Coagulation analyzers

Part 1 of 11	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de
Instrument name/first year sold	CD2000/1986	CoaData 2004/4004/2010
No. of units installed in U.S./Outside U.S.	>500/>1,000	just registered Dec. 2010/>500
No. of contracts signed between 1/1/09 and 11/30/09	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany
Operational type	batch, discrete	discrete
Reagent type	open reagent system (reconstituted manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	semiautomated manual pipette-auto start
Model type	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	5 × 12 × 8.5 in/9.2 lbs/1 sq ft	10.7 × 13.7 × 4.9 in/8.6 lbs/2 sq ft
FDA-cleared clotting-based tests	PT, PTT, fib., any citrated plasma clot-based assay	PT, APTT
FDA-cleared chromogenic tests	—	—
FDA-cleared immunologic tests	—	—
Other FDA-cleared tests	—	—
User-defined tests in clinical use	—	—
Tests submitted for 510(k) clearance	—	APTT
Tests in development but not yet submitted	—	fibrinogens, D-dimer, factor assay (clotting and points)
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing–optical detection	clot detection, optical; turbodensitometric
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no
No. of different measured assays onboard simultaneously	2 (PT, APTT)	1
No. of different assays programmed and calib. at one time	1 (fib.)	2
No. of user-definable (open) channels	2	2
Of those defined, No. active simultaneously	2	2
Factor assays require manual manipulation or dilutions	yes	yes
No. of reag. containers onboard at once/Tests per container	5 or more/reagent manufacturer defined	4/reagent manufacturer defined
Reagents refrigerated onboard	no	no
Multiple reag. configurations supported	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes
Max. time same lot No. of reag. can be used	laboratory dependent	reagent manufacturer defined
Walkaway capacity: No. of specimens/No. of tests	—/—	18 incubational positions/2
Min. sample vol. aspirated precisely at one time	manual pipetting	50 µL (150 µL total volume)
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 50 µL/50 µL, min. 50 µL	100 µL/100 µL
Disposables used/Price of each	500 microcuv. w/mixers in trays/11.6¢ ea., bulk 11¢; 500 macrocuv. w/mixers in trays/12¢ ea., bulk 10.6¢; 2,304 pipette tips-trayed/5.1¢ ea., 3k tips bulk/3.9¢ ea.	individual cuvettes: 100/tray, 5 trays/box, box = $84.87; plastic reagent vials: 144/box, box = $36.51; 3,000 pipettes/box, box = $167.71
Supports direct-from-track sampling	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	no/no
Sample bar-code reading capability	no	no
Reagent bar-code reading capability	no	no
Onboard test automatic inventory	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	no
Hemolysis/Turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/no
Lag time during which hypercoagulable samp. not detected	yes (3 sec)	no
Read time extended for prolonged clotting times	yes, up to 999 sec	yes, selectable on operator menus
User can set different-than-standard:		
• Reag. volumes/Sample volumes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes
• Incub. times/Reading times	yes/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	120 sec/user defined	limited by user pipetting capabilities
• PT, PTT	240 sec/user defined	limited by user pipetting capabilities
• Fibrinogen	300 sec/user defined	limited by user pipetting capabilities
• Factor VIII activity assay	300 sec/user defined	limited by user pipetting capabilities
Time delay from ordering stat to aspir. of sample	—, all preanalytical	—
Auto. transfer of QC results to LIS	no	no
Data management capability	no	onboard
Interface supplied by instrument vendor	no	no
Interfaces in active user sites for:	call technical support for inquiry	not yet
Bidirectional interface capability	no	no
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	no	no
How labs get LOINC codes for reagent kits	—	in development
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no
Modem servicing	no	—
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 30 sec; monthly: 5 min	per shift: <1 min (cleaning housing); daily: <1 min (cleaning housing); weekly: <5 min (cleaning housing and incubating block)
Onboard maintenance records	no	no
Training provided with purchase	videotape; on-site training extra	1
Approx. No. of training hours needed per tech	2 hours	1
List price	$900, special pricing upon written request for quote	—
Ann. svc. contract cost (24/7)/Warranty with purchase	add. 1-yr init. contract $500 (opt.)/1 yr, $300 renewal	1 year
Unique advantages (provided by vendors)	smaller clinic; office, private, vet labs; low acquisition and service cost, low maintenance; refurbished units available at reduced prices; able to handle turbid/colored samples	inexpensive 2-channel (2004) and 4-channel (4004) protime instruments with few moving parts; for small lab or doctor's office; updated version of a popular coagumeter (CoaData/Accustasis); low maintenance and repair costs (service contract)

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Survey Editor: Raymond Aller, MD

Coagulation analyzers

Part 2 of 11	Bio/Data Corporation Kay Callahan kay.callahan@biodatacorp.com 155 Gibraltar Road Horsham, PA 19044 www.biodatacorp.com	Cepheid Brian Sunkel brian.sunkel@cepheid.com 904 Caribbean Drive, Sunnyvale, CA 94089 888-838-3222 www.cepheid.com	Chrono-Log Corp. Kathy Jacobs jacobs@chronolog.com Havertown, PA 19083 610-853-1130 www.chronolog.com
Instrument name/first year sold	Platelet Aggregation Profiler, Model-PAP 8E/2005	GeneXpert/2005	Whole Blood-Optical Lumi-Aggregation System, Model 700-2/700-4/2006
No. of units installed in U.S./Outside U.S.	>100/>250	>540/>690	160/205
No. of contracts signed between 1/1/09 and 11/30/09	—	—	—
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, continuous random access	batch, random access
Reagent type	open reagent system, assay kits, reagents, controls, diluents, buffer, specialty products, others	self-contained single-use catridges/packages/slides (lyophilized reconstituted manually)	open reagent system, assay kits, reference plasmas, controls (lyophilized reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	whole blood	whole blood, spun plasma
Sample handling system	programmable electronic pipette	self-contained cartridge	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	22.5 × 14.0 × 21.7 in/45 lbs/2.2 sq ft	GX IV: 14 × 11.75 × 12.25 in/26 lbs/.999 sq ft GX XVI: 30 × 21 × 15 in/125 lbs/.999 sq ft	8.5 × 14.0 × 18.0 in/40 lbs/ M700-2: 1.75; M700-4: 3.5 sq ft
FDA-cleared clotting-based tests	—	—	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	ristocetin cofactor assay, ristocetin and heparin-induced platelet aggregation, platelet aggreg. (ADP, EPI, arachidonic acid, trap< collagen), spontaneous aggregation, sticky platelets, dose response/EC/IC50, others	molecular PCR testing for Factor II/V	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	Xpert HemosIL Factor II/V	platelet dense granule secretion, whole blood impedance aggreg., LTA aggreg. w/all stand. reagents, ristocetin cofactor assay
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	proprietary	—	—
Methodologies supported	UV LED, platelet agglutination, platelet aggreg., turbidometric & rate reaction assays, digital circuitry and software	molecular PCR testing	turbidimetric, platelet dense granule secretion, whole blood impedance aggreg., LTA aggreg., ristocetin cofactor assay
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	yes, 1 assay per pack/—	no/—
No. of different measured assays onboard simultaneously	up to 10	GX IV: 4; GX XVI: 16	2 to 4
No. of different assays programmed and calib. at one time	>256	1 to 16	4 to 8
No. of user-definable (open) channels	8	—	2 to 4
Of those defined, No. active simultaneously	8	GX IV: 4; GX XVI: 16	2 to 4
Factor assays require manual manipulation or dilutions	yes	no	yes
No. of reag. containers onboard at once/Tests per container	2 stirred, adapters for various sized vials/varies	GX IV: 4; GX XVI: 16/1	no/—
Reagents refrigerated onboard	no	no, temp: 15° to 30°C	no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	no	no
Max. time same lot No. of reag. can be used	up to 18 months	—	12–30 months
Walkaway capacity: No. of specimens/No. of tests	—/8	GX-IV: 4; GX-XVI: 16/GX-IV: 4; GX-SVI: 16	2–4/4–8
Min. sample vol. aspirated precisely at one time	25 µL	—	—
Standard specimen vol. required to run PT or PTT/Factor VIII activity	—/—	—/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	siliconized test tubes: 100 @ $25.25, plastic-coated stir bars: 50 @ $13.50, pipette tips: 960 @ $30.55	Xpert Cartridge	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 bar-code reading capability	yes	yes	no
Reagent bar-code reading capability	yes	yes	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. detection of adequate reag. for aspir. & anal.	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 samp. not detected	no	—	—/—
Read time extended for prolonged clotting times	no	—	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	no/no	yes/yes
• No. and sources of reag.	yes	no	yes
• Incub. times/Reading times	yes/yes	no/no	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/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	—/—	—/—	—/—
• PT, PTT	—/—	—/—	—/—
• Fibrinogen	—/—	—/—	—/—
• Factor VIII activity assay	—/—	—/—	—/—
Time delay from ordering stat to aspir. of sample	—	—	—
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	yes (onboard, includes QC: L-J plots, Westgard)	yes (onboard, includes QC)	yes (onboard)
Interface supplied by instrument vendor	no	no	yes
Interfaces in active user sites for:	—	HL7 and ASTM compatible	—
Bidirectional interface capability	yes (host query)	yes (broadcast download & 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	e-mail 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 min; monthly: 30 min	daily: 5 min; weekly: 15 min; monthly: 60 min	30 min when optical calibration required
Onboard maintenance records	yes	no	yes
Training provided with purchase	1.5 days on site	1 day on site	1.5 days on site
Approx. No. of training hours needed per tech	4–6 hours	2 hours	8 hours
List price	$15,490	GX IV: $78,200	M700-2: $19,500; M700-4: $32,000
Ann. svc. contract cost (24/7)/Warranty with purchase	$1,990 for 1 yr, $2,990 for 2 yrs/2 yrs	$9,150/12 months	M700-2: $1,804; M700-4: $3,008 for 3 years
Unique advantages (provided by vendors)	two-year warranty; no-charge software upgrades during warranty period; optional PDQ platelet function centrifuge standardizes sample preparation, reduces preparation time to five minutes	walkaway real-time PCR system; self-contained assay cartridges perform sample clean-up and extraction; contains PCR reagents, primers, and probes; internal controls; integrated detection tube; bar codes identify sample test cartridge; <2 min. hands-on per sample; factor II & V results ~30 min. from sample prep through result reporting	tests platelet aggregation; measures ATP release in 4 samples simult. using whole blood, PRP, washed, or gel-filtered platelets; continuously monitors temp. and stirring speed w/front-panel error messages; optical calibration by lab personnel; dedicated software pkgs. calculate amplitude, slope, lag time, area under curve, ATP release in nmoles, and more

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Coagulation analyzers

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Instrument name/first year sold	**STA Satellite/2010**	**STA-R Evolution Hemostasis System/2005**	**STA Compact CT/2001**
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/09 and 11/30/09	—	—	—
Country where analyzer designed/Manufactured	France/France	France/France	France/France
Operational type	random access	continuous random access	continuous random access
Reagent type	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	carousel	rack with continuous specimen access	continuous specimen access—primary tube
Model type	benchtop	floor standing	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	27.4 × 21.1 × 25.5 in/72 lbs/4 sq ft	49.2 × 50.3 × 32.2 in/507 lbs/26.8 sq ft	25.2 × 38.8 × 25.8 in/351 lbs/25.6 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C & S, lupus anticoagulant, dRVVT, screeen and confirm	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C & S, lupus anticoagulant, dRVVT
FDA-cleared chromogenic tests	heparin (UFH, LMWH), AT	heparin (UFH & LMWH), protein C, AT, plasminogen, antiplasmin	—
FDA-cleared immunologic tests	D-dimer	D-dimer, VWF, total & free protein S, AT antigen	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	APCR, other clotting chromogenic & immunological tests with user-defined applications	APCR, other clotting tests can have user-defined applications
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clot detection, mechanical; chromogenic; immunologic	clot detection: mechanical; chromogenic; immunologic	clot detection, mechanical
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	up to 80	up to 200	up to 80
No. of different assays programmed and calib. at one time	up to 80	up to 200	up to 80
No. of user-definable (open) channels	70	200	70
Of those defined, No. active simultaneously	70	200	70
Factor assays require manual manipulation or dilutions	—	no	no
No. of reag. containers onboard at one time/Tests per container	16/varies	70/varies	45/varies
Reagents refrigerated onboard	yes (15° to 19°C)	yes (15° to 19°C)	yes (15° to 19°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	no	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18 months	18 months	18 months
Walkaway capacity: No. of specimens/No. of tests	20/12 per specimen	215/32	96/12 per specimen
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/5 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes & wash solution/varies with volume	cuvettes & wash solution/varies with volume	cuvettes & wash solution/varies with volume
Supports direct-from-track sampling	no	yes (Beckman Coulter, Bayer LabCell, Roche MPA)	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	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. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for mechanical detection technology)	no/no (not necessary for mechanical detection technology)	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 samp. not detected	no	no	no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. 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	7 min/52 specimens	<6 min/~300 specimens	<6 min/150 specimens
• PT, PTT	7 min/36 specimens	7 min/~150 specimens	7 min/75 specimens
• Fibrinogen	7 min/36 specimens	7 min/~180 specimens	7 min/75 specimens
• Factor VIII activity assay	—/—	7 min/~180 specimens	7 min/70 specimens
Time delay from ordering stat to aspir. of sample	<15 sec	<15 sec	<15 sec
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots)	onboard (L-J plots)	onboard (incl. QC: 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 (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	yes (Beckman Coulter, Bayer LabCell, Roche MPA)	no
Modem servicing	no	yes	no
Time required for maintenance by lab personnel	weekly: <30 min; monthly: 30 min	daily: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <30 min; monthly: <30 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	2 days on site	varies on site, 4 days at vendor offices	varies on site, 3 days at vendor office
Approx. No. of training hours needed per tech	2 hours	~3–5 hours	2 hours basic
List price	$45,000	$161,900	$50,000
Ann. svc. contract cost (24/7)/Warranty with purchase	prices available on request/1 yr	prices available upon request/1 yr	prices available on request/1 yr
Unique advantages (provided by vendors)	viscosity-based detection system; standardization across all STA analyzers allows consistent reporting throughout hospital groups; complete walkaway automation for low-volume coagulation laboratories	viscosity-based detection system; connectivity to lab automation systems; software for password protection and result traceability; able to standardize with other STA analyzers	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; able to standardize with other STA systems

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Coagulation analyzers

Part 4 of 11	Diagnostica Stago Inc. Bob Bachkosky bob.bachkosky@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Larry Wright larry.wright@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com
Instrument name/first year sold	Start 4/1998	STA Compact Hemostasis System/1996	AggRAM/2005
No. of units installed in U.S./Outside U.S.	—/—	—/—	80/100+
No. of contracts signed between 1/1/09 and 11/30/09	—	—	—
Country where analyzer designed/Manufactured	France/France	France/France	U.S./U.S.
Operational type	batch	continuous random access	batch, random access
Reagent type	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma, PRP
Sample handling system	manual	continuous specimen access—primary tube	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	4.7 × 16.1 × 16.5 in/12.5 lbs/1.8 sq ft	25.2 × 38.8 × 25.8 in/351 lbs/25.6 sq ft	6 × 10 × 17 in/15 lbs/—
FDA-cleared clotting-based tests	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C & S, lupus anticoagulant	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C & S, lupus anticoagulant, dRVVT, screeen and confirm	none
FDA-cleared chromogenic tests	none	heparin (UFH & LMWH), protein C, AT, plasminogen, antiplasmin	none
FDA-cleared immunologic tests	none	D-dimer, VWF, total & free protein S, AT antigen	none
Other FDA-cleared tests	—	—	ristocetin cofactor and platelet aggreg.
User-defined tests in clinical use	dRVVT screen & confirm assays, APCR, other clotting tests with user-defined applications	APCR, other clotting chromogenic & immunological tests with user-defined applications	ristocetin cofactor, platelet aggreg.–ADP, EPI, COL, ristocetin, arach. acid
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clotting tests	clotting, chromogenic, & immunologic assays	ristocetin cofactor, platelet aggreg.
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	1	up to 80	4–8
No. of different assays programmed and calib. at one time	20	up to 80	4–8
No. of user-definable (open) channels	4	70	12
Of those defined, No. active simultaneously	1	70	4–8
Factor assays require manual manipulation or dilutions	yes	no	yes
No. of reag. containers onboard at one time/Tests per container	4/varies	45/varies	—/—
Reagents refrigerated onboard	no	yes (15° to 19°C)	no
Multiple reag. configurations supported	yes	yes	no
Reag., consumables loaded without interrupting testing	no	yes	no
Same capabilities when 3rd-party reag. used	yes	yes	—
Max. time same lot No. of reag. can be used	18 months	18 months	12 months
Walkaway capacity: No. of specimens/No. of tests	4/1	96/12 per specimen	no
Min. sample vol. aspirated precisely at one time	25 µL	5 µL	—
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/5 µL	50 µL/5 µL	Plt. aggreg.: 225 µL PRP, Risto cofactor: 50 µL
Disposables used/Price of each	cuvettes, balls/varies	cuvettes & wash solution/varies with volume	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 (not applicable)	yes/yes	no
Sample bar-code reading capability	no	yes	no
Reagent bar-code reading capability	no	yes	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	—
Auto. detection of adequate reag. for aspir. & anal.	no	yes	no
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for mechanical detection technology)	no/no (not necessary for mechanical detection technology)	no/no
Dilution of patient samples onboard	no	yes	no
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	no/no
Lag time during which hypercoagulable samp. not detected	no	no	—
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	—
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	no	no (not necessary)/no (not necessary)	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<1 min/up to 120 specimens	<6 min/150 specimens	—
• PT, PTT	—/—	7 min/75 specimens	—
• Fibrinogen	<1 min/up to 120 specimens	7 min/75 specimens	—
• Factor VIII activity assay	varies/varies	7 min/70 specimens	—
Time delay from ordering stat to aspir. of sample	<15 sec	<15 sec	—
Auto. transfer of QC results to LIS	no	yes	yes
Data management capability	no	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	Cerner, Misys, Meditech, others	—
Bidirectional interface capability	no	yes (host query)	no
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	—
Time required for maintenance by lab personnel	daily: none; weekly: <5 min; monthly: <5 min	daily: none; weekly: <30 min; monthly: <30 min	daily: 15 min; weekly: 15 min; monthly: 1 hour
Onboard maintenance records	no	yes	yes
Training provided with purchase	1 day on site	varies on site, 3 days at vendor offices	2 days on site
Approx. No. of training hours needed per tech	1 hour	2 hours basic	4–8 hours
List price	$9,600	$75,000	$14,995
Ann. svc. contract cost (24/7)/Warranty with purchase	prices available on request/1 yr	prices available on request/1 yr	$1,800/1 yr
Unique advantages (provided by vendors)	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	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; able to standardize with other STA analyzers	specialized coag instrument intended for platelet aggreg. & ristocetin cofactor

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Coagulation analyzers

Part 5 of 11	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com	Instrumentation Laboratory Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-4252 www.beckmancoulter.com
Instrument name/first year sold	**Cascade M-4/1992**	**Cascade M/1991**	**ACL AcuStar/2010**
No. of units installed in U.S./Outside U.S.	200+/30	300+/100	0/10
No. of contracts signed between 1/1/09 and 11/30/09	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	random access	batch	random access
Reagent type	open reagent system	open reagent system	self-contained multi-use cartridges-packages-slides (liquid)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	8 × 15 × 13 in/25 lbs/1.4 sq ft	8 × 15 × 13 in/25 lbs/1.4 sq ft	21 × 34 × 24 in/170 lbs/15 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TCT, factor assays II, V, VII–XII	PT, APTT, fib., TCT, factor assays II, V, VII–XII	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	D-dimer (chemiluminescent)
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	PT, APTT, fib., TCT, factor assays II, V, VII–XII	PT, APTT, fib., TCT, factor assays II, V, VII–XII	—
Tests submitted for 510(k) clearance	—	—	anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM
Tests in development but not yet submitted	dRVVT	dRVVT	HIT IgG, HIT total
Methodologies supported	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric	immunologic (chemiluminescent)
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	4	1	20
No. of different assays programmed and calib. at one time	4	1	20
No. of user-definable (open) channels	4	2	0
Of those defined, No. active simultaneously	2	1	—
Factor assays require manual manipulation or dilutions	yes	yes	—
No. of reag. containers onboard at one time/Tests per container	0/—	—/—	20/varies by assay
Reagents refrigerated onboard	no	—	yes (4°C)
Multiple reag. configurations supported	no	—	no
Reag., consumables loaded without interrupting testing	no	no	no
Same capabilities when 3rd-party reag. used	yes	yes	no
Max. time same lot No. of reag. can be used	12 months	12 months	—
Walkaway capacity: No. of specimens/No. of tests	no	no	30/—
Min. sample vol. aspirated precisely at one time	manual-50 µL	manual-50 µL	—
Standard specimen vol. required to run PT or PTT/Factor VIII activity	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)	—/—
Disposables used/Price of each	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvettes/price available upon request
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/—	no/—	yes (most tubes validated)/no
Sample bar-code reading capability	no	no	yes
Reagent bar-code reading capability	no	no	yes
Onboard test automatic inventory	no	no	yes
Measures No. of tests remaining/Short sample detection	no/no	no/no	yes/yes
Clot detection as preanalytical variable in plasma sample	—	—	no
Auto. detection of adequate reag. for aspir. & anal.	no	no	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	no	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/no
Lag time during which hypercoagulable samp. not detected	yes (PT: 4 sec, PTT: 14 sec)	yes (PT: 4 sec, PTT: 14 sec)	—
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	—
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	no/no
• No. and sources of reag.	yes	yes	no
• Incub. times/Reading times	yes/yes	yes/yes	no/no
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	yes/yes
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	3 min/140 specimens	3 min/120 specimens	—
• PT, PTT	7 min/80 specimens	7 min/50 specimens	—
• Fibrinogen	3 min/160 specimens	3 min/140 specimens	—
• Factor VIII activity assay	7 min/80 specimens	7 min/50 specimens	—
Time delay from ordering stat to aspir. of sample	—	—	<1 min
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	no (includes QC: L-J plots)	no (includes QC: L-J plots)	onboard (includes QC: L-J plots and Westgard multirule)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	no	yes (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
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 10 min; weekly: 10 min; monthly: 30 min	daily: 10 min; weekly: 10 min; monthly: 20 min	daily: 10 min; weekly: 10 min
Onboard maintenance records	no	no	no
Training provided with purchase	1 day on site	1 day on site	—
Approx. No. of training hours needed per tech	2 hours	2–4 hours	6 hours
List price	$9,635	$7,127	—
Ann. svc. contract cost (24/7)/Warranty with purchase	$966/1 yr	$714/1 yr	—
Unique advantages (provided by vendors)	4-channel manual analyzer; QC program onboard; singles or duplicates	QC program onboard; curve storage; suitable for office lab or as backup analyzer	easy to use, utilizing sensitive chemilumiescent technology, providing results <1 hour; for many complex coag assays, replaces the need to run manual, time-consuming ELISA assays; test menu will include assays whose rapid results will improve patient care and lab efficiences

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Coagulation analyzers

Part 6 of 11	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea 92821 714-961-4252 www.beckmancoulter.com	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea 92821 714-961-4252 www.beckmancoulter.com	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea 92821 714-961-4252 www.beckmancoulter.com
Instrument name/first year sold	ACL TOP 500 CTS/2008	ACL Elite Series/2006	ACL TOP Series/2004
No. of units installed in U.S./Outside U.S.	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)
No. of contracts signed between 1/1/09 and 11/30/09	150	210	45
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	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	racks, allowing continuous loading of samples	tray-primary tubes	racks, continuous loading of primary tubes
Model type	benchtop, floor-standing	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 43 × 35 in/312 lbs/14 sq ft	23.6 × 36.2 × 23.6 in/138.6 lbs/6 sq ft	28.7 × 59.4 × 35 in/330.7 lbs/21 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, factors, lupus (SCT & dRVVT), protein C/S, APCR factor V leiden	PT, APTT, fib., TT, factors, protein C/S, lupus (SCT & dRVVT), APCR-V	PT, APTT, fib., TT, factors, lupus (SCT & dRVVT), APCR-V, protein C/S
FDA-cleared chromogenic tests	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	heparin Xa, protein C, AT plasminogen, plasmin inhibitor, factor VIII	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor
FDA-cleared immunologic tests	D-dimer, D-dimer HS, vWF (Act. & Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer, vWF (Act. & Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer, D-dimer HS, vWF (Act. & Ag.), free protein S, factor XIII Ag., homocysteine
Other FDA-cleared tests	—	none	none
User-defined tests in clinical use	—	none	none
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	global protein C pathway	—	global protein C pathway
Methodologies supported	clot detection, LED optical, chromogenic; immunologic (turbidimetric)	clot detection, LED optical (nephelometric); chromogenic; immunologic	clot detection, LED optical, chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	500	22	500
No. of different assays programmed and calib. at one time	500	300	500
No. of user-definable (open) channels	250	100	250
Of those defined, No. active simultaneously	30	20	30
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	40/varies by assay	22/varies by test	60/varies
Reagents refrigerated onboard	yes	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18 months	18 months	18 months
Walkaway capacity: No. of specimens/No. of tests	80/800	40/260	120/800
Min. sample vol. aspirated precisely at one time	4 µL	5 µL	4 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	PT and PTT: 50 µL; FVIII: 25 µL	PT and PTT: 60 µL; FVIII: 18 µL	PT and PTT: 50 µL; FVIII: 25 µL
Disposables used/Price of each	cuvettes/varies	rotors/varies	cuvettes/varies
Supports direct-from-track sampling	no	no	yes (model available)
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes/yes (optional)
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. detection of adequate reag. for aspir. & anal.	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 samp. not detected	no	yes (PT & PTT: 3 sec)	no
Read time extended for prolonged clotting times	yes (selectable on operator menus)	yes	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. 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	not needed	not needed	not needed
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 min/240 specimens	4 min/175 specimens	<3 min/360 specimens
• PT, PTT	8 min/90 specimens	8 min/125 specimens	8 min/165 specimens
• Fibrinogen	<3 min/78 specimens	4 min/175 specimens	<3 min/108 specimens
• Factor VIII activity assay	8 min/77 specimens	8 min/125 specimens	8 min/100 specimens
Time delay from ordering stat to aspir. of sample	minimal	15 sec	minimized
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes (incl. QC: L-J plots, Westgard)	yes	yes
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 & host query)	yes (broadcast download & 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	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
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: <10 min; weekly: 10 min	daily: <5 min; weekly: 10 min; monthly: 5 min	daily: <10 min; wkly: 10 min; no monthly maintenance
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
Approx. No. of training hours needed per tech	24–40 hours	24 hours	24–40 hours
List price	$130,900	$54,000	$145,000
Ann. svc. contract cost (24/7)/Warranty with purchase	various options available/1 yr	various options available/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	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 hep with universal cal curve for UFH and LMWH	test menu featuring D-dimer; bar-code reagent management; ACL family harmonization; HemosIL INR plasma sets for INR test system validation and/or calibration; HemosIL liq. hep with universal cal curve for UFH and LMWH	features clot signature curve analysis; continuous operation w/o 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 and/or calibration; HemosIL liq. hep with universal cal curve for UFH and LMWH

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Coagulation analyzers

Part 7 of 11	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea 92821 714-961-4252 www.beckmancoulter.com	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.siemens.com/diagnostics
Instrument name/first year sold	ACL Classic Series/1997	BFT II/U.S.: 1999	Sysmex CA-530/2006
No. of units installed in U.S./Outside U.S.	4,000+ (all models combined)/8,000+ (all models combined)	—/—	—/—
No. of contracts signed between 1/1/09 and 11/30/09	35	—	—
Country where analyzer designed/Manufactured	Italy/U.S.	Germany/Germany	Japan/Japan
Operational type	random programming	batch	continuous random access
Reagent type	open reagent system	open reagent system (reconst. manually)	open reagent system (reconst. manually), optimized for Siemens instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray-primary tubes or sample cups	manual	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	17.7 × 29.5 × 24.8 in/114 lbs/6 sq ft	3.9 × 7.9 × 11.8 in/8.4 lbs/1.5 sq ft	19 × 21 × 18.5 in/99 lbs/9 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, factors, protein C/S, lupus (dRVVT), APCR-V	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, reptilase time, protien C clot, factor assays
FDA-cleared chromogenic tests	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	—	Innovance AT, Berichrom AT, protein C chromo, heparin
FDA-cleared immunologic tests	—	—	
Other FDA-cleared tests	—	none	none
User-defined tests in clinical use	—	none	—
Tests submitted for 510(k) clearance	—	none	—
Tests in development but not yet submitted	—	none	PT multi-calibrators
Methodologies supported	clot detection, LED optical, (nephelometric); chromogenic; immunologic	turbodensitometric	clot detection: optical; turbidimetric, chromogenic; immunol.
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	4	1	5
No. of different assays programmed and calib. at one time	up to 27	3	7
No. of user-definable (open) channels	0	—	7
Of those defined, No. active simultaneously	4	1	5
Factor assays require manual manipulation or dilutions	no	—	no
No. of reag. containers onboard at one time/Tests per container	7/varies by test	4/up to 200	11/varies, up to 200
Reagents refrigerated onboard	yes (15°C)	no	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	no	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18 months	12 months	12 months
Walkaway capacity: No. of specimens/No. of tests	18/20	1/1	10/50
Min. sample vol. aspirated precisely at one time	10 µL	50 µL	10 µL/50 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	PT and PTT: 50 µL/—	50 µL	50 µL/—
Disposables used/Price of each	rotors/varies	cuvettes, printer paper/varies with volume	reaction tubes, CA clean I, thermal paper/varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	no/no	yes (3-5 mL)/no
Sample bar-code reading capability	yes	no	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	no	yes
Measures No. of tests remaining/Short sample detection	no/yes	no/no	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	yes/no
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable samp. not detected	yes (PT & PTT: 5.6 sec)	yes (PT: 5 sec, APTT: 15 sec)	yes (<7 sec for PT; <15 sec for APTT)
Read time extended for prolonged clotting times	yes	no	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	no/no	yes/yes	yes/yes
• No. and sources of reag.	no	yes	yes
• Incub. times/Reading times	no/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	not needed	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	5.5 min/175 specimens	1 min/—, manual	7 min/54 results
• PT, PTT	8.5 min/110 specimens	—, manual	8 min/43 results
• Fibrinogen	5.5 min/175 specimens	<1 min/—, manual	7 min/54 results
• Factor VIII activity assay	9.5 min/110 specimens	—	—
Time delay from ordering stat to aspir. of sample	15 sec	—	2 min
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	yes	no	onboard (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	—	no
Interfaces in active user sites for:	most major LIS vendors	—	all major LIS vendors
Bidirectional interface capability	yes (host query)	no	yes (host query after manual ID input)
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	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: 1 min	daily: <5 min; weekly: 1 min; quarterly: <5 min
Onboard maintenance records	yes	no	no
Training provided with purchase	2 days on site	Web CD training course	2 days on site, online training course, Web CD training
Approx. No. of training hours needed per tech	12 hours	2 hours	2 hours
List price	$21,500	$8,685	$34,812
Ann. svc. contract cost (24/7)/Warranty with purchase	various options available/1 yr	prices available upon request	prices available upon request
Unique advantages (provided by vendors)	ACL model to fit your testing needs	2-channel micro reagent volume clot-based technology; opto-mechanical detection accurate on lipemic, icteric samples; automatic INR calculation, curve storage, built-in thermal printer; perfect for low-volume testing/backup to larger systems	small footprint; onboard quality control package; primary tube sampling and removable reagent trays

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Coagulation analyzers

Part 8 of 11	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road, Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road, Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road, Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics
Instrument name/first year sold	Sysmex CA-560/U.S.: 2003	Sysmex CA-1500/U.S.: 2000; worldwide: 1999	Sysmex CA-7000/2002
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/09 and 11/30/09	—	—	—
Country where analyzer designed/Manufactured	Japan/Japan	Japan/Japan	Japan/Japan
Operational type	continuous random access	continuous random access	continuous random access
Reagent type	open reagent system (reconst. manually), optimized for Siemens instruments	open reagent system (lyoph., reconst. manually), optimized for Siemens instruments	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack	10-tube position sample rack × 5	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	19 × 21 × 18.5 in/99 lbs/9 sq ft	20 × 31.2 × 31.2 in/186 lbs/6.8 sq ft	24.8 × 42 × 43.8 in/345.4 lbs/12.78 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays	PT, APTT, fibrinogen, TT, reptilase time, factor assays, dRVVT screen & confirm, factor V Leiden, protein C clot, protein S activity	PT, APTT, fib., TT, reptilase time, factor assays, dRVVT screen & confirm, factor V Leiden, protein C clot, protein S activity
FDA-cleared chromogenic tests	Innovance AT, Berichrom AT, 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	Advanced D-dimer, Innovance D-dimer	Advanced D-dimer, Innovance D-dimer	Advanced D-dimer, Innovance D-dimer
Other FDA-cleared tests	none	none	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	PT multicalibrators	PT multicalibrators	PT multicalibrators
Methodologies supported	clot detect., optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	5	15	20
No. of different assays programmed and calib. at one time	7	25	40
No. of user-definable (open) channels	7	25	40
Of those defined, No. active simultaneously	5	15	20
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	11/varies, up to 200	39/up to 200	58/varies up to 200
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	consumables yes, reagents no	some consumables yes, reagents no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12 months	12 months	12 months
Walkaway capacity: No. of specimens/No. of tests	10/50	50/up to 1,000	100/550 per hour PT and APTT, 300 per hour PT
Min. sample vol. aspirated precisely at one time	10 µL	5 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/10 µL	50 µL/10 µL
Disposables used/Price of each	reaction tubes, CA clean I, thermal paper/varies with volume	reaction tubes, sample plates, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/varies with volume	reaction tubes, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/ varies with volume
Supports direct-from-track sampling	no	yes (Sysmex CST series)	yes (custom automation solutions available)
Primary tube sampling supported/Pierces caps on primary tubes	yes (3–5 mL)/no	yes (3–5 mL)/yes	yes (3–5 mL)/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	no	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. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/no	yes/no	yes/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/yes	yes/yes
Lag time during which hypercoagulable samp. not detected	yes (PT: <7 sec, APTT: <15 sec)	yes (PT: 7 sec, APTT: 15 sec)	yes (PT: 7 sec, APTT: 15 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. 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	7 min/54 results	7 min/120 results	7 min/280 results
• PT, PTT	8 min/43 results	8 min/80 results	8 min/480 results
• Fibrinogen	7 min/54 results	8 min/120 results	8 min/280 results
• Factor VIII activity assay	—	8 min/—	8 min/300 results
Time delay from ordering stat to aspir. of sample	2 min	2 min	2 min
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots & Westgard)	onboard (incl. QC: L-J plots & Westgard)
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	no	yes (Sysmex CST series)	custom automated connectivity with StreamLab
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: <5 min; weekly: 1 min; quarterly: < 5 min	daily: <5 min; weekly: 1 min; quarterly: <5 min	daily: <10 min; weekly: 1 min; monthly: <5 min; quarterly: <5 min
Onboard maintenance records	no	no	no
Training provided with purchase	2 days on site, online training course, Web CD training	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
Approx. No. of training hours needed per tech	2 hours	6 hours	8 hours on site
List price	$47,634	$97,529 standard model; $110,544 cap-piercing model	$196,451
Ann. svc. contract cost (24/7)/Warranty with purchase	prices available upon request	prices available upon request	prices available upon request
Unique advantages (provided by vendors)	five-parameter true random-access clotting/ chromogenic/immunologic technology; complete automation, specialty assay capability; low operating expense	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

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Coagulation analyzers

Part 9 of 11	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics	Trinity Biotech Kevin McGlinchey kevin.mcglinchey@trinityusa.com 400 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech Kevin McGlinchey kevin.mcglinchey@trinityusa.com 400 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	BCS XP/2006	KC1△/2001	KC4△/2001
No. of units installed in U.S./Outside U.S.	—/—	>250/>100	>100/>100
No. of contracts signed between 1/1/09 and 11/30/09	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	batch, continuous random access	semiautomatic, single channel	semiautomatic, 4 channels
Reagent type	open reagent system (reconst. manually), optimized for Siemens instruments	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	37 × 49 × 25 in/330 lbs/14 sq ft	3.25 × 5.5 × 8.25 in/2.5 lbs/<1 sq ft	4.7 × 13.9 × 17.7 in/14 lbs/1.7 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	PT, APTT, fib.	PT, APTT, fib., TT, atroxin, intrinsic & extrinsic factors
FDA-cleared chromogenic tests	Innovance AT, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin,	—	—
FDA-cleared immunologic tests	Advanced D-dimer, Innovance D-dimer	—	—
Other FDA-cleared tests	BC von Willebrand-risto. cofactor assay (agglut of fixed plts)	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	ETP (for research use only), PT multicalibrators	—	—
Methodologies supported	clot detection, optical (xenon flasher lamp); chromogenic; immunologic	clot detection, mechanical	clot detection, mechanical
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	>100 tests/samples	1	5
No. of different assays programmed and calib. at one time	99	manual	1/1
No. of user-definable (open) channels	7,999	—	—
Of those defined, No. active simultaneously	>100	—	up to 4
Factor assays require manual manipulation or dilutions	no	yes	yes
No. of reag. containers onboard at one time/Tests per container	90/varies, up to 200	1/varies for each assay	5/varies for test kit
Reagents refrigerated onboard	yes (<15°C)	no	no
Multiple reag. configurations supported	yes	no	no
Reag., consumables loaded without interrupting testing	yes	—, manual	—, manual
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12 months	12–18 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	100 samples/400 cuvettes	—, manual	—, manual
Min. sample vol. aspirated precisely at one time	3 µL	—	—
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/20 µL, min 100 µL (incl. dead vol)/50 µL, min 100 µL	50 µL/—	50 µL/10 µL
Disposables used/Price of each	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/varies with volume	cuvettes & ball dispenser/available on request	cuvettes & ball dispenser/available on request
Supports direct-from-track sampling	no	—	—
Primary tube sampling supported/Pierces caps on primary tubes	yes (all up to 100 mm long, ext. diam. 11-16 mm)/no	—	—
Sample bar-code reading capability	yes	—	—
Reagent bar-code reading capability	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. detection of adequate reag. for aspir. & anal.	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 samp. not detected	yes (7 sec for PT & APTT)	yes (PT & PTT: 4.5 sec)	yes (PT & PTT: 4.5 sec)
Read time extended for prolonged clotting times	yes	yes	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/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	<5 min/~380 results (including abnormals)	75 sec/48 tests	75 sec/48 tests
• PT, PTT	<5 min/~325 results (including abnormals)	350 sec/10 tests	350 sec/10 tests
• Fibrinogen	<5 min (if curve available)~315 results	65 sec/55 tests	65 sec/55 tests
• Factor VIII activity assay	<5 min (if curve available)~280 results	275 sec/13 tests	275 sec/13 tests
Time delay from ordering stat to aspir. of sample	varies by test in progress, appox. >5 min	—	—
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes, onboard (incl. QC: L-J plots)	yes	yes
Interface supplied by instrument vendor	no	no	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	yes	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 min; weekly: <10 min.; monthly: 15 min	none	none
Onboard maintenance records	yes	—	—
Training provided with purchase	3 days at vendor offices for 2 key operators, online training course	as needed on site	as needed on site
Approx. No. of training hours needed per tech	8 hours on site	2 hours	2 hours
List price	$171,921	$2,206	$9,660
Ann. svc. contract cost (24/7)/Warranty with purchase	prices available upon request	available upon request	available upon request
Unique advantages (provided by vendors)	user-definable calibration curve expiration and prewarning alerts; user-definable bar-code utility enables customizable reagent protocols; user-friendly Windows XP software	patented ball technology for reproducible and reliable results; provides significant cost savings when used with Trinity's reagents and controls	4 test positions can be used simultaneously; patented ball method for reproducible and reliable results; provides significant cost savings when used with Trinity's reagents and controls

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Coagulation analyzers

Part 10 of 11	Trinity Biotech Kevin McGlinchey kevin.mcglinchey@trinityusa.com 400 Connell Drive, Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech Kevin McGlinchey kevin.mcglinchey@trinityusa.com 400 Connell Drive, Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech Kevin McGlinchey kevin.mcglinchey@trinityusa.com 400 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	Coag-A-Mate XM/1989	Coag-A-Mate MTX/1997	Destiny Plus/2005
No. of units installed in U.S./Outside U.S.	>2,000 worldwide	>500 worldwide	>160/>500
No. of contracts signed between 1/1/09 and 11/30/09	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	Germany & U.S./Germany	Germany & U.S./Germany
Operational type	discrete	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 pipetting into cuvette (4 wells at a time)	rotor (32 positions)	continuous rack loading
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	4.6 × 14.7 × 20 in/20 lbs/2 sq ft	19.7 × 30.7 × 21.3 in/100 lbs/5 sq ft, 8 w/ PC	22 × 33 × 27 in/165 lbs/6.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, XII
FDA-cleared chromogenic tests	none	AT III, hep. antifactor Xa, protein C	AT, heparin Xa
FDA-cleared immunologic tests	none (latex immunologic assay in development)	none (latex immunologic assay in development)	D-dimer
Other FDA-cleared tests	none	none	—
User-defined tests in clinical use	none	alpha-2 antiplasmin, plasminogen, PT mix, APTT mix, LMWH (antifactor Xa)	—
Tests submitted for 510(k) clearance	none	none	—
Tests in development but not yet submitted	none	quantitative D-dimer immunoassay	—
Methodologies supported	clotting assays; photo-optical	clotting, chromogenic assays; photo-optical	clot detection, mechanical & optical (turbidimetric); chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	2	8	10
No. of different assays programmed and calib. at one time	16	32	unlimited
No. of user-definable (open) channels	16	up to 32	unlimited
Of those defined, No. active simultaneously	2	8	10
Factor assays require manual manipulation or dilutions	yes	no	no
No. of reag. containers onboard at one time/Tests per container	4/30–100	16 cooled, 12 room temp. total 28/25–200	31–51/varies
Reagents refrigerated onboard	no	yes (15°C)	yes (12° to 16°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12–18 months	12–18 months	varies by reagent—routine reagents 12 months
Walkaway capacity: No. of specimens/No. of tests	4/4	32/32	50/240
Min. sample vol. aspirated precisely at one time	—	2 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	100 µL/10 µL, min. 10 µL	50 µL/5 µL, min. 2 µL	25 µL/10 µL
Disposables used/Price of each	cuvettes, stir bars, optional: printer & paper/ available on request	cuvette rings, pipettor wash solution, cleaning solution/available on request	reaction trays, ProWash
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes/no	yes (all standard, pediatric, micro)/no
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	no	in development
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/no	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	not necessary
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	yes/yes
Lag time during which hypercoagulable samp. not detected	yes (PT: 7 sec, APTT: 20 sec)	yes (PT: 3 sec, APTT: 5 sec)	no
Read time extended for prolonged clotting times	yes	yes	
User can set different-than-standard:			yes
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	yes/yes
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	2 min/200 results (manual)	2 min/90 results	<3 min/180 tests
• PT, PTT	5 min/50 PTT results (manual)	5 min/60 results	<6 min/90 tests
• Fibrinogen	2–3 min/100 results (manual)	2 min/75 results	<6 min/105 tests
• Factor VIII activity assay	5 min/50 results (manual)	5 min/60 results	<6 min/58 tests
Time delay from ordering stat to aspir. of sample	≤2 min	30–60 sec	varies by test
Auto. transfer of QC results to LIS	no	yes	yes
Data management capability	no	yes (incl. QC: L-J plots)	onboard (incl. QC: LJ plots, Westgard)
Interface supplied by instrument vendor	no	yes (additional cost)	no
Interfaces in active user sites for:	—	all commonly used LISs in North America	all major LIS vendors
Bidirectional interface capability	no	yes	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	no	yes	yes
LOINC codes transmitted with all results	no	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	no
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	daily: none; weekly: ~5 min; monthly: none	daily: ~5 min; weekly: ~1 min; monthly: ~5 min	daily: <5 min; weekly: <30 min; monthly: <30 min
Onboard maintenance records	no	no	yes
Training provided with purchase	half day on site	3 days at vendor offices	2-4 days on site; 3 days at vendor offices
Approx. No. of training hours needed per tech	1–2 hours	2–3 hours	8 hours
List price	$5,173	$52,500	$79,500
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request	available upon request	available upon request
Unique advantages (provided by vendors)	simple to operate: clot detection starts automatically on addition of start reagent; flexibility; test params. can be modified to accommodate various reagent systems	normalization of PT & APTT results between Trinity automated systems; stat results within 2–5 min; flexibility; MTX supports new assays easily through user-programmable method files; internal bar-code reader for sample and test identification	¼-volume patient sample and reagent usage for PT, PTT, fib; mechanical and optical clot detection in one platform; easy to learn and retain IntuiTouch software

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Coagulation analyzers

Part 11 of 11	Trinity Biotech Kevin McGlinchey kevin.mcglinchey@trinityusa.com 400 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech Kevin McGlinchey kevin.mcglinchey@trinityusa.com 400 Connell Drive, Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	Destiny Max/2009	MDA II/1999
No. of units installed in U.S./Outside U.S.	>5/>25	>400 worldwide
No. of contracts signed between 1/1/09 and 11/30/09	0	—
Country where analyzer designed/Manufactured	Germany/Germany	U.S./U.S.
Operational type	continuous random access	continuous random access
Reagent type	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	continuous rack loading	racks
Model type	benchtop	floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	29.5 × 59 × 27 in/340 lbs/11.03 sq ft	58 × 75 × 31 in/840 lbs/18 sq ft w/PC
FDA-cleared clotting-based tests	Open system: All clottable assays can be run on the Destiny Max (PT, PTT, FIB, TT, factors, venom time, prot C, prot S, aPCR, lupus screen and confirm)	PT screening (moderate & low ISI), PT factors, quick%, APTT screening, APTT factors, PT mix, APTT mix, TT, fib.
FDA-cleared chromogenic tests	Open System: All chromogenic assays can be run on the Destiny Max (prot C, AT IIa and Xa based), heparin Xa, plasminogen	hep. antifactor Xa, AT III, protein C, plasminogen, alpha-2 antiplasmin, lupus (dRVVT screen and confirm), APCR
FDA-cleared immunologic tests	Open System: All latex immunoassays can be run on the Destiny Max (D-dimer)	D-dimer (latex immunoassay)
Other FDA-cleared tests	—	none
User-defined tests in clinical use	—	clottable C & S, PNP, P & P (1 & 2), vWF, open assays—user definable for clotting, chrom. & microlatex assays
Tests submitted for 510(k) clearance	—	none
Tests in development but not yet submitted	all coagulation tests	none
Methodologies supported	clot detection, mechanical & optical; chromogenic; immunologic	clotting; chromogenic; immunoassay; photo-optical
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no
No. of different measured assays onboard simultaneously	unlimited	16
No. of different assays programmed and calib. at one time	unlimited	72
No. of user-definable (open) channels	unlimited	20
Of those defined, No. active simultaneously	unlimited	16
Factor assays require manual manipulation or dilutions	no	no
No. of reag. containers onboard at one time/Tests per container	—/varies by test	30/25–400
Reagents refrigerated onboard	yes (12° to 16°C)	yes (8° to 15°C)
Multiple reag. configurations supported	yes	yes
Reag., consumables loaded without interrupting testing	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	no	yes
Max. time same lot No. of reag. can be used	varies—routine reagents 12 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	120/71,000	170/480
Min. sample vol. aspirated precisely at one time	25 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	25 µL/10 µL	50 µL/10 µL
Disposables used/Price of each	reaction trays, ProWash	cuvettes, bar-code labels, MDA probe cleaner/ available on request
Supports direct-from-track sampling	yes	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability	yes	yes (internal bar-code scanner)
Reagent bar-code reading capability	yes	yes
Onboard test automatic inventory	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes
Hemolysis/Turbidity detection-quantitation	not necessary/not necessary	yes/yes (detects bilirubin, corrects for lipemia)
Dilution of patient samples onboard	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	no/no
Lag time during which hypercoagulable samp. not detected	no	yes (PT: default 3 sec, APTT: default 5 sec)
Read time extended for prolonged clotting times	yes	yes (selectable on menus)
User can set different-than-standard:	yes	
• Reag. volumes/Sample volumes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes
• Incub. times/Reading times	yes/yes	no/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	yes/yes	yes/yes
Stat time to complete all analytes/Throughput per hour for:		
• PT alone	<3 min/~350 tests	12 min/180 results
• PT, PTT	<6 min/~232 tests	12 min/180 results
• Fibrinogen	<6 min/~200 tests	12 min/180 results
• Factor VIII activity assay	<6 min/~200 tests	12 min/180 results
Time delay from ordering stat to aspir. of sample	<3 min	<1 min
Auto. transfer of QC results to LIS	yes	yes
Data management capability	onboard (incl. QC: LJ plots, Westgard)	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	yes (additional cost)
Interfaces in active user sites for:	—	all commonly used LISs in North America
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	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	yes
Modem servicing	yes	yes
Time required for maintenance by lab personnel	daily: <5 min; weekly: <10 min; monthly: <30 min	daily: ~35 min; weekly: 45 min; monthly: 10 min
Onboard maintenance records	yes	no
Training provided with purchase	3–5 days on site; 5 days at vendor offices	3–5 days on site, 4 days at vendor offices
Approx. No. of training hours needed per tech	5 hours	4–5 hours
List price	$129,000	$92,295
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request	available upon request
Unique advantages (provided by vendors)	mechanical clot detection via the patented ball method; ¼-volume patient sample and reagent usage for PT, PTT, fib; waveform analysis, dyes in routine reagents for vol. delivery check, factor parallelism; normalization of PT & PTT results between Trinity automated instruments	patented waveform analysis tech. with flags for ident. abnormal waveforms (for example, biphasic samples); sensitive quantitative D-dimer assay for use in VTE diagnosis; dyes in routine reagents for vol. delivery chk; throughput same, regardless of test mix

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