Coagulation analyzers

Part 1 of 10	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	Bio/Data Corporation William M. Trolio bill.trolio@biodatacorp.com 155 Gibraltar Road Horsham, PA 19044 www.biodatacorp.com
Instrument name/first year sold	CD2000/1986	CoaLab/1991	Platelet Aggregation Profiler, Model-PAP 8E/2006
No. of units installed in U.S./Outside U.S.	>500/>1,000	—/—	>50/>215
No. of contracts signed between 1/1/08 and 11/30/08	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	U.S./U.S.
Operational type	batch, discrete	discrete, batch	batch, random access
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)	open reagent system, assay kits, reagents and diluents, controls, reference plasma
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	cuvette ring (automated)	programmable electronic pipette (manual)
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	5 × 12 × 8.5 in/9.2 lbs/1 sq ft	14 × 18 × 41 in/138.6 lbs/6 sq ft	22.5 × 14.0 × 21.7 in/45 lbs/2.2 sq ft
FDA-cleared clotting-based tests	PT, PTT, fib., any citrated plasma clot-based assay	any clot-based detection, PT, APTT, TT, PT-based fibrinogen, Clauss fibrinogen, factor assays, protein C, protein S, LAC screen, LAC confirm, APCR-V	none
FDA-cleared chromogenic tests	none	none	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	none	ristocetin cofactor assay, ristocetin and heparin induced platelet aggregation, platelet aggreg. (ADP, arachidonic acid, collagen, epinephrine), spontaneous aggregation, sticky platelets, dose response/EC/IC50, WBC aggreg.
User-defined tests in clinical use	none	none	trap-6-amide, thrombinj induced platelet aggregation, fibrinogen inhibited thrombin aggregation, other
Tests submitted for 510(k) clearance	none	none	—
Tests in development but not yet submitted	none	none	—
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing–optical detection	clot detection, optical (tungsten, turbidimetric)	UV LED, turbidimetric, ristocetin cofactor, PLT & WBC aggregation
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 (PT, APTT)	30	up to 10
No. of different assays programmed and calib. at one time	1 (fib.)	30	up to 255
No. of user-definable (open) channels	2	2	8
Of those defined, No. active simultaneously	2	varies with test-reagent combination	up to 10
Factor assays require manual manipulation or dilutions	yes	no	yes
No. of reag. containers onboard at once/Tests per container	5 or more/ reag. mftr. dependent	10/varies	2 stirred, adaptors for various size vials/varies
Reagents refrigerated onboard	no	no	no
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	no
Max. time same lot No. of reag. can be used	laboratory dependent	18 months	12–15 months
Walkaway capacity: No. of specimens/No. of tests	—/—	32/30	8/8
Min. sample vol. aspirated precisely at one time	manual pipetting	5 µL	—
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 50 µL/50 µL, min. 50 µL	50 µL, min. 50 µL/<50 µL, min. 50 µL	limited to three tests: PAP *E specimen volumes: PRP, 225 µL for plt agg, 25 µL for ristocetin cofator
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.	sample cups, measurement cuvette rings/varies	test tubes/100 @ $20.75; disposable stirbars/50 @ $19.25; pipette tips/960 @ $28.00
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (13 × 64, 75, 100 mm; 11.5 × 64, 92 mm)/no	no/no
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	no	yes (optional)
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. detection of adequate reag. for aspir. & anal.	no	yes	no
Hemolysis/Turbidity detection-quantitation	no/no	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	yes (3 sec)	yes (3 sec)	no
Read time extended for prolonged clotting times	yes, up to 999 sec	yes (selectable on menus)	no
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/no	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	120 sec/user defined	4 min/140 specimens	—/—
• PT, PTT	240 sec/user defined	8 min/140 specimens	—/—
• Fibrinogen	300 sec/user defined	4 min/140 specimens	—/—
• Factor VIII activity assay	300 sec/user defined	varies/varies	—/—
Time delay from ordering stat to aspir. of sample	none—all preanalytical	15 sec	—
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	yes (incl. QC: L-J plots)	yes (onboard, includes QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	call technical support for inquiry	—	—
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	yes	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 30 sec; monthly: 5 min	daily: 10 min; week: 10 min; month: 5 min; biweek: 5 min	weekly: 15 min; monthly: 30 min
Onboard maintenance records	no	yes	yes
Training provided with purchase	videotape; on-site training extra	varies per site	1.5 days on site
Approx. No. of training hours needed per tech	2 hours	varies	4–6 hours
List price	$900, special pricing upon written request for quote	$25,000	$19,900
Ann. svc. contract cost (24/7)/Warranty with purchase	add. 1-yr init. contract $500 (opt.)/1 yr, $300 renewal	various options available/1 yr	$1,990 for 1 yr, $2,990 for 2 yrs/2 yrs
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	clot code electronic signatures available for each assay run, visualization, and printouts; extensive menu of clotting; positive displacement pipetting for low maintenance and high precision	platelet aggreg., ristocetin cofactor and specialty platelet function tests; dedicated PDQ platelet function centrifuge for platelet rich, poor, and free plasma; intuitive touchscreen operation w/online procedure guides and templates; specialized software avail. for clinical trials

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Survey Editor: Raymond Aller, MD

Coagulation analyzers

Part 2 of 10	Diagnostica Stago Inc. Melissa M. Cole melissa.cole@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	Diagnostica Stago Inc. Larry Wright larry.wright@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	STA Satellite/2009	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 1/1/08 and 11/30/08	—	—	—
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, DRVV, screeen and confirm	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C & S, lupus anticoagulant, DRVV
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

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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.	—/—	—/—	75/100
No. of contracts signed between 1/1/08 and 11/30/08	—	—	—
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, DRVV, 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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Instrument name/first year sold	Cascade M-4/1992	Cascade M/1991	ACL TOP 500 CTS/2008
No. of units installed in U.S./Outside U.S.	200+/25	300+/100	4,000+/8,000+ (all models combined)
No. of contracts signed between 1/1/08 and 11/30/08	—	—	50 (U.S.)
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	random access	batch	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	manual	racks, allowing continuous loading of samples
Model type	benchtop	benchtop	benchtop, floor-standing
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	29 × 43 × 35 in/312 lbs/14 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	PT, APTT, fib. (Clauss & PT based), TT, factors, lupus (SCT & dRVVT), protein C/S, APCR factor V leiden
FDA-cleared chromogenic tests	none	none	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor
FDA-cleared immunologic tests	none	none	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	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	none	none	—
Tests in development but not yet submitted	dRVVT	dRVVT	liquid heparin Xa (w/universal calibrator), INR plasma set, global protein C pathway
Methodologies supported	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric	clot detection, LED optical, chromogenic; immunologic (turbidimetric)
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	500
No. of different assays programmed and calib. at one time	4	1	500
No. of user-definable (open) channels	4	2	250
Of those defined, No. active simultaneously	2	1	30
Factor assays require manual manipulation or dilutions	yes	yes	no
No. of reag. containers onboard at one time/Tests per container	0/—	—/—	40/varies by assay
Reagents refrigerated onboard	no	—	yes
Multiple reag. configurations supported	no	—	yes
Reag., consumables loaded without interrupting testing	no	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	18 months
Walkaway capacity: No. of specimens/No. of tests	no	no	80/800
Min. sample vol. aspirated precisely at one time	manual-50 µL	manual-50 µL	4 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.)	PT: 50–150 µL; PTT: 25–150 µL/25–150 µL
Disposables used/Price of each	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	yes/yes
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/yes
Lag time during which hypercoagulable samp. not detected	yes (PT: 4 sec, PTT: 14 sec)	yes (PT: 4 sec, PTT: 14 sec)	no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on operator 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	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	not needed
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	3 min/140 specimens	3 min/120 specimens	<3 min/240 specimens
• PT, PTT	7 min/80 specimens	7 min/50 specimens	8 min/90 specimens
• Fibrinogen	3 min/160 specimens	3 min/140 specimens	<3 min/78 specimens
• Factor VIII activity assay	7 min/80 specimens	7 min/50 specimens	8 min/77 specimens
Time delay from ordering stat to aspir. of sample	—	—	minimal
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	no (incl. QC: L-J plots)	no (incl. QC: L-J plots)	yes (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	most major vendors
Bidirectional interface capability	no	no	yes (broadcast download & 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	yes
Training provided with purchase	1 day on site	1 day on site	5 days at vendor offices
Approx. No. of training hours needed per tech	2 hours	2–4 hours	24–40 hours
List price	$9,635	$7,127	$130,900
Ann. svc. contract cost (24/7)/Warranty with purchase	$966/1 yr	$714/1 yr	various options available/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	complete assay menu including D-dimer and D-dimer HS with VTE exclusion; features 671 nm LED detection for clotting and other assays, which minimizes interference from lipemia, hemoglobin, and bilirubin; Windows operating system features sample/reagent mgmt.

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Coagulation analyzers

Part 5 of 10	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-993-8687 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-993-8687 www.beckmancoulter.com	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-993-8687 www.beckmancoulter.com
Instrument name/first year sold	ACL Elite Series/2006	ACL TOP Series/2004	ACL Classic Series/1997
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+ (all models combined)/8,000+ (all models combined)
No. of contracts signed between 1/1/08 and 11/30/08	200 (U.S.)	75 (U.S.)	45 (U.S.)
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	Italy/U.S.
Operational type	modified random access	continuous random access	random programming
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	tray-primary tubes	racks, continuous loading of primary tubes	tray-primary tubes or sample cups
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	23.6 × 36.2 × 23.6 in/138.6 lbs/6 sq ft	28.7 × 59.4 × 29.9 in/330.7 lbs/21 sq ft	17.7 × 29.5 × 24.8 in/114 lbs/6 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (Clauss & PT based), TT, factors, protein C/S, lupus (SCT & dRVVT), APCR-V	PT, APTT, fib. (Clauss & PT based), TT, factors, lupus (SCT & dRVVT), APCR-V, protein C/S	PT, APTT, fib. (Clauss & PT based), TT, factors, protein C/S, lupus (dRVVT), APCR-V
FDA-cleared chromogenic tests	heparin Xa, protein C, AT plasminogen, plasmin inhibitor, factor VIII	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor
FDA-cleared immunologic tests	D-dimer, vWF (Act. & Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer, D-dimer HS, vWF (Act. & Ag.), free protein S, XIII Ag., homocysteine	—
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	none
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	INR plasma set	liquid heparin Xa with universal calibrator, INR plasma set, global protein C pathway	INR plasma set
Methodologies supported	clot detection, LED optical (nephelometric); chromogenic; immunologic	clot detection, LED optical, chromogenic; immunologic	clot detection, LED optical, (nephelometric); 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	22	500	4
No. of different assays programmed and calib. at one time	300	500	up to 27
No. of user-definable (open) channels	100	250	0
Of those defined, No. active simultaneously	20	30	4
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	22/varies by test	60/varies	7/varies by test
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	yes	yes	no
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	40/260	120/800	18/20
Min. sample vol. aspirated precisely at one time	5 µL	4 µL	10 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	PT: 60 µL/18 µL	PT: 50 µL/25 µL	50 µL (PT)/40 µL
Disposables used/Price of each	rotors/varies	cuvettes/varies	rotors/varies
Supports direct-from-track sampling	no	yes (in development)	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/yes (optional)	yes/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	yes	no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	no/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	no/no
Lag time during which hypercoagulable samp. not detected	yes (PT & PTT: 3 sec)	no	yes (PT & PTT: 5.6 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	no/no
• No. and sources of reag.	yes	yes	no
• Incub. times/Reading times	yes/yes	yes/yes	no/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	not needed	not needed	not needed
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	4 min/175 specimens	<3 min/360 specimens	5.5 min/175 specimens
• PT, PTT	8 min/125 specimens	8 min/165 specimens	8.5 min/110 specimens
• Fibrinogen	4 min/175 specimens	<3 min/108 specimens	5.5 min/175 specimens
• Factor VIII activity assay	8 min/125 specimens	8 min/100 specimens	9.5 min/110 specimens
Time delay from ordering stat to aspir. of sample	15 sec	minimized	15 sec
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes	yes	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major vendors	most major vendors	most major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & 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	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: <5 min; weekly: 10 min; monthly: 5 min	daily: <10 min; wkly: 10 min; no monthly maintenance	daily: 10 min; weekly: 15 min; monthly: 10 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	5 days at vendor offices	5 days at vendor offices	2 days on site
Approx. No. of training hours needed per tech	24 hours	24–40 hours	12 hours
List price	$54,000	$145,000	$21,500
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)	test menu featuring D-dimer; bar-code reagent management; ACL family harmonization	features clot signature curve analysis; continuous operation w/o interruption to workflow; minimized operator intervention using intuitive Windows 2000 Prof. software; 2D bar code for reagent, calibration, and control assay value import	ACL model to fit your testing needs

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Coagulation analyzers

Part 6 of 10	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	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	BFT II/U.S.: 1999	Sysmex CA-530/2006	Sysmex CA-560/U.S.: 2003
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/08 and 11/30/08	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Japan/Japan	Japan/Japan
Operational type	batch	continuous random access	continuous random access
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually), optimized for Siemens instruments	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	manual	10-tube position sample rack	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	3.9 × 7.9 × 11.8 in/8.4 lbs/1.5 sq ft	19 × 21 × 18.5 in/99 lbs/9 sq ft	19 × 21 × 18.5 in/99 lbs/9 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, reptilase time, protien C clot, factor assays	PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays
FDA-cleared chromogenic tests	—	AT III, protein C chromo, heparin	AT III, protein C chromo, heparin
FDA-cleared immunologic tests	—		Advanced D-dimer, Innovance D-dimer
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	—	—
Tests submitted for 510(k) clearance	none	Innovance antithrombin	Innovance antithrombin
Tests in development but not yet submitted	none	PT multi-calibrators, heparin calibrators and controls	PT multicalibrators, heparin calibrators and controls
Methodologies supported	turbodensitometric	clot detection: optical; turbidimetric, chromogenic; immunol.	clot detect., 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	1	5	5
No. of different assays programmed and calib. at one time	3	7	7
No. of user-definable (open) channels	—	7	7
Of those defined, No. active simultaneously	1	5	5
Factor assays require manual manipulation or dilutions	—	no	no
No. of reag. containers onboard at one time/Tests per container	4/up to 200	11/varies, up to 200	11/varies, up to 200
Reagents refrigerated onboard	no	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	consumables yes, reagents no	consumables yes, reagents no
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	1/1	10/50	10/50
Min. sample vol. aspirated precisely at one time	50 µL	10 µL/50 µL	10 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL	50 µL/—	50 µL/—
Disposables used/Price of each	cuvettes, printer paper/varies with volume	reaction tubes, CA clean I, thermal 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	no/no	yes (3-5 mL)/no	yes (3–5 mL)/no
Sample bar-code reading capability	no	no	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	yes/no	yes/no
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable samp. not detected	yes (PT: 5 sec, APTT: 15 sec)	yes (<7 sec for PT; <15 sec for APTT)	yes (PT: <7 sec, APTT: <15 sec)
Read time extended for prolonged clotting times	no	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	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	1 min/—, manual	7 min/54 results	7 min/54 results
• PT, PTT	—, manual	8 min/43 results	8 min/43 results
• Fibrinogen	<1 min/—, manual	7 min/54 results	7 min/54 results
• Factor VIII activity assay	—	—	—
Time delay from ordering stat to aspir. of sample	—	2 min	2 min
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)
Interface supplied by instrument vendor	—	no	no
Interfaces in active user sites for:	—	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	no	yes (host query after manual ID input)	yes (host query)
Results transferred to LIS as soon as test time complete	no	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 1 min	daily: <5 min; weekly: 1 min; quarterly: <5 min	daily: <5 min; weekly: 1 min; quarterly: < 5 min
Onboard maintenance records	no	no	no
Training provided with purchase	Web CD training course	2 days on site, online training course, Web CD training	2 days on site, online training course, Web CD training
Approx. No. of training hours needed per tech	2 hours	2 hours	2 hours
List price	$8,685	$34, 812	$47,634
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)	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	five-parameter true random-access clotting/chromogenic/immunologic technology; complete automation, specialty assay capability; low operating expense

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Coagulation analyzers

Part 7 of 10	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	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	**Sysmex CA-1500/U.S.: 2000; worldwide: 1999**	**Sysmex CA-7000/2002**	**BCS XP/2006**
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/08 and 11/30/08	—	—	—
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 (lyoph., reconst. manually), optimized for Siemens instruments	open reagent system	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	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 in/186 lbs/6.8 sq ft	24.8 × 42 × 43.8 in/345.4 lbs/12.78 sq ft	37 × 49 × 25 in/330 lbs/14 sq ft
FDA-cleared clotting-based tests	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	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	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin	AT III, 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	—	BC von Willebrand-risto. cofactor assay (agglut of fixed plts)
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	Innovance antithrombin	Innovance antithrombin	Innovance antithrombin
Tests in development but not yet submitted	PT multicalibrators, heparin calibrators and controls	PT multicalibrators, heparin calibrators and controls	ETP (for research use only), PT multicalibrators, heparin calibrators and controls
Methodologies supported	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical (xenon flasher lamp); 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	15	20	>100 tests/samples
No. of different assays programmed and calib. at one time	25	40	99
No. of user-definable (open) channels	25	40	7,999
Of those defined, No. active simultaneously	15	20	>100
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	39/up to 200	58/varies up to 200	90/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	some consumables yes, reagents no	yes	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	50/up to 1,000	100/550 per hour PT and APTT, 300 per hour PT	100 samples/400 cuvettes
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	3 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/10 µL	50 µL/10 µL	50 µL/20 µL, min 100 µL (incl. dead vol)/50 µL, min 100 µL
Disposables used/Price of each	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	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. diam. 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. 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	yes/yes	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 (7 sec for PT & APTT)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	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	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 min/120 results	7 min/280 results	<5 min/~380 results (including abnormals)
• PT, PTT	8 min/80 results	8 min/480 results	<5 min/~325 results (including abnormals)
• Fibrinogen	8 min/120 results	8 min/280 results	<5 min (if curve available)~315 results
• Factor VIII activity assay	8 min/—	8 min/300 results	<5 min (if curve available)~280 results
Time delay from ordering stat to aspir. of sample	2 min	2 min	varies by test in progress, appox. >5 min
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots & Westgard)	onboard (incl. QC: L-J plots & Westgard)	yes, onboard (incl. 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 min; weekly: 1 min; quarterly: <5 min	daily: <10 min; weekly: 1 min; monthly: <5 min; quarterly: <5 min	daily: <5 min; weekly: <10 min.; monthly: 15 min
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
Approx. No. of training hours needed per tech	6 hours	8 hours on site	8 hours on site
List price	$97,529 standard model; $110,544 cap-piercing model	$196,451	$171,921
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)	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

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Coagulation analyzers

Part 8 of 10	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	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	**KC1△/2001**	**KC4△/2001**	**Coag-A-Mate XM/1989**
No. of units installed in U.S./Outside U.S.	>250/>100	>100/>100	>2,000 worldwide
No. of contracts signed between 1/1/08 and 11/30/08	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	U.S./U.S.
Operational type	semiautomatic, single channel	semiautomatic, 4 channels	discrete
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	manual	manual pipetting into cuvette (4 wells at a time)
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	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	4.6 × 14.7 × 20 in/20 lbs/2 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib.	PT, APTT, fib., TT, atroxin, intrinsic & extrinsic factors	PT, APTT, TT, fib., PT & APTT factor assays
FDA-cleared chromogenic tests	—	—	none
FDA-cleared immunologic tests	—	—	none (latex immunologic assay in development)
Other FDA-cleared tests	—	—	none
User-defined tests in clinical use	—	—	none
Tests submitted for 510(k) clearance	—	—	none
Tests in development but not yet submitted	—	—	none
Methodologies supported	clot detection, mechanical	clot detection, mechanical	clotting assays; photo-optical
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	5	2
No. of different assays programmed and calib. at one time	manual	1/1	16
No. of user-definable (open) channels	—	—	16
Of those defined, No. active simultaneously	—	up to 4	2
Factor assays require manual manipulation or dilutions	yes	yes	yes
No. of reag. containers onboard at one time/Tests per container	1/varies for each assay	5/varies for test kit	4/30–100
Reagents refrigerated onboard	no	no	no
Multiple reag. configurations supported	no	no	yes
Reag., consumables loaded without interrupting testing	—, manual	—, manual	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	12–18 months
Walkaway capacity: No. of specimens/No. of tests	—, manual	—, manual	4/4
Min. sample vol. aspirated precisely at one time	—	—	—
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/10 µL	100 µL/10 µL, min. 10 µL
Disposables used/Price of each	cuvettes & ball dispenser/available on request	cuvettes & ball dispenser/available on request	cuvettes, stir bars, optional: printer & paper/ available on request
Supports direct-from-track sampling	—	—	no
Primary tube sampling supported/Pierces caps on primary tubes	—	—	no/no
Sample bar-code reading capability	—	—	no
Reagent bar-code reading capability	—	—	no
Onboard test automatic inventory	—	—	no
Measures No. of tests remaining/Short sample detection	—	—	no/no
Clot detection as preanalytical variable in plasma sample	—	—	no
Auto. detection of adequate reag. for aspir. & anal.	—	—	no
Hemolysis/Turbidity detection-quantitation	—	—	no/no
Dilution of patient samples onboard	—	—	no
Automatic rerun capability/Auto reflex testing capability	—	—	no/no
Lag time during which hypercoagulable samp. not detected	yes (PT & PTT: 4.5 sec)	yes (PT & PTT: 4.5 sec)	yes (PT: 7 sec, APTT: 20 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	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	75 sec/48 tests	75 sec/48 tests	2 min/200 results (manual)
• PT, PTT	350 sec/10 tests	350 sec/10 tests	5 min/50 PTT results (manual)
• Fibrinogen	65 sec/55 tests	65 sec/55 tests	2–3 min/100 results (manual)
• Factor VIII activity assay	275 sec/13 tests	275 sec/13 tests	5 min/50 results (manual)
Time delay from ordering stat to aspir. of sample	—	—	≤2 min
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	yes	yes	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	—	—	no
Results transferred to LIS as soon as test time complete	yes	yes	no
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	—	—	no
Time required for maintenance by lab personnel	none	none	daily: none; weekly: ~5 min; monthly: none
Onboard maintenance records	—	—	no
Training provided with purchase	as needed on site	as needed on site	half day on site
Approx. No. of training hours needed per tech	2 hours	2 hours	1–2 hours
List price	$2,206	$9,660	$5,173
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request	available upon request	available upon request
Unique advantages (provided by vendors)	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	simple to operate: clot detection starts automatically on addition of start reagent; flexibility; test params. can be modified to accommodate various reagent systems

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Coagulation analyzers

Part 9 of 10	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	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 MTX/1997	Destiny Plus/2005	Destiny Max
No. of units installed in U.S./Outside U.S.	>500 worldwide	>160/>500	0/0 (submitted for FDA approval in Dec. 2008)
No. of contracts signed between 1/1/08 and 11/30/08	—	—	0
Country where analyzer designed/Manufactured	Germany & U.S./Germany	Germany & U.S./Germany	Germany/Germany
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	rotor (32 positions)	continuous rack loading	continuous rack loading
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	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	29.5 × 59 × 27 in./340 lbs/11.03 sq ft
FDA-cleared clotting-based tests	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	AT III, hep. antifactor Xa, protein C	AT, heparin Xa	—
FDA-cleared immunologic tests	none (latex immunologic assay in development)	D-dimer	—
Other FDA-cleared tests	none	—	—
User-defined tests in clinical use	alpha-2 antiplasmin, plasminogen, PT mix, APTT mix, LMWH (antifactor Xa)	—	—
Tests submitted for 510(k) clearance	none	—	—
Tests in development but not yet submitted	quantitative D-dimer immunoassay	—	all coagulation tests
Methodologies supported	clotting, chromogenic assays; photo-optical	clot detection, mechanical & optical (turbidimetric); chromogenic; immunologic	clot detection, mechanical & 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	8	10	unlimited
No. of different assays programmed and calib. at one time	32	unlimited	unlimited
No. of user-definable (open) channels	up to 32	unlimited	unlimited
Of those defined, No. active simultaneously	8	10	unlimited
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	16 cooled, 12 room temp. total 28/25–200	31–51/varies	—/varies by test
Reagents refrigerated onboard	yes (15°C)	yes (12° to 16°C)	yes (12° to 16°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	no
Max. time same lot No. of reag. can be used	12–18 months	varies by reagent—routine reagents 12 months	varies—routine reagents 12 months
Walkaway capacity: No. of specimens/No. of tests	32/32	50/240	120/71,000
Min. sample vol. aspirated precisely at one time	2 µL	5 µL	25 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/5 µL, min. 2 µL	25 µL/10 µL	25 µL/10 µL
Disposables used/Price of each	cuvette rings, pipettor wash solution, cleaning solution/available on request	reaction trays, ProWash	reaction trays, ProWash
Supports direct-from-track sampling	no	no	yes
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	no	in development	yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/no	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	not necessary/not necessary
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/no	yes/yes	yes/yes
Lag time during which hypercoagulable samp. not detected	yes (PT: 3 sec, APTT: 5 sec)	no	no
Read time extended for prolonged clotting times	yes		yes
User can set different-than-standard:		yes	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	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	yes/yes	yes/yes
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	2 min/90 results	<3 min/180 tests	<3 min/~350 tests
• PT, PTT	5 min/60 results	<6 min/90 tests	<6 min/~232 tests
• Fibrinogen	2 min/75 results	<6 min/105 tests	<6 min/~200 tests
• Factor VIII activity assay	5 min/60 results	<6 min/58 tests	<6 min/~200 tests
Time delay from ordering stat to aspir. of sample	30–60 sec	varies by test	<3 min
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes (incl. QC: L-J plots)	onboard (incl. QC: LJ plots, Westgard)	onboard (incl. QC: LJ plots, Westgard)
Interface supplied by instrument vendor	yes (additional cost)	no	no
Interfaces in active user sites for:	all commonly used LISs in North America	all major LIS vendors	—
Bidirectional interface capability	yes	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	yes	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	no	no	yes
Modem servicing	no	yes	yes
Time required for maintenance by lab personnel	daily: ~5 min; weekly: ~1 min; monthly: ~5 min	daily: <5 min; weekly: <30 min; monthly: <30 min	daily: <5 min; weekly: <10 min; monthly: <30 min
Onboard maintenance records	no	yes	yes
Training provided with purchase	3 days at vendor offices	2-4 days on site; 3 days at vendor offices	3–5 days on site; 5 days at vendor offices
Approx. No. of training hours needed per tech	2–3 hours	8 hours	5 hours
List price	$52,500	$79,500	$129,000
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request	available upon request	available upon request
Unique advantages (provided by vendors)	normalization of PT & APTT results between Trinity automated systems; stat results within 2–5 min; flexibility; MTX supports new assays easily thru 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	mechanical clot detection via the patented BallMethod; ¼ volume patient sample and reagent usage for PT, PTT, Fib; waveform analysis, dyes in routine reagents for volume delivery check, factor parallelism; normalization of PT & PTT results between Trinity automated instruments

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Coagulation analyzers

Part 10 of 10	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	MDA II/1999
No. of units installed in U.S./Outside U.S.	>400 worldwide
No. of contracts signed between 1/1/08 and 11/30/08	—
Country where analyzer designed/Manufactured	U.S./U.S.
Operational type	continuous random access
Reagent type	open reagent system
Operates on whole blood or spun plasma	spun plasma
Sample handling system	racks
Model type	floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	58 × 75 × 31 in/840 lbs/18 sq ft w/PC
FDA-cleared clotting-based tests	PT screening (moderate & low ISI), PT factors, quick%, APTT screening, APTT factors, PT mix, APTT mix, TT, fib.
FDA-cleared chromogenic tests	hep. antifactor Xa, AT III, protein C, plasminogen, alpha-2 antiplasmin, lupus (dRVVT screen and confirm), APCR
FDA-cleared immunologic tests	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	none
Methodologies supported	clotting; chromogenic; immunoassay; photo-optical
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no
No. of different measured assays onboard simultaneously	16
No. of different assays programmed and calib. at one time	72
No. of user-definable (open) channels	20
Of those defined, No. active simultaneously	16
Factor assays require manual manipulation or dilutions	no
No. of reag. containers onboard at one time/Tests per container	30/25–400
Reagents refrigerated onboard	yes (8° to 15°C)
Multiple reag. configurations supported	yes
Reag., consumables loaded without interrupting testing	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes
Max. time same lot No. of reag. can be used	12–18 months
Walkaway capacity: No. of specimens/No. of tests	170/480
Min. sample vol. aspirated precisely at one time	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/10 µL
Disposables used/Price of each	cuvettes, bar-code labels, MDA probe cleaner/ available on request
Supports direct-from-track sampling	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes
Sample bar-code reading capability	yes (internal bar-code scanner)
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/yes (detects bilirubin, corrects for lipemia)
Dilution of patient samples onboard	yes
Automatic rerun capability/Auto reflex testing capability	no/no
Lag time during which hypercoagulable samp. not detected	yes (PT: default 3 sec, APTT: default 5 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)
User can set different-than-standard:	
• Reag. volumes/Sample volumes	yes/yes
• No. and sources of reag.	yes
• Incub. times/Reading times	no/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes
Auto shutdown/Auto startup programmable	yes/yes
Stat time to complete all analytes/Throughput per hour for:	
• PT alone	12 min/180 results
• PT, PTT	12 min/180 results
• Fibrinogen	12 min/180 results
• Factor VIII activity assay	12 min/180 results
Time delay from ordering stat to aspir. of sample	<1 min
Auto. transfer of QC results to LIS	yes
Data management capability	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	yes (additional cost)
Interfaces in active user sites for:	all commonly used LISs in North America
Bidirectional interface capability	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes
LOINC codes transmitted with all results	no
How labs get LOINC codes for reagent kits	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes
Modem servicing	yes
Time required for maintenance by lab personnel	daily: ~35 min; weekly: 45 min; monthly: 10 min
Onboard maintenance records	no
Training provided with purchase	3–5 days on site, 4 days at vendor offices
Approx. No. of training hours needed per tech	4–5 hours
List price	$92,295
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request
Unique advantages (provided by vendors)	patented waveform analysis tech. with flags for ident. abnormal waveforms (e.g. 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

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