SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 1 of 10 *See accompanying article, page 18*	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	Dade Behring Inc. **Jackie Hauser** jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com
Instrument name/first year sold	CD2000/1986	CoaLab/1991	BCS XP/2006
No. of units installed in U.S./Outside U.S.	>500/>1,000	—/—	—/—
No. of contracts signed between 1/1/06 and 12/31/06	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	batch, discrete	discrete, batch	continuous random access
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)	open reagent system (reconst. manually), optimized for Dade Behring instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	cuvette ring (automated)	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x 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	37 × 49 × 25 in/330 lbs/14 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, fibrinogen, TT, reptilase time, factor assays, dRVVT screen and confirm, factor V Leiden, protein C clot, protein S activity
FDA-cleared chromogenic tests	none	none	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin
FDA-cleared immunologic tests	none	none	advanced D-dimer
Other FDA-cleared tests	none	none	BC von Willebrand-risto. cofactor assay (agglut of fixed plts)
User-defined tests in clinical use	none	none	n/a
Tests submitted for 510(k) clearance	none	none	n/a
Tests in development but not yet submitted	none	none	ETP (for research use only)
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing–optical detection	clot detection, optical (tungsten, turbidimetric)	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	2 (PT, APTT)	30	>40 tests/samples
No. of different assays programmed and calibrated at one time	1 (fib.)	30	99
No. of user-definable (open) channels	2	2	8,999
Of those defined, No. active simultaneously	2	varies with test-reagent combination	>100
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	90/varies, up to 200
Reagents refrigerated onboard	no	no	yes (<15°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	12 months
Walkaway capacity: No. of specimens/No. of tests	no	32/30	100 samples/400 cuvettes
Min. sample vol. aspirated precisely at one time	manual pipetting	5 µL	3 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, min 100 µL (including dead vol)/50 µL, min 100 µL
Disposables used/Price of each	500 microcuvette w/ mixers in trays/11.6¢ ea., bulk 11¢ ea.; 500 macrocuv. w/ mixers in trays/12¢ ea., bulk 10.6¢ ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3k tips bulk/3.9¢ ea.	sample cups, measurement cuvette rings/prices vary	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/price varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes (all up to 100 mm long, ext. diam. 10-16 mm)/no
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	yes/yes
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (3 sec)	yes (3 sec)	yes (7 sec for PT & PTT)
Read time extended for prolonged clotting times	yes, up to 999 sec	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
Autocalibration or autocalib. alert/Multipoint calibration supported	no/no	no/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	120 sec/user defined	4 min/140 specimens	<5 min/~380 results (including abnormals)
• PT, PTT	240 sec/user defined	8 min/140 specimens	<5 min/~325 results (including abnormals)
• Fibrinogen	300 sec/user defined	4 min/140 specimens	<5 min (if curve available)~315 results
• Factor VIII activity assay	300 sec/user defined	varies/varies	<5 min (if curve available)~280 results
Time delay from ordering stat to aspir. of sample	none—all preanalytical	15 sec	varies by test in progress, appox. >5 min
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	yes (incl. QC: L-J plots)	yes, onboard (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	call technical support for inquiry	n/a	in development
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	no
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: <5 min; weekly: >10 min.; monthly: 15 min
Onboard maintenance records	no	yes	yes
Training provided with purchase	videotape; on-site training extra	varies per site	5 days at vendor offices for 2 operators
Approx. No. of training hours needed per tech	2 hours	varies	8 hours on site
List price	$900, special pricing avail. upon written request for quote	$25,000	$167,401
Ann. svc. contract cost (24/7)/Warranty with purchase	additional 1-yr initial contract $500 (optional)/1 yr, $300 renewal	various options available/1 yr	$17,600/1 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	• user-definable calibration curve expiration and prewarning alerts • user-definable bar-code utility enables customizable reagent protocols • user-friendly Windows XP software

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

Survey editor: Raymond D. Aller, MD

Coagulation Analyzers

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Instrument name/first year sold	**Sysmex CA-530/2006**	**BFT II/U.S.: 1999**	**Sysmex CA-560/U.S.: 2003**
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/06 and 12/31/06	—	—	—
Country where analyzer designed/Manufactured	Japan/Japan	Germany/Germany	Japan/Japan
Operational type	batch, continuous random access	batch	continuous random access
Reagent type	open reagent system (reconst. manually), optimized for Dade Behring instruments	open reagent system (reconst. manually)	open reagent system (reconst. manually), optimized for Dade Behring instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack	manual	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	19 × 21 × 18.5 in/99 lbs/9 sq ft	3.9 × 7.9 × 11.8 in/8.4 lbs/1.5 sq ft	19 × 21 × 18.5 in/99 lbs/9 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, reptilase time, protien C clot	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, reptilase time, protein C clot
FDA-cleared chromogenic tests	AT III, protein C chromo, heparin	n/a	AT III, protein C chromo, heparin
FDA-cleared immunologic tests	—	n/a	advanced D-dimer
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	n/a	none	n/a
Tests submitted for 510(k) clearance	n/a	none	none
Tests in development but not yet submitted	n/a	none	n/a
Methodologies supported	clot detection: optical; turbidimetric, chromogenic; immunol.	turbodensitometric	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	5	1	5
No. of different assays programmed and calibrated at one time	7	3	7
No. of user-definable (open) channels	7	n/a	7
Of those defined, No. active simultaneously	5	1	5
Factor assays require manual manipulation or dilutions	n/a	n/a	n/a
No. of reag. containers onboard at one time/Tests per container	11/vaires, up to 200	4/up to 2,000	11/varies, up to 200
Reagents refrigerated onboard	yes (15°C)	no	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	consumables yes, reagents no	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12 months	12 months	12 months
Walkaway capacity: No. of specimens/No. of tests	10/50	1/1	10/50
Min. sample vol. aspirated precisely at one time	10 µL/50 µL	50 µL	10 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	n/a/n/a	50 µL	50 µL/n/a
Disposables used/Price of each	reaction tubes, CA clean I, thermal paper/price varies with volume	cuvettes, printer paper/price varies with volume	reaction tubes, CA clean I, thermal paper/price varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (3-5 mL)/no	no/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	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	no/yes	no/no	no/yes
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (<7 sec for PT; <15 sec for PTT)	yes (PT: 5 sec, APTT: 15 sec)	yes (PT: <7 sec, PTT: <15 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	no	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/no	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/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/54 results	1 min/n/a manual	7 min/54 results
• PT, PTT	8 min/43 results	n/a manual	8 min/43 results
• Fibrinogen	7 min/54 results	<1 min/n/a manual	7 min/54 results
• Factor VIII activity assay	n/a	n/a	n/a
Time delay from ordering stat to aspir. of sample	2 min	n/a	2 min
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	onboard (incl. QC: L-J plots)	no	onboard (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	n/a	no
Interfaces in active user sites for:	Cerner, Misys, others	n/a	Cerner, Misys, Meditech, others
Bidirectional interface capability	yes (host query)	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	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: <5 min	daily: 1 min	daily: <5 min
Onboard maintenance records	no	no	no
Training provided with purchase	2 days	video	2 days on site
Approx. No. of training hours needed per tech	2 hours	2 hours	2 hours
List price	$33,897	$8,457	$46,382
Ann. svc. contract cost (24/7)/Warranty with purchase	$4,824/1 yr	depot service (repair)/1 yr	$4,824 (business hours)/1 yr
Unique advantages (provided by vendors)	• smallest footprint in its class • onboard quality control package • primary tube sampling and removeable reagent trays	• 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

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Coagulation Analyzers

Part 3 of 10 *See accompanying article, page 18*	Dade Behring Inc. Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	Dade Behring Inc. Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	Diagnostica Stago Inc. Audrey Woodbeck audrey.woodbeck@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	Sysmex CA-1500/U.S.: 2000; worldwide: 1999	Sysmex CA-7000/2002	STA-R Evolution Hemostasis System/2005
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/06 and 12/31/06	—	—	—
Country where analyzer designed/Manufactured	Japan/Japan	Japan/Japan	France/France
Operational type	continuous random access	continuous random access	continuous random access
Reagent type	open reagent system (lyoph., reconst. manually), optimized for Dade Behring instruments	open reagent system	open reagent system (lyoph., reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack × 5	rack	rack with continuous specimen access
Model type	benchtop	benchtop	floor standing
Dimensions (H x W x 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	49.2 × 50.3 × 32.2 in/507 lbs/26.8 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, TT, fib., reptilase, factor assays, proteins C & S, lupus anticoag. screen & confirm
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	heparin (UFH & LMWH), protein C, AT, plasminogen, antiplasmin
FDA-cleared immunologic tests	advanced D-dimer	advanced D-dimer	D-dimer, VWF, total & free protein S/C, AT, antigen
Other FDA-cleared tests	none	n/a	n/a
User-defined tests in clinical use	n/a	n/a	dRVVT screen & confirm assays, APCR, and other clot-based, chromogenic, and immunological tests with user-defined applications
Tests submitted for 510(k) clearance	n/a	n/a	n/a
Tests in development but not yet submitted	—	—	n/a
Methodologies supported	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic	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	15	20	up to 200
No. of different assays programmed and calibrated at one time	25	40	up to 200
No. of user-definable (open) channels	25	40	200
Of those defined, No. active simultaneously	15	20	200
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	70/up to 83
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	yes (15–19°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	18 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	215/32
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/10 µL	50 µL/10 µL	50 µL/5 µL
Disposables used/Price of each	reaction tubes, sample plates, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/prices vary with volume	reaction tubes, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/prices vary with volume	cuvettes & wash-clean solution/varies with volume
Supports direct-from-track sampling	yes (Sysmex CST series)	yes (custom automation solutions available)	yes (Beckman Coulter, Bayer LabCell, Roche CLAS)
Primary tube sampling supported/Pierces caps on primary tubes	yes (3–5 mL)/yes	yes (3–5 mL)/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/yes	no/yes	no/no (not necessary for mechanical detection tech.)
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	yes/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 7 sec, PTT: 15 sec)	yes (PT: 7 sec, PTT: 15 sec)	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	no/yes	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	7 min/120 results	7 min/280 results	<6 min/~300
• PT, PTT	8 min/80 results	8 min/480 results	7 min/~150
• Fibrinogen	8 min/˜120 results	8 min/280 results	7 min/~180
• Factor VIII activity assay	8 min/n/a	8 min/300 results	7 min/~180
Time delay from ordering stat to aspir. of sample	2 min	2 min	<15 sec
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)	onboard (L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others
Bidirectional interface capability	yes (host query)	yes (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	Web site
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes (Sysmex CST series)	custom automated connectivity with StreamLab	yes (Beckman Coulter, Bayer LabCell, Roche CLAS)
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	daily: <5 min; weekly: <40 min; monthly: 1 min	per shift: <5 min; daily: <10 min; wkly: 1 min; qrtrly: 5 min	daily: none; weekly: <30 min; monthly: <30 min
Onboard maintenance records	no	no	yes
Training provided with purchase	varies on site, 4 days at vendor offices plus self-directed online class	varies on site, 5 days at vendor offices for 2 operators	varies on site, 5 days at vendor offices
Approx. No. of training hours needed per tech	6 hours	8 hours on site	~3–5 hours
List price	$94,965 standard model; $107,638 cap-piercing model	$191,286	$161,900/1 yr
Ann. svc. contract cost (24/7)/Warranty with purchase	$10,404 standard model; $11,708 cap-piercing/1 yr	$16,792/1 yr	prices available upon request/1 yr
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	• fastest throughput available for routine testing • continuous loading of reagents, consumables, and patient samples without interruption • connectivity to lab automation system	• viscosity-based detection system • connectivity to lab automation systems • exclusive software for password protection and result traceability

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	Diagnostica Stago Inc. **Audrey Woodbeck** audrey.woodbeck@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. **Audrey Woodbeck** audrey.woodbeck@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. **Audrey Woodbeck** audrey.woodbeck@stago-us.com 5 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 1/1/06 and 12/31/06	—	—	—
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 x W x 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, fib., reptilase, factors, proteins C & S, lupus anticoag. screen & confirm	PT, APTT, TT, fib., reptilase, factors, proteins C & S, lupus anticoag. screen & confirm	PT, APTT, TT, fib., reptilase, factors, proteins C & S, lupus anticoag. screen & confirm
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	dRVVT screen & confirm assays, APCR, other clotting-based chromogenic & immunological tests with user-defined applications	dRVVT screen & confirm assays, APCR, other clotting-based tests can have user-defined applications	dRVVT screen & confirm assays, APCR, other clotting-based tests with user-defined applications
Tests submitted for 510(k) clearance	2	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 (15–19°C)	yes (15–19°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

Part 5 of 10

See accompanying article, page 18

	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Laboratories Jim Campbell jcampbell@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com
Instrument name/first year sold	Cascade M/1991	Cascade M-4/1992	AggRAM/2005
No. of units installed in U.S./Outside U.S.	200/100	150/25	50/75
No. of contracts signed between 1/1/06 and 12/31/06	—	—	—
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 x W x 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 preanalytic 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 h
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 hrs 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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Coagulation Analyzers

Part 6 of 10 *See accompanying article, page 18*	Instrumentation Laboratory/Beckman Coulter Inc. Venita Shirley vshirley@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-993-8687 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Venita Shirley vshirley@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-993-8687 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Venita Shirley vshirley@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-993-8687 www.beckmancoulter.com
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 1/1/06 and 12/31/06	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 x W x 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	D-dimer, VWF (Act. & Ag.) (ACL 7000)	D-dimer, vWF (Act. & Ag.), free protein S, factor XIII Ag.	D-dimer, vWF (Act. & Ag.), free protein S, factor XIII Ag.
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	none
Tests submitted for 510(k) clearance	—	homocysteine	homocysteine
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/price varies	rotors/price varies	cuvettes/price 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	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	no/no	yes/yes	yes/yes
• No. and sources of reag.	no	yes	yes
• Incub. times/Reading times	no/yes	yes/yes	yes/yes
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	$54,995	$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

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Coagulation Analyzers

Part 7 of 10

See accompanying article, page 18

	Instrumentation Laboratory/Beckman Coulter Inc. Venita Shirley vshirley@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822 714-993-8687 www.beckmancoulter.com	Thermo Scientific Ron Evancheck ronald.evancheck@thermofisher.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.thermofisher.com	Thermo Scientific Ron Evancheck ronald.evancheck@thermofisher.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.thermofisher.com
Instrument name/first year sold	ACL TOP Series/2004	ThromboScreen 200/1994	ThromboScreen 400c/1996
No. of units installed in U.S./Outside U.S.	4,000+/8,000+ (all models combined)	>50/>300	15/>150
No. of contracts signed between 1/1/06 and 12/31/06	75 (U.S.)	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	Germany/Germany
Operational type	continuous random access	batch, discrete	batch, discrete
Reagent type	open reagent system	open reagent system (reconst. manually)	open reagent system (reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	racks, continuous loading of primary tubes	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	28.7 × 59.4 × 29.9 in/330.7 lbs/21 sq ft	4 × 8 × 12 in/5 lbs/1 sq ft	5 × 12 × 12 in/10 lbs/1 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (Clauss & PT based), TT, factors, lupus (SCT & dRVVT), APCR-V	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance, proteins C&S
FDA-cleared chromogenic tests	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	none	AT III, heparin
FDA-cleared immunologic tests	D-dimer, D-dimer HS, vWF (Act. & Ag.), free protein S, XIII Ag.	none	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	n/a	n/a
Tests submitted for 510(k) clearance	homocysteine	none	none
Tests in development but not yet submitted	INR plasma set, global protein C pathway	none	none
Methodologies supported	clot detection, LED optical, chromogenic; immunologic	clot detection, optical	clot detection, optical, chromogenic
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	2	2
No. of different assays programmed and calibrated at one time	500	14	18
No. of user-definable (open) channels	250	n/a	n/a
Of those defined, No. active simultaneously	30	1	1
Factor assays require manual manipulation or dilutions	no	yes	yes
No. of reag. containers onboard at one time/Tests per container	60/varies	3/varies	3/varies
Reagents refrigerated onboard	yes (15°C)	no	no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18 months	18–24 months	18–24 months
Walkaway capacity: No. of specimens/No. of tests	120/800	n/a/n/a	n/a/n/a
Min. sample vol. aspirated precisely at one time	4 µL	25 µL	50 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	PT: 50 µL/25 µL	50 µL, min. 50 µL/—	50 µL, min. 50 µL/—
Disposables used/Price of each	cuvettes/price varies	cuvettes & pipette tips/prices vary	cuvettes & pipette tips/prices vary
Supports direct-from-track sampling	yes (in development)	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes (optional)	no/no	no/no
Sample bar-code reading capability	yes	no	no
Reagent bar-code reading capability	yes	no	no
Onboard test automatic inventory	yes	no	no
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no	no
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	yes	no	no
Automatic rerun capability/Auto reflex testing capability	yes/yes	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	no	no	no
Read time extended for prolonged clotting times	yes	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
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	no/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	<1 min/120 specimens	<1 min/120 specimens
• PT, PTT	8 min/165 specimens	varies	varies
• Fibrinogen	<3 min/360 specimens	<1 min/120 specimens	<1 min/120 specimens
• Factor VIII activity assay	8 min/165 specimens	n/a	n/a
Time delay from ordering stat to aspir. of sample	minimized	n/a	n/a
Auto. transfer of QC results to LIS	yes	no	no
Data management capability	yes	no	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major vendors	—	n/a
Bidirectional interface capability	yes (broadcast download & host query)	no	no
Results transferred to LIS as soon as test time complete	yes	no	no
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	n/a	n/a
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: <10 min; weekly: 10 min; no monthly maintenance	daily: 5 min; weekly: 5 min; monthly: 5 min	daily: 5 min; weekly: 5 min; monthly: 5 min
Onboard maintenance records	yes	no	no
Training provided with purchase	5 days at vendor offices	as needed on site	as needed on site
Approx. No. of training hours needed per tech	24–40 hours	1 hour	1 hour
List price	$145,000	$3,800	$6,100
Ann. svc. contract cost (24/7)/Warranty with purchase	various options available/1 yr	varies/1 yr	varies/1 yr
Unique advantages (provided by vendors)	• state-of-the-art technology featuring clot signature curve analysis • robust system offering continuous operation w/o interruption to workflow • minimized operator intervention using intuitive Windows 2000 Professional software • 2D bar code for reagent, claibration, and control assay value import	• low volume or backup • small footprint—fits anywhere • simple to operate	• small footprint—fits anywhere • chromogenic assay capability • performs kinetic and endpoint determination

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SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 8 of 10 *See accompanying article, page 18*	**Thermo Scientific** **Ron Evancheck** ronald.evancheck@thermofisher.com 8365 Valley Pike Middletown, VA 22645 540-869-8224 www.thermofisher.com	**Trinity Biotech** **Brooke McCutchan** brooke.mccutchan@trinityusa.com 400 Connell Drive, Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	**Trinity Biotech** **Brooke McCutchan** brooke.mccutchan@trinityusa.com 400 Connell Drive, Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	ThromboScreen 1000/2003	Coag-A-Mate MTX I I I/2005 (sold as MTX since 1997)	Coag-A-Mate XM/1989
No. of units installed in U.S./Outside U.S.	>40/10	>500 worldwide	>2,000 worldwide
No. of contracts signed between 1/1/06 and 12/31/06	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany & U.S./Germany	U.S./U.S.
Operational type	batch, random access	random access	discrete
Reagent type	open reagent system (reconst. manually)	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	carousel	rotor (32 positions)	manual pipetting into cuvette (4 wells at a time)
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	28 × 22 × 18 in/35 lbs/3 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, fibrinogen	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays
FDA-cleared chromogenic tests	none	AT III, hep. antifactor Xa, protein C	none
FDA-cleared immunologic tests	none	none (latex immunologic assay in development)	none (latex immunologic assay in development)
Other FDA-cleared tests	none	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	none	none	none
Tests in development but not yet submitted	none	quantitative D-dimer immunoassay	—
Methodologies supported	optical turbodensitometry	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	3	8	2
No. of different assays programmed and calibrated at one time	3	32	16
No. of user-definable (open) channels	3	up to 32	16
Of those defined, No. active simultaneously	3	8	2
Factor assays require manual manipulation or dilutions	n/a	no	yes
No. of reag. containers onboard at one time/Tests per container	6/varies	16 cooled, 12 room temp. total 28/25–200	4/30–100
Reagents refrigerated onboard	no	yes (15°C)	no
Multiple reag. configurations supported	yes	yes	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	18–24 months	12–18 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	18/3	32/32	4/4
Min. sample vol. aspirated precisely at one time	10 µL	2 µL	n/a
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 50 µL/—	50 µL/5 µL, min. 2 µL	100 µL/10 µL, min. 10 µL
Disposables used/Price of each	cuvette bars/prices vary	cuvette rings, pipettor wash solution, cleaning solution/prices available on request	cuvettes, stir bars, optional: printer & paper/prices available on request
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/no	no/no
Sample bar-code reading capability	yes	yes	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	no
Measures No. of tests remaining/Short sample detection	no/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/no	no/no	no/no
Dilution of patient samples onboard	yes	yes	no
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 7 sec; PTT: 14 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	<5 min/100 specimens	2 min/90 results	2 min/200 results (manual)
• PT, PTT	<5 min/50 specimens	5 min/60 results	5 min/50 PTT results (manual)
• Fibrinogen	<5 min/80 specimens	2 min/75 results	2–3 min/100 results (manual)
• Factor VIII activity assay	n/a	5 min/60 results	5 min/50 results (manual)
Time delay from ordering stat to aspir. of sample	<3 min	30–60 sec	2 min
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	no	yes (incl. QC: L-J plots)	no
Interface supplied by instrument vendor	no	yes (additional cost)	no
Interfaces in active user sites for:	n/a	all commonly used LISs in North America	n/a
Bidirectional interface capability	no	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	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 5 min; weekly: 15 min; monthly: 15 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	half day on site	3 days at vendor offices	half day on site
Approx. No. of training hrs needed per tech	4 hours	2–3 hours	1–2 hours
List price	$18,000	$49,995	$5,198
Ann. svc. contract cost (24/7)/Warranty with purchase	varies/1 yr	—/1 yr	depot service (repair)/1 yr
Unique advantages (provided by vendors)	• fibrinogen curve provided for reagents used on instrument • low cost, fully automated analyzer for routine coagulation tests • simple to operate • optional bar-code scanner	• normalization of PT & APTT results between automated systems • stat results within 2–5 min • flexibility; MTX can support new assays easily through 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

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Coagulation Analyzers

Part 9 of 10

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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 1/1/06 and 12/31/06	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	US & Germany/Germany
Operational type	continuous random access	discrete	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	50 positions/5 racks
Model type	floor standing	handheld portable	benchtop
Dimensions (H x W x 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/150 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	—	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	—/50	30/varies
Reagents refrigerated onboard	yes (8-15°C)	no	yes (12–16°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	50/240
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/prices 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	—/—	<3 min/110 tests
• PT, PTT	12 min/180 results	—/—	—/60 tests
• Fibrinogen	12 min/180 results	—/—	—/60 tests
• Factor VIII activity assay	12 min/180 results	—/—	—/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
Interfaces in active user sites for:	all commonly used LISs in North America	—	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	—
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 hrs 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	—/1 yr	—/1 yr	—/1 yr
Unique advantages (provided by vendors)	• patented waveform analysis technology with flags for identifying abnormal waveforms (e.g. biphasic samples) • sensitive quantitative D-dimer assay for use in diagnosis of VTE • dyes in routine reagents for volume delivery check • throughput remains the 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, any time stat access

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Instrument name/first year sold	AMAX Destiny Plus/2005	KC1∆/2001	KC4∆/2001
No. of units installed in U.S./Outside U.S.	100/>100	>100/>100	>100/>100
No. of contracts signed between 1/1/06 and 12/31/06	—	—	—
Country where analyzer designed/Manufactured	Germany & U.S./Germany	Germany/Germany	Germany/Germany
Operational type	random access	semiautomatic, single channel	semiautomatic, 4 channels
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	50 positions/5 racks	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	22 × 33 × 27 in./165 lbs/150 sq ft	3.25 × 5.5 × 8.25 in/2.5 lbs/<1 sq ft	4.7 × 13.9 × 17.7 in/14 lbs/1.7 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, XII	PT, APTT, fib.	PT, APTT, fib., TT, atroxin, intrinsic & extrinsic factors
FDA-cleared chromogenic tests	AT, heparin Xa	n/a	n/a
FDA-cleared immunologic tests	D-dimer	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	n/a
Tests in development but not yet submitted	—	n/a	n/a
Methodologies supported	clot detection, mechanical & optical (turbidimetric); chromogenic; immunologic	clot detection, mechanical	clot detection, mechanical
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	10	1	5
No. of different assays programmed and calibrated at one time	unlimited	manual	1/1
No. of user-definable (open) channels	unlimited	n/a	n/a
Of those defined, No. active simultaneously	10	n/a	up to 4
Factor assays require manual manipulation or dilutions	no	yes	yes
No. of reag. containers onboard at one time/Tests per container	30/varies	1/varies for each assay	5/varies for test kit
Reagents refrigerated onboard	yes (12-16°C)	no	no
Multiple reag. configurations supported	yes	no	no
Reag., consumables loaded without interrupting testing	yes	n/a, manual	n/a, manual
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	varies by reagent—routine reagents 12 months	12–18 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	50/240	n/a, manual	n/a, manual
Min. sample vol. aspirated precisely at one time	5 µL	n/a	n/a
Standard specimen vol. required to run PT or PTT/Factor VIII activity	25 µL/10µL	50 µL/n/a	50 µL/10 µL
Disposables used/Price of each	reaction trays, ProWash	cuvettes & ball dispenser/inquire	cuvettes & ball dispenser/inquire
Supports direct-from-track sampling	no	n/a	n/a
Primary tube sampling supported/Pierces caps on primary tubes	yes (all standard, pediatric, micro)/no	n/a	n/a
Sample bar-code reading capability	yes	n/a	n/a
Reagent bar-code reading capability	in development	n/a	n/a
Onboard test automatic inventory	yes	n/a	n/a
Measures No. of tests remaining/Short sample detection	yes/yes	n/a	n/a
Clot detection as preanalytical variable in plasma sample	no	n/a	n/a
Auto. detection of adequate reag. for aspir. & anal.	yes	n/a	n/a
Hemolysis/Turbidity detection-quantitation	not neccesary	n/a	n/a
Dilution of patient samples onboard	yes	n/a	n/a
Automatic rerun capability/Auto reflex testing capability	yes/yes	n/a	n/a
Lag time during which hypercoagulable samples will not be detected	no	yes (PT & PTT: 4.5 sec)	yes (PT & PTT: 4.5 sec)
Read time extended for prolonged clotting times	yes	yes	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	yes/yes	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	< 3 min/180 tests	75 sec/48 tests	75 sec/48 tests
• PT, PTT	—/90 tests	350 sec/10 tests	350 sec/10 tests
• Fibrinogen	—/105 tests	65 sec/55 tests	65 sec/55 tests
• Factor VIII activity assay	—/58 tests	275 sec/13 tests	275 sec/13 tests
Time delay from ordering stat to aspir. of sample	varies by test	n/a	n/a
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: LJ plots, Westgard)	yes	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	all major LIS vendors	—	—
Bidirectional interface capability	yes (broadcast download & host query)	n/a	n/a
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	—	—	—
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	n/a	n/a
Modem servicing	yes	n/a	n/a
Time required for maintenance by lab personnel	daily: <5 min; weekly: <30 min; monthly: <30 min	none	none
Onboard maintenance records	yes	n/a	n/a
Training provided with purchase	2-4 days on site; 3 days at vendor offices	as needed on site	as needed on site
Approx. No. of training hours needed per tech	8 hours	2 hours	2 hours
List price	$79,500	$2,100	$9,200
Ann. svc. contract cost (24/7)/Warranty with purchase	—/1 yr	$650 (M–F, 8–5)/1 yr	$936 (M–F, 8–5)/1 yr
Unique advantages (provided by vendors)	• one-quarter volume testing for PT and APTT • mechanical and optical clot detection in one platform • easy to learn and retain IntuiTouch software	• patented ball technology for extremely 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 extremely reproducible and reliable results • provides significant cost savings when used with Trinity's reagents and controls

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