Coagulation analyzers

Part 1 of 9	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 3329 Durham Chapel Hill Blvd., Suite 200, Durham, NC 27707 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org and www.labitec.de	Bio/Data Corporation Kay Callahan kay.callahan@biodatacorp.com 155 Gibraltar Road Horsham, PA 19044 www.biodatacorp.com	Chrono-Log Corp. Kathy Jacobs jacobs@chronolog.com Havertown, PA 19083 610-853-1130 www.chronolog.com
Instrument name/First year sold	CD2000/1986	Platelet Aggregation Profiler, Model-PAP 8E/2005	Whole Blood-Optical Lumi-Aggregation System, Model 700-2/700-4/2006
Number of units installed in U.S./Outside U.S.	>500/>1,000	>500 worldwide	160/205
Number of contracts signed between 1/1/12 and 11/30/12	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	U.S./U.S.	U.S./U.S.
Operational type	batch, discrete	batch, random access	batch, random access
Reagent type	open reagent system (reconstituted manually)	open reagent system, assay kits, reagents, controls, diluents, buffer, specialty products, others	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	cuvette, semiautomated	programmable electronic pipette, optional bar-code scanner	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	5 × 12 × 8.5 inches/9.2 lbs/1 square foot	22.5 × 14.0 × 21.7 inches/45 lbs/2.2 square feet	8.5 × 14.0 × 18.0 inches/40 lbs/ M700-2: 1.75 square feet; M700-4: 3.5 square feet
FDA-cleared clotting-based tests	PT, PTT, fibrinogen, any citrated plasma clot-based assay	—	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	—	ristocetin cofactor assay, ristocetin and heparin-induced platelet aggregation, platelet aggregation (ADP, EPI, arachidonic acid, trap, collagen), spontaneous aggregation, sticky platelets, dose response, EC, IC50, others	platelet-dense granule secretion, whole blood impedance aggregation, LTA aggregation, ristocetin cofactor assay
User-defined tests in clinical use	—	templates for user-defined tests included in software, specialty agonists, antiplatelet compounds, others	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	clot detection, optical; turbodensitometry stir bar mixing–optical detection	UV LED, platelet agglutination, platelet aggreg., turbidometric and rate reaction assays, digital circuitry and software	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	2 (PT, APTT)	8	2–4
Number of different assays programmed and calib. at one time	1 (fibrinogen)	>8	4–8
Number of user-definable (open) channels	2	8	2–4
Of those defined, number active simultaneously	2	8	2–4
Factor assays require manual manipulation or dilutions	yes	yes	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	5 or more/reagent manufacturer defined/no	2 stirred, adapters for various sized vials/varies/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	yes	yes	no
Maximum time same lot number of reagents can be used	laboratory dependent	up to 18 months	12–30 months
Walkaway capacity: Number of specimens/Number of tests	—/—	8/8	2–4/4–8
Minimum sample volume aspirated precisely at one time	manual pipetting	25 µL	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL, minimum 50 µL/50 µL, minimum 50 µL	—	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	500 microcuv. with mixers in trays: 11.6¢ ea., bulk 11¢; 500 macrocuv. with mixers in trays: 12¢ ea., bulk 10.6¢; 2,304 pipette tips-trayed: 5.1¢ ea., 3,000 tips bulk: 3.9¢ ea.	siliconized test tubes: 100 @ $30.75; plastic-coated stir bars: 50 @ $16.25; pipette tips: 960 @ $42.25; MagneTubes: 50 @ $43.00	cuvettes: 144 @ $34, stir bars: 144 @ $30, impedance probes: 25 @ $130, pipette tips: 1,000 @ $73, $55 and $60
Supports direct-from-track sampling/Primary tube sampling supported/Pierces caps on primary tubes	no/no/no	no/no/no	no/no/no
Sample/Reagent bar-code reading capability	no/no	yes/yes	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/no
Dilution of patient samples onboard	no	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/no
Lag time during which hypercoagulable sample not detected	yes (3 seconds)	no	—/—
Read time extended for prolonged clotting times	yes, up to 999 seconds	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/no	V2.1 hardware/software update adds optical calibration	yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	120 seconds/user defined	—	
• PT, PTT	240 seconds/user defined	—	—
• Fibrinogen	300 seconds/user defined	—	—
• Factor VIII activity assay	300 seconds/user defined	—	—
Time delay from ordering stat to aspiration of sample	—	—	—
Automatic transfer of QC results to LIS	no	no	no
Data-management capability	no	yes (onboard, includes QC: L-J plots, Westgard Multirules)	yes (onboard)
Interface supplied by instrument vendor	no	no	yes
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	yes	no	no
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	yes	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 30 seconds; weekly: 30 seconds; monthly: 5 minutes	weekly: 15 minutes; monthly: 30 minutes	30 minutes when optical calibration required
Onboard maintenance records	no	yes	yes
Training provided with purchase	video; on-site training extra	1.5 days on site	1.5 days on site
Approximate number of training hours needed per tech	2	4–6	8
List price	$900, special pricing upon written request for quote	$19,990	M700-2: $19,500; M700-4: $32,000
Annual service contract cost (24/7)/Warranty with purchase	add. 1-year init. contract $500 (opt.)/1 year, $300 renewal	$1,990 for 1 year, $2,990 for 2 years/—	M700-2: $1,804; M700-4: $3,008 for 3 years/1 year
Distinguishing features (supplied by company)	smaller clinic; office, private, vet labs; low acquisition and service cost, low maintenance; refurbished units available at reduced prices; can handle turbid and colored samples	two-year warranty; no-charge software upgrades during warranty period; optional PDQ platelet function centrifuge standardizes sample preparation, reduces preparation time to five minutes; on-demand optical calibration; unlimited user-defined test types; selectable washed platelet sample test type; adjustable temperature settings	tests platelet aggregation; measures ATP release in four 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

Coagulation analyzers

Part 2 of 9	Diagnostica Stago Inc. **Ron Evancheck** ronald.evancheck@us.stago.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. **Hamid Erfanian** hamid.erfanian@us.stago.com 5 Century Drive Parsippany, NJ 07054 888-222-COAG www.stago-us.com	Diagnostica Stago Inc. **Barry Ray** barry.ray@us.stago.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/First year sold	**STA Satellite/2010**	**Destiny Plus/2005**	**STA Compact Hemostasis System/1996**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/12 and 11/30/12	—	—	—
Country where analyzer designed/Manufactured	France/France	Germany and U.S./Germany	France/France
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	carousel (primary tubes)	continuous rack loading	continuous specimen access—primary tube
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	27.4 × 21.1 × 25.5 inches/72 lbs/4 square feet	22 × 33 × 27 inches/165 lbs/6.8 square feet	25.2 × 38.8 × 25.8 inches/351 lbs/7 square feet
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	open system: all clottable assays can be run on the Destiny Plus (PT, PTT, FIB, TT, factors, venom time, proteins C and S, aPCR, lupus screen and confirm)	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT, screen and confirm
FDA-cleared chromogenic tests	heparin (UFH, LMWH), AT	open system: all chromogenic assays can be run on the Destiny Plus (prot C, AT IIa and Xa based), heparin Xa, plasminogen	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin
FDA-cleared immunologic tests	D-dimer	open system: all latex immunoassays can be run on the Destiny Plus (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	—	—	—
Tests in development but not yet submitted	—	—	—
Methodologies supported	clot detection, mechanical; chromogenic; immunologic	clot detection, mechanical and optical (turbidimetric); chromogenic; immunologic	clotting, chromogenic, and immunologic assays
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	80	10	80
Number of different assays programmed and calib. at one time	80	unlimited	80
Number of user-definable (open) channels	70	unlimited	70
Of those defined, number active simultaneously	70	10	70
Factor assays require manual manipulation or dilutions	—	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	16/varies/yes (15°–19°C)	31 to 51/varies/yes (12°–16°C)	45/varies/yes (15°–19°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	18 months	varies by reagent—routine reagents 12 months	18 months
Walkaway capacity: Number of specimens/Number of tests	20/12 per specimen	50/240	96/12 per specimen
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/—	25 µL/10 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes and wash solution/varies with volume	reaction trays, ProWash	cuvettes and wash solution/varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes (all standard, pediatric, micro)/no	yes/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	in development	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	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for mechanical detection technology)	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/no	yes/yes	yes/no
Lag time during which hypercoagulable sample not detected	no	no	no
Read time extended for prolonged clotting times	yes (selectable on menus)	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	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no (not necessary)/no (not necessary)	yes/yes	no (not necessary)/no (not necessary)
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	7 minutes/52 specimens	<3 minutes/180 tests	<6 minutes/150 specimens
• PT, PTT	7 minutes/36 specimens	<6 minutes/90 tests	7 minutes/75 specimens
• Fibrinogen	7 minutes/36 specimens	<6 minutes/105 tests	7 minutes/75 specimens
• Factor VIII activity assay	—/—	<6 minutes/58 tests	7 minutes/70 specimens
Time delay from ordering stat to aspiration of sample	<15 seconds	varies by test	<15 seconds
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots)	onboard (includes QC: LJ plots, Westgard Multirules)	onboard (includes QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	all major LIS vendors	Cerner, Misys, Meditech, others
Bidirectional interface capability	yes (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	yes	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	yes	no
Time required for maintenance by lab personnel	weekly: <30 minutes; monthly: 30 minutes	daily: <5 minutes; weekly: <30 minutes; monthly: <30 minutes	weekly: <30 minutes; monthly: <30 minutes
Onboard maintenance records	yes	yes	yes
Training provided with purchase	2 days on site	2 to 4 days on site; 3 days at vendor offices	varies on site, 3 days at vendor offices
Approximate number of training hours needed per tech	2	8	2 (basic)
List price	$45,000	$71,760	$75,000
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—/1 year	—/1 year
Distinguishing features (supplied by company)	viscosity-based detection system; standardization across all STA analyzers allows consistent reporting throughout hospital groups; complete walkaway automation for low-volume coagulation laboratories	mechanical and optical clot detection on one platform; easy to learn and retain IntuiTouch software; standardize with Destiny Max; normalization of PT and PTT results	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; can standardize with other STA analyzers

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

Tabulation does not represent an endorsement by the College of American Pathologists.

Coagulation analyzers

Part 3 of 9	Diagnostica Stago Inc. Barry Ray barry.ray@us.stago.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Barry Ray barry.ray@us.stago.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Barry Ray barry.ray@us.stago.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/First year sold	**STA Compact CT/2001**	**STA Compact Plus/—**	**STA-R Evolution Expert Series/2005**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/12 and 11/30/12	—	—	—
Country where analyzer designed/Manufactured	France/France	France/France	France/France
Operational type	continuous random access	continuous random access	continuous random access
Reagent type	open reagent system (lyophilized, reconstituted manually)	open	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	continuous specimen access (primary tube)	continous specimen access (primary tube)	rack with continuous specimen access
Model type	benchtop	benchtop	floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	25.2 × 38.8 × 25.8 inches/351 lbs/7 square feet	25.2 × 38.8 × 25.8 inches/351 lbs/7 square feet	49.2 × 50.3 × 32.2 inches/507 lbs/26.8 square feet
FDA-cleared clotting-based tests	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT screen and confirm	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), protein C, AT, plasminogen, antiplasmin
FDA-cleared immunologic tests	—	D-dimer, VWF, total and free protein S, AT antigen	D-dimer, VWF, total and free protein S, AT antigen
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	APCR, other clotting tests can have user-defined applications	APCR, other clotting chromogenic and immunological tests with user-defined applications	APCR, other clotting chromogenic and immunological tests with user-defined applications
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	—
Methodologies supported	clot detection, mechanical	clot detection, mechanical, chromogenic, immunologic	clot detection, mechanical, 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	70	70	200
Of those defined, number active simultaneously	70	70	200
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	45/varies/yes (15°–19°C)	45/—/yes (15°–19°)	70/varies/yes (15°–19°C)
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	18 months	18 months	18 months
Walkaway capacity: Number of specimens/Number of tests	96/12	96/12	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/5 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes and wash solution/varies with volume	cuvettes and wash solution/—	cuvettes and wash solution/varies with volume
Supports direct-from-track sampling	no	no	yes (Beckman Coulter, Siemens LabCell, Roche MPA)
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes (multiple sizes)/yes	yes/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	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	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for mechanical detection technology)	no/no	no/no (not necessary for mechanical detection technology)
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/no	yes/no	yes/no
Lag time during which hypercoagulable sample not detected	no	no	no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (option selectable on operator menu)	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/no	no (not necessary)/no (not necessary)
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<6 minutes/150 specimens	<6 minutes/150 specimens	<6 minutes/~300 specimens
• PT, PTT	7 minutes/75 specimens	7 minutes/75 specimens	7 minutes/~150 specimens
• Fibrinogen	7 minutes/75 specimens	7 minutes/75 specimens	7 minutes/~180 specimens
• Factor VIII activity assay	7 minutes/70 specimens	7 minutes/70 specimens	7 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)	onboard (includes QC: L-J plots, Westgard Multirules)	onboard (L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others
Bidirectional interface capability	yes (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	yes (Beckman Coulter, Siemens LabCell, Roche MPA)
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	weekly: <30 minutes; monthly: <30 minutes	weekly: <30 minutes; monthly: <30 minutes	weekly: <30 minutes; monthly: <30 minutes
Onboard maintenance records	yes	yes	yes
Training provided with purchase	varies on site, 3 days at vendor office	three days at vendor offices	varies on site, 4 days at vendor offices
Approximate number of training hours needed per tech	2 (basic)	24–32	3–5
List price	$50,000	$90,000	$161,900
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	—/1 year	prices available upon request/1 year
Distinguishing features (supplied by company)	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; able to standardize with other STA analyzers	performs simultaneous clotting (viscosity-based detection system), chromogenic, and immunological assays in true random access; manages patient results with autovalidation; delta check; incorporates expert rules to perform multi-dilution factors and lupus anticoagulant testing; abnormal results are flagged; auto-rerun capability; quality control: L-J graphs, value tables, and Westgard rules	viscosity-based detection system; connectivity to lab automation systems; software for password protection and result traceability; can standardize with other STA analyzers

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

Tabulation does not represent an endorsement by the College of American Pathologists.

Coagulation analyzers

Part 4 of 9	Diagnostica Stago Inc. Hamid Erfanian hamid.erfanian@us.stago.com 5 Century Drive, Parsippany, NJ 07054 888-222-COAG www.stago-us.com	Diagnostica Stago, Inc. Paul Riley, PhD paul.riley@us.stago.com 5 Century Drive, Parsippany, NJ 07054 973-671-1200 ext. 4238 www.stago-us.com	Diagnostica Stago Inc. Ron Evancheck ronald.evancheck@us.stago.com 5 Century Drive, Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/First year sold	**Destiny Max/2009**	**Calibrated Automated Thrombogram/2006**	**STart 4 Hemostasis Analyzer/1998**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/12 and 11/30/12	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	The Netherlands/Finland	France/France
Operational type	continuous random access	batch, discrete	batch
Reagent type	open reagent system	self-contained single-use and multi-use cartridges-packages-slides, open reagent system (lyophilized, reconstituted manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	continuous rack loading	96-well plate pipetted manually, inserted into instrument where the last reagent is automatically dispensed	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29.5 × 59 × 27 in/340 lbs/11.03 square feet	34 × 42 × 42 cm/30 lbs/2 square feet	4.7 × 16.1 × 16.5 inches/12.5 lbs/1.8 square feet
FDA-cleared clotting-based tests	open system: all clottable assays can be run on Destiny Max (PT, PTT, FIB, TT, factors, venom time, proteins C and S, aPCR, lupus screen and confirm)	—	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant
FDA-cleared chromogenic tests	open system: all chromogenic assays can be run on Destiny Max (prot C, AT IIa and Xa based), heparin Xa, plasminogen	—	—
FDA-cleared immunologic tests	open system: all latex immunoassays can be run on Destiny Max (D-dimer)	—	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	DRVVT screen and confirm assays, APCR, other clotting tests with user-defined applications
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	all coagulation tests	fluorescence-based detection of thrombin generation and microparticle determination	—
Methodologies supported	clot detection, mechanical and optical; chromogenic; immunologic	quartz-halogen, fluorescence-based detection of thrombin generation	clotting tests
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	unlimited	5	1
Number of different assays programmed and calib. at one time	unlimited	5	20
Number of user-definable (open) channels	unlimited	16	4
Of those defined, number active simultaneously	unlimited	16	1
Factor assays require manual manipulation or dilutions	no	—	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	—/varies by test/yes (12°–16°C)	—/16/no	4/varies/no
Multiple reagent configurations supported	yes		yes
Reagents, consumables loaded without interrupting testing	yes		no
Same capabilities when third-party reagent used	no		yes
Maximum time same lot number of reagents can be used	varies—routine reagents 12 months		18 months
Walkaway capacity: Number of specimens/Number of tests	120/71,000	16/16	4/1
Minimum sample volume aspirated precisely at one time	25 µL	—	25 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	25 µL/10 µL	—	50 µL/5 µL
Disposables used/Price of each	reaction trays, ProWash	—	cuvettes, balls/varies
Supports direct-from-track sampling	yes	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	no/no	no/no (not applicable)
Sample bar-code/Reagent bar-code reading capability	yes/yes	no/no	no/no
Onboard test automatic inventory	yes	no	no
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	no	no
Hemolysis/Turbidity detection-quantitation	not necessary/not necessary	no/no (not necessary for internal calibration technology)	no/no (not necessary for mechanical detection technology)
Dilution of patient samples onboard	yes	no	no
Automatic rerun capability/Auto reflex testing capability	yes/yes	no/no	no/no
Lag time during which hypercoagulable sample not detected	no	no	no
Read time extended for prolonged clotting times	yes	no	yes (selectable on menus)
User can set different-than-standard:	yes		
• 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/no	no/yes
Auto shutdown/Auto startup programmable	yes/yes	no/no	no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/~350 tests	—	<1 minute/up to 120 specimens
• PT, PTT	<6 minutes/~232 tests	—	—
• Fibrinogen	<6 minutes/~200 tests	—	<1 minute/up to 120 specimens
• Factor VIII activity assay	<6 minutes/~200 tests	—	varies/varies
Time delay from ordering stat to aspiration of sample	<3 minutes	—	<15 seconds
Automatic transfer of QC results to LIS	yes	no	no
Data-management capability	onboard (includes QC: L-J plots, Westgard Multirules)	onboard	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	yes (broadcast download and host query)	no	no
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	package insert, e-mail	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no	no
Modem servicing	yes	no	no
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: <10 minutes; monthly: <30 minutes	weekly: 15 minutes	weekly: <5 minutes; monthly: <5 minutes
Onboard maintenance records	yes	no	no
Training provided with purchase	3–5 days on site; 5 days at vendor offices	1 day on site	1 day on site
Approximate number of training hours needed per tech	5	5	1
List price	$134,160	$38,500	$9,600
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	$1,550/1 year	prices available on request/1 year
Distinguishing features (supplied by company)	mechanical and optical clot detection; closed-tube sampling; dyes in routine reagents for volume delivery check; factor parallelism; normalization of PT and PTT results; LAS ready	dynamic determination of thrombin generation during clot formation by fluorescence detection (for research use only; not for use in diagnostic procedures); sample-specific calibrator corrects for plasma color, turbidity, inner filter effect, substrate depletion	viscosity-based detection system; effective for low-volume testing or backup for optical system; programmable and preprogrammed assays with curve storage plus four independently timed measurement wells

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

Tabulation does not represent an endorsement by the College of American Pathologists.

Coagulation analyzers

Part 5 of 9	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.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	**AggRAM/2005**	**Cascade M-4/1992**	**Cascade M/1991**
Number of units installed in U.S./Outside U.S.	100+/200+	200+/40	300+/100
Number of contracts signed between 1/1/12 and 11/30/12	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	batch, random access	random access	batch
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma, PRP	spun plasma	spun plasma
Sample handling system	manual	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	6 × 10 × 17 inches/15 lbs/—	8 × 15 × 13 inches/25 lbs/1.4 square feet	8 × 15 × 13 inches/25 lbs/1.4 square feet
FDA-cleared clotting-based tests	—	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII
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	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	lumi, chromogenics, HIT	DRVVT	DRVVT
Methodologies supported	ristocetin cofactor, platelet aggregation	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	4–8	4	1
Number of different assays programmed and calib. at one time	4–8	4	1
Number of user-definable (open) channels	12	4	2
Of those defined, number active simultaneously	4–8	2	1
Factor assays require manual manipulation or dilutions	yes	yes	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	—/—/no	0/—/no	—
Multiple reagent configurations supported	no	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	12 months	12 months
Walkaway capacity: Number of specimens/Number of tests	no	no	no
Minimum sample volume aspirated precisely at one time	—	manual, 50 µL	manual, 50 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	platelet aggregation: 225 µL PRP, ristocetin cofactor: 50 µL	100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted)	100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted)
Disposables used/Price of each	cuvettes: 200 @ $55.65; pipette tips: 1,000 @ $82; stir bars: 30 @ $62.25	cuvettes: 500 @ $54; pipette tips: 1,000 @ $82	cuvettes: 500 @ $54; pipette tips: 1,000 @ $82
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no	no/—	no/—
Sample bar-code reading capability	no	no	no
Reagent bar-code reading capability	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	—	—	—
Auto. detects adequate reagents for aspiration and analysis	no	no	no
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable sample not detected	—	yes (PT: 4 seconds, PTT: 14 seconds)	yes (PT: 4 seconds, PTT: 14 seconds)
Read time extended for prolonged clotting times	—	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	no/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	—	3 minutes/140 specimens	3 minutes/120 specimens
• PT, PTT	—	7 minutes/80 specimens	7 minutes/50 specimens
• Fibrinogen	—	3 minutes/160 specimens	3 minutes/140 specimens
• Factor VIII activity assay	—	7 minutes/80 specimens	7 minutes/50 specimens
Time delay from ordering stat to aspiration of sample	—	—	—
Automatic transfer of QC results to LIS	yes	yes	no
Data-management capability	onboard (includes QC: L-J plots, Westgard Multirules)	no (includes QC: L-J plots)	no (includes QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	no	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	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	—
Modem servicing	—	no	no
Time required for maintenance by lab personnel	daily: 15 minutes; weekly: 15 minutes; monthly: 1 hour	daily: 10 minutes; weekly: 10 minutes; monthly: 30 minutes	daily: 10 minutes; weekly: 10 minutes; monthly: 20 minutes
Onboard maintenance records	yes	no	no
Training provided with purchase	2 days on site	1 day on site	1 day on site
Approximate number of training hours needed per tech	4–8	2	2–4
List price	$14,995	$9,635	$7,127
Annual service contract cost (24/7)/Warranty with purchase	$1,800/1 year	$966/1 year	$714/1 year
Distinguishing features (supplied by company)	specialized coagulation instrument intended for platelet aggregation and ristocetin cofactor	four-channel manual analyzer; QC program onboard; singles or duplicates	QC program onboard; curve storage; suitable for office lab or as backup analyzer

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

Coagulation analyzers

Part 6 of 9	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road, Bedford, MA 01730 800-955-9525 www.ilus.com	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road, Bedford, MA 01730 800-955-9525 www.ilus.com	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road, Bedford, MA 01730 800-955-9525 www.ilus.com
Instrument name/First year sold	**ACL TOP 700 Series/2004**	**ACL TOP 500 CTS/2008**	**ACL TOP 300 CTS/2012**
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 1/1/12 and 11/30/12	49	165	80
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	continuous random access	continuous random access	continuous random access
Reagent type	open reagent system	open reagent system	open
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	racks, continuous loading of primary tubes	racks, allowing continuous loading of samples	racks, continuous loading of primary tubes
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 60 × 35/331 lbs/21 square feet	29 × 43 × 35 inches/312 lbs/14 square feet	29 × 32 × 33 inches/200 lbs/8 square feet
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVVT), APCR-V, protein C/S, FVIII (with VWF)	PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVVT), protein C/S, APCR-V, FVIII (with VWF)	PT, APTT, fibrinogen, TT, factors, FVIII (with VWF)
FDA-cleared chromogenic tests	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	heparin Xa, AT
FDA-cleared immunologic tests	D-dimer, D-dimer HS, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer, D-dimer HS, vWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer HS
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	VWF=ristocetin cofactor	VWF=ristocetin cofactor	VWF=ristocetin cofactor
Tests in development but not yet submitted	HIT, global protein C pathway	HIT, global protein C pathway	HIT, global protein C pathway
Methodologies supported	clot detection, LED optical, chromogenic; immunologic	clot detection, LED optical, chromogenic; immunologic (turbidimetric)	clot detection (LED optical), 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	500	500	500
Number of different assays programmed and calib. at one time	500	500	500
Number of user-definable (open) channels	250	250	250
Of those defined, number active simultaneously	30	30	30
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	60/varies/yes	40/varies by assay/yes	24/—/yes
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	18 months	18 months	18 months
Walkaway capacity: Number of specimens/Number of tests	120/800	80/800	40/800
Minimum sample volume aspirated precisely at one time	4 µL	4 µL	4 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	PT and PTT: 50 µL; FVIII: 25 µL	PT and PTT: 50 µL; FVIII: 25 µL	50 µL/25 µL
Disposables used/Price of each	cuvettes/varies	cuvettes/varies	—
Supports direct-from-track sampling	yes (model available)	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes (optional)	yes/yes	yes/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	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	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	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	no	no
Read time extended for prolonged clotting times	yes	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/yes
Auto shutdown/Auto startup programmable	not needed	not needed	—
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/360 specimens	<3 minutes/240 specimens	<3 minutes/110 specimens
• PT, PTT	8 minutes/165 specimens	8 minutes/90 specimens	<6 minutes/55 specimens
• Fibrinogen	<3 minutes/108 specimens	<3 minutes/78 specimens	<6 minutes/60 specimens
• Factor VIII activity assay	8 minutes/100 specimens	8 minutes/77 specimens	<11 minutes/38 specimens
Time delay from ordering stat to aspiration of sample	—	—	—
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	yes	yes	onboard (includes QC: L-J plots, Westgard Multirules)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major vendors	most major vendors	most major vendors
Bidirectional interface capability	yes (broadcast download and host query)	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	yes	no	no
Modem servicing	in development	in development	in development
Time required for maintenance by lab personnel	daily: <10 minutes; weekly: 10 minutes	daily: <10 minutes; weekly: 10 minutes	daily: <10 minutes; weekly: 10 minutes
Onboard maintenance records	yes	yes	yes
Training provided with purchase	5 days at vendor offices	5 days at vendor offices	5 days at vendor offices
Approximate number of training hours needed per tech	24–40	24–40	24–40
List price	—	—	—
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—/1 year	—/1 year
Distinguishing features (supplied by company)	clot signature curve analysis; continuous operation without interruption to workflow; minimized operator intervention using intuitive Windows XP software; 2D bar code for reagent, calibration, and control assay value import; HemosIL INR plasma sets for INR test system validation or calibration, or both; HemosIL liquid heparin with universal calibration curve for UFH and LMWH	complete assay menu, including D-dimer and D-dimer HS with VTE exclusion; 671-nm LED detection, which minimizes interference from lipemia, hemoglobin, and bilirubin; HemosIL plasma sets for validation of INR test system; HemosIL liquid heparin with universal calibration curve for UFH and LMWH	complete standardization solution; 671-nm LED detection minimizes interferences from lipemia, hemoglobin, and billirubin; complete HemosIL assay menu, including D-dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid heparin with universal calibration curve for UFH and LMWH

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

Coagulation analyzers

Part 7 of 9	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road Bedford, MA 01730 800-955-9525 www.ilus.com	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road Bedford, MA 01730 800-955-9525 www.ilus.com	LABiTec GmbH Matthias Schramm matthias.schramm@labitec.de An der Strusbek 6 Ahrensburg, Germany 22926 011-49-4102-47950 www.labitec.com
Instrument name/First year sold	**ACL ELITE Series/2006**	**ACL AcuStar/2010**	**CoaLAB 1000/2009**
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)	—/150
Number of contracts signed between 1/1/12 and 11/30/12	90	3	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	Germany/Germany
Operational type	modified random access	random access	batch, random access
Reagent type	open reagent system	self-contained multi-use cartridges-packages-slides (liquid)	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray-primary tubes	rack	two fixed racks of 11 samples each plus 3 stat
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	24 × 37 × 24inches/139 lbs/6 square feet	21 × 34 × 24 inches/170 lbs/15 square feet	78 × 58 × 50 cm/30 kg (shipping)/—
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, factors, protein C/S, lupus (SCT and DRVVT), APCR-V	—	—
FDA-cleared chromogenic tests	heparin Xa, protein C, AT plasminogen, plasmin inhibitor, factor VIII	—	—
FDA-cleared immunologic tests	D-dimer, vWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine	anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	PT, APTT, fibrinogen
Tests in development but not yet submitted	—	VWF panel, HIT IgG, HIT total	—
Methodologies supported	clot detection, LED optical (nephelometric); chromogenic; immunologic	immunologic (chemiluminescent)	clot detection (optical), nephelometric, turbidimetric, chromogenic, immunologic (agglutination/aggregation)
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	22	20	15 maximum
Number of different assays programmed and calib. at one time	300	20	50
Number of user-definable (open) channels	100	0	2
Of those defined, number active simultaneously	20	—	2
Factor assays require manual manipulation or dilutions	no	—	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	22/varies by test/yes	20/varies by assay/yes (4°C)	15/200 maximum/no
Multiple reagent configurations supported	yes	no	yes
Reagents, consumables loaded without interrupting testing	yes	no	no
Same capabilities when third-party reagent used	yes	no	yes
Maximum time same lot number of reagents can be used	18 months	—	1 year
Walkaway capacity: Number of specimens/Number of tests	40/260	30/—	25 maximum/>10
Minimum sample volume aspirated precisely at one time	5 µL	—	2 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	PT and PTT: 60 µL; FVIII: 18 µL	—/—	100µl reagent/50-µL sample/50 µL APTT; 50-µL sample; 50 µL/3 reagents and 1 sample
Disposables used/Price of each	cuvettes/—	cuvettes/—	cuvette ring (32 single cuvettes per ring)/sample cups
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes (most tubes validated)/no	yes (1.7–4 mL)/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	yes	no
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	no	no	yes
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/yes
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/no	yes/no
Lag time during which hypercoagulable sample not detected	yes (PT and PTT: 3 seconds)	—	yes (PT: <10 seconds; PTT: <20 seconds)
Read time extended for prolonged clotting times	yes	—	yes
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	no/no	yes/yes
• No. and sources of reagent	yes	no	yes
• Incubation times/Reading times	yes/yes	no/no	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	not needed	yes/yes	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	4 minutes/175 specimens	—	<2 minutes/108
• PT, PTT	8 minutes/270 specimens	—	<5 minutes/60
• Fibrinogen	4 minutes/175 specimens	—	<5 minutes/90
• Factor VIII activity assay	8 minutes/125 specimens	—	depends on assay
Time delay from ordering stat to aspiration of sample	15 seconds	<1 minute	3 minutes
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	yes	onboard (includes QC: L-J plots and Westgard Multirules)	onboard (includes QC: L-J plots and Westgard Multirules)
Interface supplied by instrument vendor	no	no	yes (included)
Interfaces in active user sites for:	most major vendors	—	via LAN, Windows OS, Linux OS
Bidirectional interface capability	yes (broadcast download and host query)	yes (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	no	no	no
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: 10 minutes; monthly: 5 minutes	daily: 10 minutes; weekly: 10 minutes	per shift: <1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: calibration 15 minutes
Onboard maintenance records	yes	no	no
Training provided with purchase	5 days at vendor offices	—	3 days at vendor offices; on site on request
Approximate number of training hours needed per tech	24	6	—
List price	—	—	—
Annual service contract cost (24/7)/Warranty with purchase	various options available/1 year	—	—/12 months
Distinguishing features (supplied by company)	test menu featuring D-dimer; bar-code reagent management; ACL family harmonization; HemosIL INR plasma sets for INR test system validation or calibration, or both; HemosIL liquid heparin with universal calibration curve for UFH and LMWH	easy to use, uses sensitive chemilumiescent technology, providing results in less than one hour; for many complex coagulation assays, replaces the need to run manual, time-consuming ELISA assays	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-sized labs; special hemostasis of diagnostic assays

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

Tabulation does not represent an endorsement by the College of American Pathologists.

Coagulation analyzers

Part 8 of 9	LABiTec GmbH **Matthias Schramm** matthias.schramm@labitec.de An der Strusbek 6 Ahrensburg, Germany 22926 011-49-4102-47950 www.labitec.com	Siemens Healthcare Diagnostics **Jackie Hauser** jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 847-267-5383 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics **Jackie Hauser** jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 847-267-5383 www.siemens.com/diagnostics
Instrument name/First year sold	CoaData 2004/4004/pending FDA	Sysmex CA-600 systems/2012	BFT II/U.S.: 1999
Number of units installed in U.S./Outside U.S.	—/>500	—	—
Number of contracts signed between 1/1/12 and 11/30/12	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Japan/Japan	Germany/Germany
Operational type	discrete	continuous random access	batch
Reagent type	open reagent system	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	semiautomated manual pipette-auto start	10-tube position sample rack	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	10.7 × 13.7 × 4.9 inches/8.6 lbs/2 square feet	22.5 × 19.5 × 19.5 inches/~94.6 lbs/~3.05 square feet	3.9 × 7.9 × 11.8 inches/8.4 lbs/0.65 square feet
FDA-cleared clotting-based tests	PT, APTT	PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays	PT, APTT, fibrinogen
FDA-cleared chromogenic tests	—	Innovance AT, Berichrom AT, protein C chromo, heparin	—
FDA-cleared immunologic tests	—	Innovance D-dimer	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	PT, APTT, fibrinogen	—	—
Tests in development but not yet submitted	—	—	—
Methodologies supported	clot detection, optical; turbodensitometric	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	1	5	1
Number of different assays programmed and calib. at one time	3	7	3
Number of user-definable (open) channels	—	7	—
Of those defined, number active simultaneously	1	5	1
Factor assays require manual manipulation or dilutions	yes	no	—
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	4/reagent manufacturer defined/no	11/varies, 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	reagent manufacturer defined	12 months	12 months
Walkaway capacity: Number of specimens/Number of tests	18 incubational positions/2	10/50	1/1
Minimum sample volume aspirated precisely at one time	50 µL (150 µL total volume)	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	micro single cuvette, printer paper/—	reaction tubes, CA-clean I, CA-clean II, thermal paper/varies with volume	cuvettes, printer paper/varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (2.7–5.0 mL)/no	no/no
Sample bar-code reading capability	no	yes	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	no
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	no	yes	no
Hemolysis/Turbidity detection-quantitation	no/no	no/yes	no/no
Dilution of patient samples onboard	no	yes	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable sample not detected	no	yes (PT: <7 seconds, PTT: <15 seconds)	yes (PT: 5 seconds, APTT: 15 seconds)
Read time extended for prolonged clotting times	yes, selectable on operator menus	yes, selectable on operator 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	no/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	—	7 minutes/60 results	1 minute/—, manual
• PT, PTT	—	8 minutes/48 results	—, manual
• Fibrinogen	—	7 minutes/60 results	<1 minute/—, manual
• Factor VIII activity assay	—	—	—
Time delay from ordering stat to aspiration of sample	—	2 minutes	—
Automatic transfer of QC results to LIS	no	yes	no
Data-management capability	no	onboard (includes QC: L-J plots)	no
Interface supplied by instrument vendor	no	no	—
Interfaces in active user sites for:	not yet	all major LIS vendors	—
Bidirectional interface capability	no	yes (host query)	no
Results transferred to LIS as soon as test time complete	no	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	per shift: <1 minute (cleaning housing); daily: <1 minute (cleaning housing); weekly: <5 minutes (cleaning housing and incubating block)	daily: <10 minutes; quarterly: <5 minutes	daily: 1 minute
Onboard maintenance records	no	no	no
Training provided with purchase	1 day, on request	2 days on site, personalized education plan	Web CD training course
Approximate number of training hours needed per tech	4	2	2
List price	—	CA-620: $42,000; CA-660: $55,000	$8,685
Annual service contract cost (24/7)/Warranty with purchase	12 months	—	—
Distinguishing features (supplied by company)	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	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

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

Coagulation analyzers

Part 9 of 9	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 847-267-5383 www.usa.siemens.com/diagnostics
Instrument name/First year sold	**Sysmex CA-1500/U.S.: 2000; worldwide: 1999**	**Sysmex CA-7000/2002**	**BCS XP/2006**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/12 and 11/30/12	—	—	—
Country where analyzer designed/Manufactured	Japan/Japan	Japan/Japan	Germany/Germany
Operational type	continuous random access	continuous random access	batch, continuous random access
Reagent type	open reagent system (lyophilized, reconstituted manually), optimized for Siemens instruments	open reagent system	open reagent system (reconstructed manually), optimized for Siemens instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack × 5	rack	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	20 × 31.2 × 31.2 inches/186 lbs/6.8 square feet	24.8 × 42 × 43.8 inches/345.4 lbs/12.78 square feet	37 × 49 × 25 inches/330 lbs/8.5 square feet
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	PT, APTT, fibrinogen, TT, reptilase time, factor assays, DRVVT screen and confirm, factor V Leiden, protein C clot, protein S activity	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	Innovance AT, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin	Innovance AT, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin,
FDA-cleared immunologic tests	Innovance D-dimer	Innovance D-dimer	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	PT multi-calibrators, Innovance VWF activity assay	PT multi-calibrators, Innovance VWF activity assay	PT multi-calibrators, Innovance VWF activity assay
Tests in development but not yet submitted	—	—	ETP (for research use only)
Methodologies supported	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical (xenon flasher lamp); 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	20	>100 tests/samples
Number of different assays programmed and calib. at one time	25	40	99
Number of user-definable (open) channels	25	40	7,999
Of those defined, number active simultaneously	15	20	>100
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	39/up to 200/yes (15°C)	58/varies up to 200/yes (15°C)	90/varies, up to 200/yes (<15°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	some consumables yes, reagents 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	1 year	1 year
Walkaway capacity: Number of specimens/Number of tests	50/up to 1,000	100/550 per hour PT and APTT, 300 per hour PT	100 samples/400 cuvettes
Minimum sample volume aspirated precisely at one time	5 µL	5 µL	3 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/5 µL	50 µL/5 µL	50 µL/20 µL, minimum 100 µL (includes dead volume)/50 µL, minimum 100 µL
Disposables used/Price of each	reaction tubes, sample plates, CA clean I and II, system buffer, halogen lamp, closed container sample replacement needles/varies with volume	reaction tubes, CA clean I and II, system buffer, halogen lamp, closed container sample replacement needles/varies with volume	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/varies with volume
Supports direct-from-track sampling	yes (Sysmex CST series)	yes (custom automation solutions available)	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (3–5 mL)/yes	yes (3–5 mL)/yes	yes (all up to 100 mm long, ext. diameter 11–16 mm)/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	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	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/yes	no/yes	yes/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	yes (PT: 7 seconds, APTT: 15 seconds)	yes (PT: 7 seconds, APTT: 15 seconds)	yes (7 seconds for PT and APTT)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	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	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	7 minutes/120 results	7 minutes/280 results	<5 minutes/~380 results (including abnormals)
• PT, PTT	8 minutes/80 results	8 minutes/480 results	<5 minutes/~325 results (including abnormals)
• Fibrinogen	8 minutes/120 results	8 minutes/280 results	<5 minutes (if curve available)~315 results
• Factor VIII activity assay	8 minutes/—	8 minutes/300 results	<5 minutes (if curve available)~280 results
Time delay from ordering stat to aspiration of sample	2 minutes	2 minutes	varies by test in progress, ~>5 minutes
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots and Westgard Multirules)	onboard (includes QC: L-J plots and Westgard Multirules)	yes, onboard (includes QC: L-J plots)
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 (host query)	yes (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	yes (Sysmex CST series)	custom automated connectivity with StreamLab	no
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: 1 minute; quarterly: <5 minutes	daily: <10 minutes; weekly: 1 minute; monthly: <5 minutes; quarterly: <5 minutes	daily: <5 minutes; weekly: <10 minutes.; monthly: 15 minutes
Onboard maintenance records	no	no	yes
Training provided with purchase	3 days at vendor offices for key operator, online training course, Web CD training	3 days at vendor offices for 2 key operators, Web CD training course	3 days at vendor offices for 2 key operators, online training course
Approximate number of training hours needed per tech	6	8 (on site)	8 (on site)
List price	$97,529 standard model; $110,544 cap-piercing model	$196,451	$171,921
Annual service contract cost (24/7)/Warranty with purchase	—	—	—
Distinguishing features (supplied by company)	simultaneous curve calibrating and patient testing; ability to load multiple bottles or multiple lots of reagent; user-definable, repeat, redilute, and reflex testing	fast throughput for routine testing; continuous loading of reagents, consumables, and patient samples without interruption; connectivity to lab automation system	user-definable calibration curve expiration and prewarning alerts; user-definable bar-code utility enables customizable reagent protocols; user-friendly Windows XP software

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

Tabulation does not represent an endorsement by the College of American Pathologists.