SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 1 of 10

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

	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	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	**CD2000/1986**	**CoaLab/1991**	**STA-R Evolution Hemostasis System/2005**
No. of units installed in U.S./Outside U.S.	>500/>1,000	—/—	—/—
No. of contracts signed between 1/1/07 and 11/30/07	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	France/France
Operational type	batch, discrete	discrete, batch	continuous random access
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)	open reagent system (lyoph., reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	cuvette ring (automated)	rack with continuous specimen access
Model type	benchtop	benchtop	floor standing
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	49.2 × 50.3 × 32.2 in/507 lbs/26.8 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	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C & S, lupus anticoagulant, DRVV, screeen and confirm
FDA-cleared chromogenic tests	none	none	heparin (UFH & LMWH), protein C, AT, plasminogen, antiplasmin
FDA-cleared immunologic tests	none	none	D-dimer, VWF, total & free protein S, AT antigen
Other FDA-cleared tests	none	none	n/a
User-defined tests in clinical use	none	none	APCR, other clotting chromogenic & immunological tests with 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, optical; turbodensitometry stir bar mixing–optical detection	clot detection, optical (tungsten, turbidimetric)	clot detection: mechanical; 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 (PT, APTT)	30	up to 200
No. of different assays programmed and calibrated at one time	1 (fib.)	30	up to 200
No. of user-definable (open) channels	2	2	200
Of those defined, No. active simultaneously	2	varies with test-reagent combination	200
Factor assays require manual manipulation or dilutions	yes	no	no
No. of reag. containers onboard at one time/Tests per container	5 or more/ reag. mftr. dependent	10/varies	70/up to 83
Reagents refrigerated onboard	no	no	yes (15° to 19°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	laboratory dependent	18 months	18 months
Walkaway capacity: No. of specimens/No. of tests	—/—	32/30	215/32
Min. sample vol. aspirated precisely at one time	manual pipetting	5 µL	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	50 µL/5 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.	sample cups, measurement cuvette rings/varies	cuvettes & wash-clean solution/varies with volume
Supports direct-from-track sampling	no	no	yes (Beckman Coulter, Bayer LabCell, Roche MPA)
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (13 × 64, 75, 100 mm; 11.5 × 64, 92 mm)/no	yes/yes
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	no	yes
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no (not necessary for mechanical detection tech.)
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	yes/no
Lag time during which hypercoagulable samples will not be detected	yes (3 sec)	yes (3 sec)	no
Read time extended for prolonged clotting times	yes, up to 999 sec	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
Autocalibration or autocalib. alert/Multipoint calibration supported	no/no	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no (not necessary)/no (not necessary)
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	120 sec/user defined	4 min/140 specimens	<6 min/~300
• PT, PTT	240 sec/user defined	8 min/140 specimens	7 min/~150
• Fibrinogen	300 sec/user defined	4 min/140 specimens	7 min/~180
• Factor VIII activity assay	300 sec/user defined	varies/varies	7 min/~180
Time delay from ordering stat to aspir. of sample	none—all preanalytical	15 sec	<15 sec
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	yes (incl. QC: L-J plots)	onboard (L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	call technical support for inquiry	n/a	Cerner, Misys, Meditech, others
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	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no	yes (Beckman Coulter, Bayer LabCell, Roche MPA)
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 30 sec; monthly: 5 min	daily: 10 min; weekly: 10 min; monthly: 5 min; biweekly: 5 min	daily: none; weekly: <30 min; monthly: <30 min
Onboard maintenance records	no	yes	yes
Training provided with purchase	videotape; on-site training extra	varies per site	varies on site, 5 days at vendor offices
Approx. No. of training hours needed per tech	2 hours	varies	~3–5 hours
List price	$900, special pricing upon written request for quote	$25,000	$161,900/1 yr
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	prices available upon request/1 yr
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	■ viscosity-based detection system; ■ connectivity to lab automation systems; ■ software for password protection and result traceability; ■ able to standardize with other STA analyzers

Survey editor: Raymond D. Aller, MD

SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 2 of 10

	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	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 Compact Hemostasis System/1996**	**STA Compact CT/2001**	**Start 4/1998**
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/07 and 11/30/07	—	—	—
Country where analyzer designed/Manufactured	France/France	France/France	France/France
Operational type	continuous random access	continuous random access	batch
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	continuous specimen access—primary tube	continuous specimen access—primary tube	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	25.2 × 38.8 × 25.8 in/351 lbs/25.6 sq ft	25.2 × 38.8 × 25.8 in/351 lbs/25.6 sq ft	4.7 × 16.1 × 16.5 in/12.5 lbs/1.8 sq ft
FDA-cleared clotting-based tests	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	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C & S, lupus anticoagulant
FDA-cleared chromogenic tests	heparin (UFH & LMWH), protein C, AT, plasminogen, antiplasmin	n/a	none
FDA-cleared immunologic tests	D-dimer, VWF, total & free protein S, AT antigen	n/a	none
Other FDA-cleared tests	n/a	n/a	n/a
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	dRVVT screen & confirm assays, APCR, other clotting tests with user-defined applications
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clotting, chromogenic, & immunologic assays	clot detection, mechanical	clotting tests
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 80	1
No. of different assays programmed and calibrated at one time	up to 80	up to 80	20
No. of user-definable (open) channels	70	70	4
Of those defined, No. active simultaneously	70	70	1
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/Tests per container	45/varies, up to 83	45/varies, up to 83	4/varies, up to 100
Reagents refrigerated onboard	yes (15° to 19°C)	yes (15° to 19°C)	no
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	96/12 per sample	96/12 per specimen	4/1
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	25 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/5 µL	50 µL/5 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes & wash-clean solution/varies with volume	cuvettes & wash-clean solution/varies with volume	cuvettes, beads, balls/varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/yes	no/no (n/a)
Sample bar-code reading capability	yes	yes	no
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/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	no
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	no
Automatic rerun capability/Auto reflex testing capability	yes/no	yes/no	no/no
Lag time during which hypercoagulable samples will not be 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
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	no (not necessary)/no (not necessary)	no (not necessary)/no (not necessary)	no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	<6 min/150 specimens	<6 min/150 specimens	<1 min/up to 120 specimens
• PT, PTT	7 min/75 specimens	7 min/75 specimens	n/a/n/a
• Fibrinogen	7 min/75 specimens	7 min/75 specimens	<1 min/up to 120 specimens
• Factor VIII activity assay	7 min/70 specimens	7 min/70 specimens	varies/varies
Time delay from ordering stat to aspir. of sample	<15 sec	<15 sec	n/a
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots)	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others	n/a
Bidirectional interface capability	yes (host query)	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	n/a	n/a	n/a
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: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <5 min; monthly: <5 min
Onboard maintenance records	yes	yes	no
Training provided with purchase	varies on site, 3 days at vendor offices	varies on site, 3 days at vendor office	1 day on site
Approx. No. of training hours needed per tech	2 hours basic	2 hours basic	1 hour
List price	$75,000	$50,000	$9,600
Ann. svc. contract cost (24/7)/Warranty with purchase	prices available on request/1 yr	prices available on request/1 yr	prices available on request/1 yr
Unique advantages (provided by vendors)	■ viscosity-based detection system ■ walkaway testing for routine and specialty hemostasis assays ■ 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	■ viscosity-based detection system ■ excellent for low-volume testing or backup for optical system ■ programmable and preprogrammed assays with curve storage plus four independently timed incubation stations

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Coagulation Analyzers

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Instrument name/first year sold	Cascade M/1991	Cascade M-4/1992	AggRAM/2005
No. of units installed in U.S./Outside U.S.	300+/100	200+/25	75/100
No. of contracts signed between 1/1/07 and 11/30/07	—	—	—
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
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma, PRP
Sample handling system	manual	manual	manual
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	6 × 10 × 17 in/15 lbs/—
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	none
FDA-cleared chromogenic tests	none	none	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	none	ristocetin cofactor and platelet aggreg.
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	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	dRVVT	dRVVT	none
Methodologies supported	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric	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	4	4–8
No. of different assays programmed and calibrated at one time	1	4	4–8
No. of user-definable (open) channels	2	4	12
Of those defined, No. active simultaneously	1	2	4–8
Factor assays require manual manipulation or dilutions	yes	yes	yes
No. of reag. containers onboard at one time/Tests per container	—/—	0/n/a	n/a/n/a
Reagents refrigerated onboard	n/a	no	no
Multiple reag. configurations supported	n/a	no	no
Reag., consumables loaded without interrupting testing	no	no	no
Same capabilities when 3rd-party reag. used	yes	yes	n/a
Max. time same lot No. of reag. can be used	12 months	12 months	12 months
Walkaway capacity: No. of specimens/No. of tests	no	no	no
Min. sample vol. aspirated precisely at one time	manual-50 µL	manual-50 µL	n/a
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.)	Plt. aggreg.: 225 µL PRP, Risto cofactor: 50 µL
Disposables used/Price of each	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvettes/200 @ $55.65; pipette tips/1,000 @ $82; stir bars/30 @ $62.25
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no	no	no
Sample bar-code reading capability	no	no	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/no	no/no
Clot detection as preanalytical variable in plasma sample	—	—	—
Auto. 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	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 4 sec, PTT: 14 sec)	yes (PT: 4 sec, PTT: 14 sec)	n/a
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	n/a
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
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	3 min/120 specimens	3 min/140 specimens	—
• PT, PTT	7 min/50 specimens	7 min/80 specimens	—
• Fibrinogen	3 min/140 specimens	3 min/160 specimens	—
• Factor VIII activity assay	7 min/50 specimens	7 min/80 specimens	n/a
Time delay from ordering stat to aspir. of sample	n/a	n/a	n/a
Auto. transfer of QC results to LIS	no	yes	yes
Data management capability	no (incl. QC: L-J plots)	no (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:	n/a	—	—
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	no	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	—	no	no
Modem servicing	no	no	—
Time required for maintenance by lab personnel	daily: 10 min; weekly: 10 min; monthly: 20 min	daily: 10 min; weekly: 10 min; monthly: 30 min	daily: 15 min; weekly: 15 min; monthly: 1 hour
Onboard maintenance records	no	no	yes
Training provided with purchase	1 day on site	1 day on site	2 days on site
Approx. No. of training hours needed per tech	2–4 hours	2 hours	4–8 hours
List price	$7,127	$9,635	$14,995
Ann. svc. contract cost (24/7)/Warranty with purchase	$714/1 yr	$966/1 yr	$1,800/1 yr
Unique advantages (provided by vendors)	■ QC program onboard ■ curve storage ■ suitable for office lab or as backup analyzer	■ 4-channel manual analyzer ■ QC program onboard ■ singles or duplicates	■ specialized coag instrument intended for platelet aggreg. & ristocetin cofactor

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Instrument name/first year sold	**ACL Classic Series/1997**	**ACL Elite Series/2006**	**ACL Advance Series/2000**
No. of units installed in U.S./Outside U.S.	4,000+ (all models combined)/8,000+ (all models combined)	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)
No. of contracts signed between 1/1/07 and 11/30/07	100 (U.S.)	130 (U.S.)	150 (U.S.)
Country where analyzer designed/Manufactured	Italy/U.S.	U.S./U.S.	U.S./U.S.
Operational type	random programming	modified random access	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	tray-primary tubes or sample cups	tray-primary tubes	racks, continuous loading of primary tubes
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	17.7 × 29.5 × 24.8 in/114 lbs/6 sq ft	23.6 × 36.2 × 23.6 in/138.6 lbs/6 sq ft	32.2 × 41 × 24.8 in/185 lbs/15 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (Clauss & PT based), TT, factors, protein C/S, lupus (dRVVT), APCR-V	PT, APTT, fib. (Clauss & PT based), TT, factors, protein C/S, lupus (SCT & dRVVT), APCR-V	PT, APTT, fib (Clauss & PT based), TT, factors, protein C/S, lupus (SCT & dRVVT), APCR-V
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	n/a	D-dimer, vWF (Act. & Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer, vWF (Act. & Ag.), free protein S, factor 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	INR plasma set	INR plasma set, global protein C pathway
Methodologies supported	clot detection, LED optical, (nephelometric); chromogenic; immunologic	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	4	22	varies with test-reagent combination, limited only by No. of reag. positions
No. of different assays programmed and calibrated at one time	up to 27	300	200
No. of user-definable (open) channels	0	100	75
Of those defined, No. active simultaneously	4	20	20
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	7/varies by test	22/varies by test	42/varies by test, container size
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	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	18/20	40/260	120/264
Min. sample vol. aspirated precisely at one time	10 µL	5 µL	10 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL (PT)/40 µL	PT: 60 µL/18 µL	50 µL /10 µL
Disposables used/Price of each	rotors/varies	rotors/varies	cuvettes/varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/no	yes/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	no	yes	no
Onboard test automatic inventory	no	yes	no
Measures No. of tests remaining/Short sample detection	no/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	no/no	yes/yes	yes/no
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 5.6 sec)	yes (PT & PTT: 3 sec)	yes (PT: 7 sec., PTT: 10 sec)
Read time extended for prolonged clotting times	yes	yes	
User can set different-than-standard:			yes
• 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
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	not needed	not needed	not needed
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	5.5 min/175 specimens	4 min/175 specimens	2.5 min/240 specimens
• PT, PTT	8.5 min/110 specimens	8 min/125 specimens	8 min/180 specimens
• Fibrinogen	5.5 min/175 specimens	4 min/175 specimens	2.5 min/240 specimens
• Factor VIII activity assay	9.5 min/110 specimens	8 min/125 specimens	8 min/180 specimens
Time delay from ordering stat to aspir. of sample	15 sec	15 sec	20 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 LIS vendors	most major vendors	most major LIS vendors
Bidirectional interface capability	yes (host query)	yes (broadcast download & host query)	yes (broadcast download)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: <5 min; weekly: 10 min; monthly: 5 min	daily: 15 min; weekly: 15 min; monthly: 10 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	2 days on site	5 days at vendor offices	5 days at vendor offices
Approx. No. of training hours needed per tech	12 hours	24 hours	24 hours
List price	$21,500	$54,000	$79,500
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)	■ ACL model to fit your testing needs	■ test menu featuring D-dimer ■ bar-code reagent management ■ ACL family harmonization	■ extensive menu of clotting, chromogenic, and immunologic assays ■ high-end capabilities/small footprint ■ LED optics providing optimized results regardless of preanalytical variables

SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 5 of 10

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

	Instrumentation Laboratory/Beckman Coulter Inc. **Venita Shirley** vcshirley@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-993-8687 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 TOP Series/2004**	**BCS XP/2006**	**Sysmex CA-530/2006**
No. of units installed in U.S./Outside U.S.	4,000+/8,000+ (all models combined)	—/—	—/—
No. of contracts signed between 1/1/07 and 11/30/07	75 (U.S.)	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	Japan/Japan
Operational type	continuous random access	continuous random access	batch, continuous random access
Reagent type	open reagent system	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	racks, continuous loading of primary tubes	rack	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	28.7 × 59.4 × 29.9 in/330.7 lbs/21 sq ft	37 × 49 × 25 in/330 lbs/14 sq ft	19 × 21 × 18.5 in/99 lbs/9 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (Clauss & PT based), TT, factors, lupus (SCT & dRVVT), APCR-V	PT, APTT, fibrinogen, TT, reptilase time, factor assays, dRVVT screen and confirm, factor V Leiden, protein C clot, protein S activity	PT, APTT, fibrinogen, TT, reptilase time, protien C clot, factor assays
FDA-cleared chromogenic tests	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin,	AT III, protein C chromo, heparin
FDA-cleared immunologic tests	D-dimer, D-dimer HS, vWF (Act. & Ag.), free protein S, XIII Ag., homocysteine	advanced D-dimer	
Other FDA-cleared tests	none	BC von Willebrand-risto. cofactor assay (agglut of fixed plts)	none
User-defined tests in clinical use	none	n/a	n/a
Tests submitted for 510(k) clearance	—	n/a	n/a
Tests in development but not yet submitted	INR plasma set, global protein C pathway	ETP (for research use only), Innovance D-dimer, Innovance antithrombin	Innovance antithrombin
Methodologies supported	clot detection, LED optical, chromogenic; immunologic	clot detection, optical (xenon flasher lamp); chromogenic; immunologic	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	500	>100 tests/samples	5
No. of different assays programmed and calibrated at one time	500	99	7
No. of user-definable (open) channels	250	7,999	7
Of those defined, No. active simultaneously	30	>100	5
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	60/varies	90/varies, up to 200	11/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	yes	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	120/800	100 samples/400 cuvettes	10/50
Min. sample vol. aspirated precisely at one time	4 µL	3 µL	10 µL/50 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	PT: 50 µL/25 µL	50 µL/20 µL, min 100 µL (incl. dead vol)/50 µL, min 100 µL	n/a/n/a
Disposables used/Price of each	cuvettes/varies	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/varies with volume	reaction tubes, CA clean I, thermal paper/varies with volume
Supports direct-from-track sampling	yes (in development)	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes (optional)	yes (all up to 100 mm long, ext. diam. 11-16 mm)/no	yes (3-5 mL)/no
Sample bar-code reading capability	yes	yes	no
Reagent bar-code reading capability	yes	yes	no
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	yes/yes	no/yes
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 samples will not be detected	no	yes (7 sec for PT & APTT)	yes (<7 sec for PT; <15 sec for APTT)
Read time extended for prolonged clotting times	yes	yes	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/no
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	not needed	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	<3 min/360 specimens	<5 min/~380 results (including abnormals)	7 min/54 results
• PT, PTT	8 min/165 specimens	<5 min/~325 results (including abnormals)	8 min/43 results
• Fibrinogen	<3 min/360 specimens	<5 min (if curve available)~315 results	7 min/54 results
• Factor VIII activity assay	8 min/165 specimens	<5 min (if curve available)~280 results	n/a
Time delay from ordering stat to aspir. of sample	minimized	varies by test in progress, appox. >5 min	2 min
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes	yes, onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major vendors	in development	Cerner, Misys, others
Bidirectional interface capability	yes (broadcast download & 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	—	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no	no
Modem servicing	no	yes	no
Time required for maintenance by lab personnel	daily: <10 min; wkly: 10 min; no monthly maintenance	daily: <5 min; weekly: >10 min.; monthly: 15 min	daily: <5 min
Onboard maintenance records	yes	yes	no
Training provided with purchase	5 days at vendor offices	5 days at vendor offices for 2 operators	2 days
Approx. No. of training hours needed per tech	24–40 hours	8 hours on site	2 hours
List price	$145,000	$171,921	$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)	■ 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	■ user-definable calibration curve expiration and prewarning alerts; ■ user-definable bar-code utility enables customizable reagent protocols; ■ user-friendly Windows XP software	■ small footprint ■ onboard quality control package ■ primary tube sampling and removable reagent trays

Coagulation Analyzers

	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-560/U.S.: 2003	Sysmex CA-1500/U.S.: 2000; worldwide: 1999
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/07 and 11/30/07	—	—	—
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 (lyoph., 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 × 5
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x 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	20 × 31.2 × 31.2 in/186 lbs/6.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	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
FDA-cleared chromogenic tests	n/a	AT III, protein C chromo, heparin	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin
FDA-cleared immunologic tests	n/a	advanced D-dimer	advanced D-dimer
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	n/a	n/a
Tests submitted for 510(k) clearance	none	none	n/a
Tests in development but not yet submitted	none	Innovance D-dimer, Innovance antithrombin	Innovance D-dimer, Innovance antithrombin
Methodologies supported	turbodensitometric	clot detect., 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	1	5	15
No. of different assays programmed and calibrated at one time	3	7	25
No. of user-definable (open) channels	n/a	7	25
Of those defined, No. active simultaneously	1	5	15
Factor assays require manual manipulation or dilutions	n/a	no	no
No. of reag. containers onboard at one time/Tests per container	4/up to 200	11/varies, up to 200	39/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	some 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	50/up to 1,000
Min. sample vol. aspirated precisely at one time	50 µL	10 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL	50 µL/n/a	50 µL/10 µL
Disposables used/Price of each	cuvettes, printer paper/varies with volume	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
Supports direct-from-track sampling	no	no	yes (Sysmex CST series)
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (3–5 mL)/no	yes (3–5 mL)/yes
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	no	yes
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/yes	no/yes
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT: 5 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	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
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	—/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	1 min/n/a manual	7 min/54 results	7 min/120 results
• PT, PTT	n/a manual	8 min/43 results	8 min/80 results
• Fibrinogen	<1 min/n/a manual	7 min/54 results	8 min/120 results
• Factor VIII activity assay	n/a	n/a	8 min/n/a
Time delay from ordering stat to aspir. of sample	n/a	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 & Westgard)
Interface supplied by instrument vendor	n/a	no	no
Interfaces in active user sites for:	n/a	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others
Bidirectional interface capability	no	yes (host query)	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	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	yes (Sysmex CST series)
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 1 min	daily: <5 min	daily: <5 min; weekly: <40 min; monthly: 1 min
Onboard maintenance records	no	no	no
Training provided with purchase	video	2 days on site	varies on site, 4 days at vendor offices plus self-directed online class
Approx. No. of training hours needed per tech	2 hours	2 hours	6 hours
List price	$8,685	$47,634	$97,529 standard model; $110,544 cap-piercing model
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	■ 5-parameter true random-access clotting/chromogenic; ■ 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

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Coagulation Analyzers

SURVEY OF INSTRUMENTS

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	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road. Deerfield, IL 60015-0778 847-267-5383 www.siemens.com/diagnostics	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
Instrument name/first year sold	Sysmex CA-7000/2002	Coag-A-Mate MTX III/2005 (sold as MTX since 1997)	Coag-A-Mate XM/1989
No. of units installed in U.S./Outside U.S.	—/—	>500 worldwide	>2,000 worldwide
No. of contracts signed between 1/1/07 and 11/30/07	—	—	—
Country where analyzer designed/Manufactured	Japan/Japan	Germany & U.S./Germany	U.S./U.S.
Operational type	continuous random access	random access	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	rack	rotor (32 positions)	manual pipetting into cuvette (4 wells at a time)
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	24.8 × 42 × 43.8 in/345.4 lbs/12.78 sq ft	19.7 × 30.7 × 21.3 in/100 lbs/5 sq ft, 8 w/ PC	4.6 × 14.7 × 20 in/20 lbs/2 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, reptilase time, factor assays, dRVVT screen & confirm, factor V Leiden, protein C clot, protein S activity	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays
FDA-cleared chromogenic tests	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin	AT III, hep. antifactor Xa, protein C	none
FDA-cleared immunologic tests	advanced D-dimer	none (latex immunologic assay in development)	none (latex immunologic assay in development)
Other FDA-cleared tests	n/a	none	none
User-defined tests in clinical use	n/a	alpha-2 antiplasmin, plasminogen, PT mix, APTT mix, LMWH (antifactor Xa)	none
Tests submitted for 510(k) clearance	n/a	none	none
Tests in development but not yet submitted	Innovance D-dimer, Innovance antithrombin	quantitative D-dimer immunoassay	none
Methodologies supported	clot detection, optical, turbidimetric; chromogenic; immunologic	clotting, chromogenic assays; photo-optical	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	20	8	2
No. of different assays programmed and calibrated at one time	40	32	16
No. of user-definable (open) channels	40	up to 32	16
Of those defined, No. active simultaneously	20	8	2
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/Tests per container	58/varies up to 200	16 cooled, 12 room temp. total 28/25–200	4/30–100
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	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	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	100/550 per hour PT and APTT, 300 per hour PT	32/32	4/4
Min. sample vol. aspirated precisely at one time	5 µL	2 µL	n/a
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/10 µL	50 µL/5 µL, min. 2 µL	100 µL/10 µL, min. 10 µL
Disposables used/Price of each	reaction tubes, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/ varies with volume	cuvette rings, pipettor wash solution, cleaning solution/available on request	cuvettes, stir bars, optional: printer & paper/ available on request
Supports direct-from-track sampling	yes (custom automation solutions available)	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (3–5 mL)/yes	yes/no	no/no
Sample bar-code reading capability	yes	yes	no
Reagent bar-code reading capability	yes	no	no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	yes/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	no
Hemolysis/Turbidity detection-quantitation	no/yes	no/no	no/no
Dilution of patient samples onboard	yes	yes	no
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 7 sec, APTT: 15 sec)	yes (PT: 3 sec, APTT: 5 sec)	yes (PT: 7 sec, APTT: 20 sec)
Read time extended for prolonged clotting times	yes (selectable on 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
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	7 min/280 results	2 min/90 results	2 min/200 results (manual)
• PT, PTT	8 min/480 results	5 min/60 results	5 min/50 PTT results (manual)
• Fibrinogen	8 min/280 results	2 min/75 results	2–3 min/100 results (manual)
• Factor VIII activity assay	8 min/300 results	5 min/60 results	5 min/50 results (manual)
Time delay from ordering stat to aspir. of sample	2 min	30–60 sec	≤2 min
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	onboard (incl. QC: L-J plots & Westgard)	yes (incl. QC: L-J plots)	no
Interface supplied by instrument vendor	no	yes (additional cost)	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	all commonly used LISs in North America	n/a
Bidirectional interface capability	yes (host query)	yes	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	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	custom automated connectivity with StreamLab	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	per shift: <5 min; daily: <10 min; wkly: 1 min; qrtrly: 5 min	daily: ~5 min; weekly: ~1 min; monthly: ~5 min	daily: none; weekly: ~5 min; monthly: none
Onboard maintenance records	no	no	no
Training provided with purchase	varies on site, 5 days at vendor offices for 2 operators	3 days at vendor offices	half day on site
Approx. No. of training hours needed per tech	8 hours on site	2–3 hours	1–2 hours
List price	$196,451	$52,500	$5,173
Ann. svc. contract cost (24/7)/Warranty with purchase	prices available upon request	available upon request	available upon request
Unique advantages (provided by vendors)	■ fast throughput for routine testing ■ continuous loading of reagents, consumables, and patient samples without interruption ■ connectivity to lab automation system	■ normalization of PT & APTT results between 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	■ simple to operate: clot detection starts automatically on addition of start reagent ■ flexibility; test params. can be modified to accommodate various reagent systems

Coagulation Analyzers

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Instrument name/first year sold	MDA II/1999	MiniQuant D-dimer System/2002	Destiny Optical/2006
No. of units installed in U.S./Outside U.S.	>400 worldwide	25/<25	—/—
No. of contracts signed between 1/1/07 and 11/30/07	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	U.S. & Germany/Germany
Operational type	continuous random access	discrete	continuous random access
Reagent type	open reagent system	uses MiniQuant D-dimer reagents	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	racks	single cuvettes	continuous rack loading
Model type	floor standing	handheld portable	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	58 × 75 × 31 in/840 lbs/18 sq ft w/PC	4.3 × 7.9 × 8.9 in/2.75 lbs/1 sq ft	22 × 33 × 27 in/165 lbs/6.8 sq ft
FDA-cleared clotting-based tests	PT screening (moderate & low ISI), PT factors, quick%, APTT screening, APTT factors, PT mix, APTT mix, TT, fib.	none	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, XII
FDA-cleared chromogenic tests	hep. antifactor Xa, AT III, protein C, plasminogen, alpha-2 antiplasmin, lupus (dRVVT screen and confirm), APCR	none	AT, heparin Xa
FDA-cleared immunologic tests	D-dimer (latex immunoassay)	D-dimer, quantitative microlatex	D-dimer
Other FDA-cleared tests	none	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	D-dimer	—
Tests submitted for 510(k) clearance	none	none	—
Tests in development but not yet submitted	none	none	—
Methodologies supported	clotting; chromogenic; immunoassay; photo-optical	immunologic (quantitative microlatex)	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	16	1	10
No. of different assays programmed and calibrated at one time	72	1	unlimited
No. of user-definable (open) channels	20	n/a	unlimited
Of those defined, No. active simultaneously	16	1	10
Factor assays require manual manipulation or dilutions	no	n/a	no
No. of reag. containers onboard at one time/Tests per container	30/25–400	n/a/50	31–51/varies
Reagents refrigerated onboard	yes (8° to 15°C)	no	yes (12° to 16°C)
Multiple reag. configurations supported	yes	no	yes
Reag., consumables loaded without interrupting testing	consumables yes, reagents no	no	yes
Same capabilities when 3rd-party reag. used	yes	no	yes
Max. time same lot No. of reag. can be used	12–18 months	n/a	varies by reagent—routine reagents 12 months
Walkaway capacity: No. of specimens/No. of tests	170/480	n/a/n/a	50/200
Min. sample vol. aspirated precisely at one time	5 µL	n/a	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/10 µL	n/a/n/a	50 µL/10 µL
Disposables used/Price of each	cuvettes, bar-code labels, MDA probe cleaner/ available on request	cuvettes/—	reaction trays, ProWash
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	no/no	yes (standard, pediatric, micro)/no
Sample bar-code reading capability	yes (internal bar-code scanner)	no	yes
Reagent bar-code reading capability	yes	no	in development
Onboard test automatic inventory	yes	no	yes
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no	yes
Hemolysis/Turbidity detection-quantitation	yes/yes (detects bilirubin, corrects for lipemia)	no/no	not necessary
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT: default 3 sec, APTT: default 5 sec)	n/a	no
Read time extended for prolonged clotting times	yes (selectable on menus)	n/a	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	n/a	yes/yes
• No. and sources of reag.	yes	n/a	yes
• Incub. times/Reading times	no/yes	n/a	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	n/a/yes	no/yes
Auto shutdown/Auto startup programmable	yes/yes	n/a/n/a	yes/yes
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	12 min/180 results	n/a	<3 min/110 tests
• PT, PTT	12 min/180 results	n/a	<6 min/60 tests
• Fibrinogen	12 min/180 results	n/a	<6 min/60 tests
• Factor VIII activity assay	12 min/180 results	n/a	<6 min/40 tests
Time delay from ordering stat to aspir. of sample	<1 min	—	varies by test
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	onboard (incl. QC: L-J plots, Westgard)	no	onboard (incl. QC: L-J 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	n/a	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	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	yes
How labs get LOINC codes for reagent kits	n/a	n/a	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no	no
Modem servicing	yes	no	yes
Time required for maintenance by lab personnel	daily: ~35 min; weekly: 45 min; monthly: 10 min	daily: 5 min	daily: <5 min; weekly: <30 min; monthly: <30 min
Onboard maintenance records	no	no	yes
Training provided with purchase	3–5 days on site, 4 days at vendor offices	1 day on site	2-4 days on site
Approx. No. of training hours needed per tech	4–5 hours	2 hours	8 hours
List price	$92,295	$5,150	$39,500
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request	available upon request	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	■ quantitative D-dimer ■ read time—5 minutes ■ easy to use	■ small automated coag. analyzer capable of routine and specialty testing, including D-dimer ■ Windows-based icon-driven software easy to learn and retain ■ unlimited, anytime stat access

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Instrument name/first year sold	**Destiny Plus/2005**	**KC1△/2001**
No. of units installed in U.S./Outside U.S.	>125/>100	>250/>100
No. of contracts signed between 1/1/07 and 11/30/07	—	—
Country where analyzer designed/Manufactured	Germany & U.S./Germany	Germany/Germany
Operational type	continuous random access	semiautomatic, single channel
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	manual
Model type	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	22 × 33 × 27 in./165 lbs/6.8 sq ft	3.25 × 5.5 × 8.25 in/2.5 lbs/<1 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, XII	PT, APTT, fib.
FDA-cleared chromogenic tests	AT, heparin Xa	n/a
FDA-cleared immunologic tests	D-dimer	n/a
Other FDA-cleared tests	—	n/a
User-defined tests in clinical use	—	n/a
Tests submitted for 510(k) clearance	—	n/a
Tests in development but not yet submitted	—	n/a
Methodologies supported	clot detection, mechanical & optical (turbidimetric); chromogenic; immunologic	clot detection, mechanical
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no
No. of different measured assays onboard simultaneously	10	1
No. of different assays programmed and calibrated at one time	unlimited	manual
No. of user-definable (open) channels	unlimited	n/a
Of those defined, No. active simultaneously	10	n/a
Factor assays require manual manipulation or dilutions	no	yes
No. of reag. containers onboard at one time/Tests per container	31–51/varies	1/varies for each assay
Reagents refrigerated onboard	yes (12° to 16°C)	no
Multiple reag. configurations supported	yes	no
Reag., consumables loaded without interrupting testing	yes	n/a, manual
Same capabilities when 3rd-party reag. used	yes	yes
Max. time same lot No. of reag. can be used	varies by reagent—routine reagents 12 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	50/240	n/a, manual
Min. sample vol. aspirated precisely at one time	5 µL	n/a
Standard specimen vol. required to run PT or PTT/Factor VIII activity	25 µL/10 µL	50 µL/n/a
Disposables used/Price of each	reaction trays, ProWash	cuvettes & ball dispenser/available on request
Supports direct-from-track sampling	no	n/a
Primary tube sampling supported/Pierces caps on primary tubes	yes (all standard, pediatric, micro)/no	n/a
Sample bar-code reading capability	yes	n/a
Reagent bar-code reading capability	in development	n/a
Onboard test automatic inventory	yes	n/a
Measures No. of tests remaining/Short sample detection	yes/yes	n/a
Clot detection as preanalytical variable in plasma sample	no	n/a
Auto. detection of adequate reag. for aspir. & anal.	yes	n/a
Hemolysis/Turbidity detection-quantitation	not necessary	n/a
Dilution of patient samples onboard	yes	n/a
Automatic rerun capability/Auto reflex testing capability	yes/yes	n/a
Lag time during which hypercoagulable samples will not be detected	no	yes (PT & PTT: 4.5 sec)
Read time extended for prolonged clotting times		yes
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	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	no/yes
Auto shutdown/Auto startup programmable	yes/yes	no/no
Stat time to completion of all analytes/Throughput per hour for:		
• PT alone	<3 min/180 tests	75 sec/48 tests
• PT, PTT	<6 min/90 tests	350 sec/10 tests
• Fibrinogen	<6 min/105 tests	65 sec/55 tests
• Factor VIII activity assay	<6 min/58 tests	275 sec/13 tests
Time delay from ordering stat to aspir. of sample	varies by test	n/a
Auto. transfer of QC results to LIS	yes	yes
Data management capability	onboard (incl. QC: LJ plots, Westgard)	yes
Interface supplied by instrument vendor	no	no
Interfaces in active user sites for:	all major LIS vendors	—
Bidirectional interface capability	yes (broadcast download & host query)	n/a
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	yes	—
How labs get LOINC codes for reagent kits	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	n/a
Modem servicing	yes	n/a
Time required for maintenance by lab personnel	daily: <5 min; weekly: <30 min; monthly: <30 min	none
Onboard maintenance records	yes	n/a
Training provided with purchase	2-4 days on site; 3 days at vendor offices	as needed on site
Approx. No. of training hours needed per tech	8 hours	2 hours
List price	$79,500	$2,206
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request	available upon request
Unique advantages (provided by vendors)	■ 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	■ patented ball technology for reproducible and reliable results ■ provides significant cost savings when used with Trinity's reagents and controls

Coagulation Analyzers

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Instrument name/first year sold	**KC4Δ/2001**	**Destiny Max**
No. of units installed in U.S./Outside U.S.	>100/>100	0/0 (submitted for FDA approval in 2008)
No. of contracts signed between 1/1/07 and 11/30/07	—	0
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany
Operational type	semiautomatic, 4 channels	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	manual	continuous rack loading
Model type	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	4.7 × 13.9 × 17.7 in/14 lbs/1.7 sq ft	29.5 × 59 × 27 in./340 lbs/11.03 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, intrinsic & extrinsic factors	n/a
FDA-cleared chromogenic tests	n/a	n/a
FDA-cleared immunologic tests	n/a	n/a
Other FDA-cleared tests	n/a	n/a
User-defined tests in clinical use	n/a	n/a
Tests submitted for 510(k) clearance	n/a	—
Tests in development but not yet submitted	n/a	all coagulation tests
Methodologies supported	clot detection, mechanical	clot detection, mechanical & optical; chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no
No. of different measured assays onboard simultaneously	5	unlimited
No. of different assays programmed and calibrated at one time	1/1	unlimited
No. of user-definable (open) channels	n/a	unlimited
Of those defined, No. active simultaneously	up to 4	unlimited
Factor assays require manual manipulation or dilutions	yes	no
No. of reag. containers onboard at one time/Tests per container	5/varies for test kit	—/varies by test
Reagents refrigerated onboard	no	yes (12° to 16°C)
Multiple reag. configurations supported	no	yes
Reag., consumables loaded without interrupting testing	n/a, manual	yes
Same capabilities when 3rd-party reag. used	yes	no
Max. time same lot No. of reag. can be used	12–18 months	varies—routine reagents 12 months
Walkaway capacity: No. of specimens/No. of tests	n/a, manual	120/71,000
Min. sample vol. aspirated precisely at one time	n/a	25 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/10 µL	25 µL/10 µL
Disposables used/Price of each	cuvettes & ball dispenser/available on request	reaction trays, ProWash
Supports direct-from-track sampling	n/a	yes
Primary tube sampling supported/Pierces caps on primary tubes	n/a	yes/yes
Sample bar-code reading capability	n/a	yes
Reagent bar-code reading capability	n/a	yes
Onboard test automatic inventory	n/a	yes
Measures No. of tests remaining/Short sample detection	n/a	yes/yes
Clot detection as preanalytical variable in plasma sample	n/a	no
Auto. detection of adequate reag. for aspir. & anal.	n/a	yes
Hemolysis/Turbidity detection-quantitation	n/a	not necessary/not necessary
Dilution of patient samples onboard	n/a	yes
Automatic rerun capability/Auto reflex testing capability	n/a	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 4.5 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
• No. and sources of reag.	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	yes/yes
Stat time to completion of all analytes/Throughput per hour for:		
• PT alone	75 sec/48 tests	<3 min/~350 tests
• PT, PTT	350 sec/10 tests	<6 min/~232 tests
• Fibrinogen	65 sec/55 tests	<6 min/~200 tests
• Factor VIII activity assay	275 sec/13 tests	<6 min/~200 tests
Time delay from ordering stat to aspir. of sample	n/a	<3 min
Auto. transfer of QC results to LIS	yes	yes
Data management capability	yes	onboard (incl. QC: LJ plots, Westgard)
Interface supplied by instrument vendor	no	no
Interfaces in active user sites for:	—	n/a
Bidirectional interface capability	n/a	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	—	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	n/a	yes
Modem servicing	n/a	yes
Time required for maintenance by lab personnel	none	daily: <5 min; weekly: <10 min; monthly: <30 min
Onboard maintenance records	n/a	yes
Training provided with purchase	as needed on site	3–5 days on site; 5 days at vendor offices
Approx. No. of training hours needed per tech	2 hours	5 hours
List price	$9,660	$129,000
Ann. svc. contract cost (24/7)/Warranty with purchase	available upon request	available upon request
Unique advantages (provided by vendors)	■ 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	■ 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