishing features (supplied by company)	complete standardization solution; on-demand HIT testing; detects underfilled samples; 671-nm LED detection minimizes interferences from HIL, samples with HIL levels exceeding assay threshold are flagged; complete HemosIL assay menu, including D-Dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH	test menu featuring D-Dimer; barcoded reagent management; ACL family harmonization; HemosIL INR plasma sets for INR test system validation or calibration, or both; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH	easy to use; uses sensitive chemiluminescent technology; throughput of 60 tests per hour (<30 minutes to first test result); reagent cartridges stable up to 12 weeks onboard; reagents are precalibrated; replaces the need to run manual, time-consuming ELISA assays

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	LABiTec GmbH **Matthias Schramm** matthias.schramm@labitec.de **An der Strusbek 6, 22926 Ahrensburg, Germany** **011-49-4102-47950** www.labitec.com	**LABiTec GmbH** **Matthias Schramm** matthias.schramm@labitec.de **An der Strusbek 6, 22926 Ahrensburg, Germany** **011-49-4102-47950** www.labitec.com	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **511 Benedict Ave., Tarrytown, NY 10591** https://usa.healthcare.siemens.com/hemostasis
Instrument name/First year sold	CoaLAB 1000/2009	CoaData 2004 and 4004/—	Sysmex CS-2500 System/2016
Number of units installed in U.S./Outside U.S.	—/300	—/>500	>300/>1,000
Number of contracts signed between 1/1/17 and 11/15/17	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Japan/Japan
Operational type	batch, random access	discrete	continuous random access
Reagent type	open reagent system (reconstituted manually)	open reagent system	open reagent system (liquid, lyophilized, reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	two fixed racks of 11 samples each plus 3 stat	semiautomated manual pipette, auto start	continuous loading capped and uncapped 10-tube position primary sample rack × 5
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	30.7 × 22.9 × 19.6 in/55.1 lbs/—	10.7 × 13.7 × 4.9 in/8.6 lbs/2 sq ft	27 × 30.6 × 35.2 in/242.5 lbs/7.5 sq ft
FDA-cleared clotting-based tests	—	—	PT, APTT, fibrinogen, factors V, VII, VIII, IX, protein C, lupus, factor V Leiden
FDA-cleared chromogenic tests	—	—	Innovance Antithrombin, protein C, Innovance Heparin
FDA-cleared immunologic tests	—	—	Innovance D-Dimer
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	factors II, X, XI, XII; TT, batroxobin time, free protein S, von Willebrand factor, factor VIII chromogenic, a2-antiplasmin, plasminogen
Methodologies supported	LED optical, turbidimetric for clot detection, immunologic, chromogenic, and aggregation tests	clot detection, optical; turbodensitometric	clot detection, optical; turbidimetric; clot detection, simultaneous multiwavelength scanning and PSI checks; chromogenic; immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	15 maximum	1	60
Number of different assays programmed and calib. at one time	50	3	60
Number of user-definable (open) channels	2	—	80,000
Of those defined, number active simultaneously	2	1	60
Factor assays require manual manipulation or dilutions	no	yes	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	15/200 maximum/no	4/reagent manufacturer defined/no	40/up to 200/yes (10°C ± 2°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	no	yes	yes
Same capabilities when third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	1 year	reagent manufacturer defined	1 year
Walkaway capacity: Number of specimens/Number of tests	25 maximum/>10	18 incubational positions/2	50/up to 500
Minimum sample volume aspirated precisely at one time	2 µL	50 µL (150 µL total volume)	5 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	PT: 100 µL reagent, 50 µL sample; APTT: 50 µL reagent, 50 µL sample, 50 µL CACl2/50 µL APTT, 50 µL deficient plasma, 50 µL sample, 50 µL CACl2	50 µL/—	50 µL/—
Disposables used/Price of each	cuvette ring (32 single cuvettes per ring), sample cups/—	micro single cuvette, printer paper/—	reaction tubes, CA clean I and II/—
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (1.7–4 mL)/no	no/no	yes (1–4.5 mL)/yes
Sample/Reagent barcode reading capability	yes/no	no/no	yes/yes
Onboard test automatic inventory	yes	no	yes
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	yes/yes
Clot detection as preanalytical variable in plasma sample	yes	no	yes
Auto. detects adequate reagents for aspiration and analysis	yes	no	yes
Hemolysis/Turbidity detection-quantitation	no/yes	no/no	yes/yes
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/Auto reflex testing capability	yes/no	no/no	yes/yes
Lag time during which hypercoagulable sample not detected	yes (PT: <10 seconds; PTT: <20 seconds)	no	yes (PT: 7 seconds; PTT: 15 seconds)
Read time extended for prolonged clotting times	yes	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incubation times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<2 minutes/120 specimens	—	6.5 minutes/180 results
• PT, PTT	<5 minutes/71 specimens	—	6.5 minutes/180 results
• Fibrinogen	<5 minutes/50 specimens	—	6.5 minutes/—
• Factor VIII activity assay	depends on assay	—	—
Time delay from ordering stat to aspiration of sample	3 minutes	—	1 minute
Automatic transfer of QC results to LIS	yes	no	yes
Data-management capability	onboard (includes QC: L-J plots and Westgard multirules)	no	onboard (includes QC: L-J plots and Westgard multirules)
Interface supplied by instrument vendor	yes (included)	no	no
Interfaces in active user sites for:	via LAN, Windows OS, Linux OS	—	most major vendors
Bidirectional interface capability	yes (host query)	no	yes (broadcast download and host query)
Results transferred to LIS as soon as test time complete	yes	no	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	per shift: <1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: calibration 15 minutes	per shift: <1 minute (cleaning housing); daily: <1 minute (cleaning housing); weekly: <5 minutes (cleaning housing and incubating block)	daily: <6 minutes; weekly: 1 minute; monthly: <1 minute
Onboard maintenance records	no	no	yes
Training provided with purchase	3 days at vendor offices, on site on request	1 day, on request	3 days at vendor offices; varies on site
Approximate number of training hours needed per tech	—	4	6
List price	—	—	$155,000
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—/1 year	—/1 year
Distinguishing features (supplied by company)	standalone device, requires no additional PC monitor to control, onboard software, only external printer; flexible and extendable by software add-ons; different wavelength available; optimized for small to mid-size labs; special hemostasis of diagnostic assays	inexpensive two-channel (2004) and four-channel (4004) protime instruments with few moving parts; for small lab/physician office; updated version of CoaData/Accustasis; low maintenance and repair costs	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 maximum efficiency; consistency: for multisite patient monitoring, with sample result traceability for in-depth audit capabilities

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Part 7 of 8 See **captodayonline.com/productguides** for an interactive version of guide	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **511 Benedict Ave., Tarrytown, NY 10591** https://usa.healthcare.siemens.com/hemostasis	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **511 Benedict Ave., Tarrytown, NY 10591** https://usa.healthcare.siemens.com/hemostasis	**Siemens Healthineers** **Jason Lam** jason.lam@siemens-healthineers.com **511 Benedict Ave., Tarrytown, NY 10591** https://usa.healthcare.siemens.com/hemostasis
Instrument name/First year sold	Sysmex CS-5100 System/2016	Sysmex CA-600 Systems/2012	BFT II/1999
Number of units installed in U.S./Outside U.S.	>50/>500	—	—
Number of contracts signed between 1/1/17 and 11/15/17	—	—	—
Country where analyzer designed/Manufactured	Japan/Japan	Japan/Japan	Germany/Germany
Operational type	continuous random access	continuous random access	batch
Reagent type	open reagent system (liquid, lyophilized, reconstituted manually)	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	continuous loading capped and uncapped 10-tube position primary sample rack × 10	10-tube position sample rack	manual
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	22.5 × 19.5 × 19.5 in/~94.6 lbs/~3.05 sq ft	3.9 × 7.9 × 11.8 in/8.4 lbs/0.65 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, factors V, VII, VIII, IX, protein C, lupus, factor V Leiden	PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays	PT, APTT, fibrinogen
FDA-cleared chromogenic tests	Innovance Antithrombin, protein C, Innovance Heparin	Innovance AT, Berichrom AT, protein C chromo, heparin	—
FDA-cleared immunologic tests	Innovance D-Dimer	Innovance D-dimer	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	factors II, X, XI, XII; TT, batroxobin time, free protein S, von Willebrand factor, factor VIII chromogenic, a2-antiplasmin, plasminogen	—	—
Methodologies supported	clot detection, optical; turbidimetric; clot detection, simultaneous multiwavelength scanning and PSI checks; chromogenic; immunologic	clot detection, optical; turbidimetric, chromogenic, immunologic	turbodensitometric
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	60	5	1
Number of different assays programmed and calib. at one time	60	7	3
Number of user-definable (open) channels	80,000	7	—
Of those defined, number active simultaneously	60	5	1
Factor assays require manual manipulation or dilutions	no	no	—
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	40/up to 200/yes (10°C ± 2°C)	11/up to 200/yes (15°C)	4/up to 200/no
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	1 year	12 months	12 months
Walkaway capacity: Number of specimens/Number of tests	100/up to 1,000	10/50	1/1
Minimum sample volume aspirated precisely at one time	5 µL	5 µL	50 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/5 µL	50 µL/—
Disposables used/Price of each	reaction tubes, CA clean I and II/—	reaction tubes, CA clean I, CA clean II, thermal paper/varies with volume	cuvettes, printer paper/varies with volume
Supports direct-from-track sampling	yes (Siemens Aptio Automation)	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (1–4.5 mL)/yes	yes (2.7–5.0 mL)/no	no/no
Sample/Reagent barcode reading capability	yes/yes	yes/no	no/no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	no/no
Clot detection as preanalytical variable in plasma sample	yes	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	no
Hemolysis/Turbidity detection-quantitation	yes/yes	no/yes	no/no
Dilution of patient samples onboard	yes	yes	no
Automatic rerun capability/Auto reflex testing capability	yes/yes	no/no	no/no
Lag time during which hypercoagulable sample not detected	yes (PT: 7 seconds; PTT: 15 seconds)	yes (PT: <7 seconds; PTT: <15 seconds)	yes (PT: 5 seconds; APTT: 15 seconds)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	no
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incubation times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	6.5 minutes/400 results	7 minutes/60 results	1 minute/— (manual)
• PT, PTT	6.5 minutes/400 results	8 minutes/48 results	<5 minutes/— (manual)
• Fibrinogen	6.5 minutes/—	7 minutes/60 results	<1 minute/— (manual)
• Factor VIII activity assay	—	—	—
Time delay from ordering stat to aspiration of sample	1 minute	2 minutes	—
Automatic transfer of QC results to LIS	yes	yes	no
Data-management capability	onboard (includes QC: L-J plots and Westgard multirules)	onboard (includes QC: L-J plots)	no
Interface supplied by instrument vendor	no	no	—
Interfaces in active user sites for:	most major vendors	all major LIS vendors	—
Bidirectional interface capability	yes (broadcast download and host query)	yes (host query)	no
Results transferred to LIS as soon as test time complete	yes	yes	no
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	upon request	upon request
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: <6 minutes; weekly: 1 minute; monthly: <1 minute	daily: <10 minutes; quarterly: <5 minutes	daily: 1 minute
Onboard maintenance records	yes	no	no
Training provided with purchase	3 days at vendor offices; varies on site	2 days on site, personalized education plan online training course	quick reference guide
Approximate number of training hours needed per tech	6	2	2
List price	$205,000	CA-620: $42,000; CA-660: $55,000	$8,685
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—	—
Distinguishing features (supplied by company) *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	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 and point-in-space automation ready; consistency: for multisite patient monitoring, with sample result traceability for in-depth audit capabilities	maximizes counter space with compact footprint in low-volume labs; increases uptime and reduces service expenses; two models to meet individual laboratory needs: CA-620 system for routine clotting-based testing, CA-660 system for clotting, chromogenic, and immunologic testing needs	two-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

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COAGULATION ANALYZERS

Part 8 of 8

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

Siemens Healthineers
Jason Lam jason.lam@siemens-healthineers.com
511 Benedict Ave., Tarrytown, NY 10591
https://usa.healthcare.siemens.com/hemostasis

Instrument name/First year sold	BCS XP/2006
Number of units installed in U.S./Outside U.S.	—
Number of contracts signed between 1/1/17 and 11/15/17	—
Country where analyzer designed/Manufactured	Germany/Germany
Operational type	batch, continuous random access
Reagent type	open reagent system (liquid, lyophilized, reconstituted manually), optimized for Siemens instruments
Operates on whole blood or spun plasma	spun plasma
Sample handling system	10-tube position sample rack
Model type	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	37 × 49 × 25 in/330 lbs/8.5 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, reptilase time, factor assays, DRVVT (screen and confirm), factor V Leiden, protein C clot, protein S activity
FDA-cleared chromogenic tests	Innovance AT, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin
FDA-cleared immunologic tests	Innovance D-dimer
Other FDA-cleared tests	BC VWF-ristocetin cofactor assay (agglutination of fixed platelets)
User-defined tests in clinical use	—
Tests submitted for 510(k) clearance	—
Tests in development but not yet submitted	ETP (for research use only)
Methodologies supported	clot detection, optical (xenon flasher lamp); chromogenic, immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no
Number of different measured assays onboard simultaneously	>100 tests, samples
Number of different assays programmed and calib. at one time	99
Number of user-definable (open) channels	7,999
Of those defined, number active simultaneously	>100
Factor assays require manual manipulation or dilutions	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	90/up to 200/yes (<15°C)
Multiple reagent configurations supported	yes
Reagents, consumables loaded without interrupting testing	yes
Same capabilities when third-party reagent used	yes
Maximum time same lot number of reagents can be used	1 year
Walkaway capacity: Number of specimens/Number of tests	100 samples/400 cuvettes
Minimum sample volume aspirated precisely at one time	3 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/20 µL, minimum 100 µL (includes dead volume); 50 µL, minimum 100 µL
Disposables used/Price of each	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/varies with volume
Supports direct-from-track sampling	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (all up to 100 mm long, ext. diameter 11–16 mm)/no
Sample/Reagent barcode reading capability	yes/yes
Onboard test automatic inventory	yes
Measures No. of tests remaining/Short sample detection	yes/yes
Clot detection as preanalytical variable in plasma sample	no
Auto. detects adequate reagents for aspiration and analysis	yes
Hemolysis/Turbidity detection-quantitation	yes/no
Dilution of patient samples onboard	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes
Lag time during which hypercoagulable sample not detected	yes (7 seconds for PT and APTT)
Read time extended for prolonged clotting times	yes
User can set different-than-standard:	
• Reagent volumes/Sample volumes	yes/yes
• No. and sources of reagent	yes
• Incubation times/Reading times	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes
Auto shutdown/Auto startup programmable	no/no
Stat time to complete all analytes/Throughput per hour for:	
• PT alone	<5 minutes/~380 results (including abnormals)
• PT, PTT	<5 minutes/~325 results (including abnormals)
• Fibrinogen	<5 minutes (if curve available)/~315 results
• Factor VIII activity assay	<5 minutes (if curve available)/~280 results
Time delay from ordering stat to aspiration of sample	varies by test in progress, ~>5 minutes
Automatic transfer of QC results to LIS	yes
Data-management capability	onboard (includes QC: L-J plots)
Interface supplied by instrument vendor	no
Interfaces in active user sites for:	all major LIS vendors
Bidirectional interface capability	yes (host query)
Results transferred to LIS as soon as test time complete	yes
LOINC codes transmitted with all results	no
How labs get LOINC codes for reagent kits	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no
Modem servicing	yes
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: <10 minutes; monthly: 15 minutes
Onboard maintenance records	yes
Training provided with purchase	3 days at vendor offices for 2 key operators, personalized education plan online training course
Approximate number of training hours needed per tech	8 on site
List price	$171,921
Annual service contract cost (24/7)/Warranty with purchase	—
Distinguishing features (supplied by company)	user-definable calibration curve expiration and prewarning alerts; user-definable barcode utility enables customizable reagent protocols; user-friendly Windows XP software

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