What's cool in coag: clot signature curves

Anne Ford

The newest trend in coagulation analyzers isn't so new after all. Clot signature curves have been around since the 1980s, but their potential for improving patient care has only recently begun to attract attention. "Patients that have early diffuse intravascular coagulation have an abnormal blip in the waveform" of their clots, explains Susan Taylor, BioMérieux hemostasis marketing manager. "We've been able to correlate this drop to patients who are very ill or potentially very ill." On the company's MDA II analyzer, this abnormality is indicated with a marker known as the A2 flag. "Quite often you can have this A2 flag two to 48 hours prior to any other lab results changing," she says.

Aside from their clinical implications, says David Schaffner, PhD, MT(ASCP), Beckman Coulter market manager for hemostasis, clot signature curves are also useful for troubleshooting. "You can look at the curve and see that maybe the blood wasn't spun, or maybe there was an instrument malfunction," he says. The curves' potential is still unfolding, he adds: "We're just beginning to look at this new form of information. It's something that really has a future."

Meanwhile, the future has already arrived for laboratories who want coagulation analyzers with D-dimer capabilities. More and more manufacturers are meeting that demand as "economy-class syndrome," or flight-induced blood clotting, has caught the public's attention. "Everybody's looking at thrombosis and the effect it's having, so the need to do D-dimer testing is becoming more imperative," says Venita Shirley, hemostasis marketing manager for Trinity Biotech. The company's Amax Destiny hemostasis analyzer offers smaller laboratories quantitative D-dimer capabilities without additional instrumentation.

With its recently released Sysmex CA-560 analyzer, Dade Behring, too, aims to provide D-dimer testing to low-volume laboratories. Medium-volume labs can look forward to the summer release of BioMérieux's Coag-A-Mate MTX III, an updated version of the MTX II that will feature automated D-dimer capabilities.

As with almost all instrumentation, coagulation analyzers are increasingly driven by the medical technologist and technician shortage. American Labor president Mike Shiflett sees the shortage reflected in lab requests for an automated coagulation analyzer that performs prothrombin time tests only. "They want them done quickly with minimal tech intervention," he says.

Schaffner adds that while laboratories have fewer staff members, "they also have more generalists. We don't have the core of really skilled specialists that have been in coag for 30 years. So not only do the instruments need to do more, but they need to have an easier user interface." He says the ACL 10000 analyzer, which is manufactured by Instrumentation Laboratory and distributed by Beckman Coulter, offers an intuitive interface with color-coded Windows software and icons.

Smaller labs, says Trinity Biotech's Shirley, face even tighter personnel restrictions: "Those techs are definitely multitasking. The Amax Destiny analyzer was designed to accommodate those folks." Incorporated into the Destiny is the IntuiTouch software system, which, she says, "alleviates the training need for the technologists running it, because it has icons that direct them what to do. All they have to do is follow the arrows."

Dade Behring marketing manager Jackie Hauser, MT(ASCP), points out that another trend—health system standardization—is affecting coagulation testing. "It seems like they're doing a lot of their specialty testing at the main facility, and smaller facilities are more like stat labs, doing the PTs, PTTs, D-dimers," she says. "So folks are looking for standardization of their technology and their results. Dade Behring is well positioned to do that with our analyzer line. We have something for every size hospital."

Helena Laboratories and Beckman Coulter, meanwhile, are addressing other personnel-related issues. By June Helena hopes to offer the Agg-Ram, a platelet aggregation analyzer with a coagulation module, for larger hospitals with specialized coagulation laboratories. "Many times they're removed from the routine clinical labs," says point of care division manager Jim Campbell, "and if they're working up a von Willebrand's or other problem patient, they may need to do additional clotting tests. It's sometimes difficult for them to get the sample to the clinical lab and have it run in a timely manner. So many of them want to have a small coag analyzer right there, and this'll just be part of the standard platelet aggregation analyzer."

Beckman Coulter's Schaffner says one technological trend, the availability of closed-tube sampling on coagulation analyzers, affords workers protection from both bloodborne pathogens and work-related injuries such as carpal tunnel syndrome. "Many people say they wouldn't consider a system without it," he says. "A single carpal tunnel incident costs a lab $5,000—if it's minor. If it's a long-term injury from a broken tube or something like that, you're looking at over $100,000."

CAP TODAY's lineup of coagulation analyzers includes, in addition to those mentioned here, American Labor/Lab A.C.M.'s CD2000 and Coa-Lab; BioMérieux's Coag-A-Mate Max and Coag-A-Mate XM; Dade Behring's BFT II, BCS, and Sysmex CA-7000 and CA-1500; Diagnostica Stago's STA-R, STA Compact, STA Compact CT, Start 4, and Start 8; Fisher Diagnostics' ThromboScreen 200, 400, and 1000; Helena Laboratories' Cascade M, Cascade M-4, and Packs-4; Instrumentation Laboratory/Beckman Coulter's Electra 1400C and 1800C and ACL 100, 1000, 7000, 8000, 9000, and Advance; and Trinity Biotech's KC1Δ, KC4Δ, Amax 200 and 400, and MiniQuant D-dimer system. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is CAP TODAY *senior editor.*

SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 1 of 13	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de
Instrument name/first year sold	CD2000/1986	CoaLab/1991
No. of units installed in U.S./outside U.S.	>500/>1,000	—/—
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany
Operational type	batch, discrete	discrete, batch
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	cuvette ring (automated)
Model type	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	5 x 12 x 8.5 in/9.2 lbs/1 sq ft	14 x 18 x 41 in/138.6 lbs/6 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
FDA-cleared chromogenic tests	none	none
FDA-cleared immunologic tests	none	none
Other FDA-cleared tests	none	none
User-defined tests in clinical use	none	none
Tests submitted for 510(k) clearance	none	none
Tests in development but not yet submitted	none	none
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing–optical detection	clot detection, optical (tungsten, turbidimetric)
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no
No. of different measured assays onboard simultaneously	2 (PT, APTT)	30
No. of different assays programmed and calibrated at one time	1 (fib.)	30
No. of user-definable (open) channels	2	2
Of those defined, No. active simultaneously	2	varies with test-reagent combination
Factor assays require manual manipulation or dilutions	yes	no
No. of reag. containers onboard at one time/tests per container	5 or more/ reag. mftr. dependent	10/varies
Reagents refrigerated onboard	no	no
Multiple reag. configurations supported	yes	yes
Reag., consumables loaded without interrupting testing	yes	no
Same capabilities when 3rd-party reag. used	yes	yes
Max. time same lot number of reag. can be used	laboratory dependent	18 months
Walkaway capacity: No. of specimens/No. of tests	no	32/30
Min. sample vol. aspirated precisely at one time	manual pipetting	5 µL
Standard specimen vol. required to run PT or PTT/factor VIII activity	50 µL, min. 50 µL/50 µL, min. 50 µL	50 µL, min. 50 µL/<50 µL, min. 50 µL
Disposables used/price of each	500 microcuvette w/ mixers in trays/11.6¢ ea., bulk 11¢ ea.; 500 macrocuvette w/ mixers in trays/12¢ ea., bulk 10.6¢ ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3,000 tips bulk/3.9¢ ea.	sample cups, measurement cuvette rings/prices vary
Supports direct-from-track sampling	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
Sample bar-code reading capability	no	yes
Reagent bar-code reading capability	no	no
Onboard test automatic inventory	no	yes
Measures No. of tests remaining	no	yes
Short sample detection	no	yes
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard	no	yes
Automatic rerun capability/auto reflex testing capability	no/no	yes/no
Lag time during which hypercoagulable samples will not be detected	yes (3 sec)	yes (3 sec)
Read time extended for prolonged clotting times	yes, up to 999 sec	yes (selectable on menus)
User can set different-than-standard:		
• Reag. volumes/sample volumes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes
• Incub. times/reading times	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/no	no/yes
Auto shutdown/auto startup programmable	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
• PT, PTT	240 sec/user defined	8 min/140 specimens
• Fibrinogen	300 sec/user defined	4 min/140 specimens
• Factor VIII activity assay	300 sec/user defined	varies/varies
Time delay from ordering stat to aspir. of sample	none—all preanalytical	15 sec
Auto. transfer of QC results to LIS	no	no
Data management capability	no	yes (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	no
Interfaces in active user sites for:	call technical support for inquiry	n/a
Bidirectional interface capability	no	no
Results transferred to LIS as soon as test time complete	yes	no
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
Modem servicing	no	no
Time required for maintenance by lab personnel	daily: 30 sec (temp. check, cloth cleaning); weekly: 30 sec; monthly: 5 min (temp. calib. if needed)	daily: 10 min; weekly: 10 min; monthly: 5 min; biweekly: 5 min
Onboard maintenance records	no	yes
Training provided with purchase	videotape; on-site training extra	varies per site
Approx. No. of training hours needed per tech	2 h	varies
List price	$4,200, special pricing available upon written request for quote	$25,000
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	additional 2-yr initial contract $900 (optional)/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	• smaller clinic; office, private, vet labs • low acquisition & 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

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Survey editor: Raymond Aller, MD

Coagulation Analyzers

Part 2 of 13

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Instrument name/first year sold	Coag-A-Mate Max/1999	Coag-A-Mate MTX II/1999 (sold as MTX since 1997)	Coag-A-Mate XM/1989
No. of units installed in U.S./outside U.S.	>185 worldwide	>500 worldwide	>2,000 worldwide
Country where analyzer designed/manufactured	Germany/Germany	Germany & U.S./Germany	U.S./U.S.
Operational type	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	2 rotors (31 positions each)	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	15.3 x 40.2 x 28.3 in/134.5 lbs/8 sq ft, 11 w/ PC	19.7 x 30.7 x 21.3 in/100 lbs/5 sq ft, 8 w/ PC	4.6 x 14.7 x 20 in/20 lbs/2 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., PT & APTT factors	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays
FDA-cleared chromogenic tests	AT III, hep. antifactor Xa	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	PT mix, APTT mix, lupus (dRVVT screen & confirm.), reptilase, proteins C & S (clotting), protein C (chromo.), APCR, LMWH (antifactor Xa)	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	—	quantitative D-dimer immunoassay	—
Methodologies supported	clotting, chromogenic assays; photo-optical	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	10	8	2
No. of different assays programmed and calibrated at one time	40	32	16
No. of user-definable (open) channels	18	up to 32	16
Of those defined, No. active simultaneously	10	8	2
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/tests per container	21 cooled, 16 for reagents, 5 for controls/15–160	16 cooled, 12 room temp. total 28/25–200	4/30–100
Reagents refrigerated onboard	yes (18°C)	yes (15°C)	no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	consumables yes, reagents no	no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12–18 mos	12–18 mos	12–18 mos
Walkaway capacity: No. of specimens/No. of tests	62/232	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	60 µL/10 µL	50 µL/5 µL, min. 2 µL	100 µL/10 µL, min. 10 µL
Disposables used/price of each	cuvette racks, probe cleaner, predilution strips/prices available upon request	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 (2 internal bar-code scanners)	yes	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining	yes	yes	no
Short sample detection	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	yes/yes	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 9 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	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	no/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	yes/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/180 results	2 min/90 results	2 min/200 results (manual)
• PT, PTT	<7 min/120–140 results	5 min/60 results	5 min/50 PTT results (manual)
• Fibrinogen	<7 min/140–180 results	2 min/75 results	2–3 min/100 results (manual)
• Factor VIII activity assay	<7 min/120–140 results	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	yes (incl. QC: L-J plots)	yes (incl. QC: L-J plots)	no
Interface supplied by instrument vendor	yes (additional cost)	yes (additional cost)	no
Interfaces in active user sites for:	all commonly used LISs in North America	all commonly used LISs in North America	n/a
Bidirectional interface capability	yes	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: 30 min; monthly: <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	3 days at vendor offices	3 days at vendor offices	1/2 day on site
Approx. No. of training hours needed per tech	1–2 h/30 min or less for basic operation	2–3 h	1–2 h
List price	$55,000	$49,995	$5,198
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$6,300/1 yr	$7,300/1 yr	depot service (repair)/1 yr
Unique advantages (provided by vendors)	• normalization of PT & APTT assays with other BioMérieux automated systems • workhorse analyzer for medium- to high-volume routine workload • easy operation & simple software means minimal training required	• normalization of PT & APTT results between BioMérieux 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 & 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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SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 3 of 13 ***See accompanying article, page 56***	**BioMérieux Inc.** **Susan Taylor** susan.taylor@na.biomerieux.com **100 Rodolphe St., Durham, NC 27712** **919-620-2000** www.biomerieux-usa.com	**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
Instrument name/first year sold	**MDA II/1999**	**BFT II/U.S.: 1999**	**Sysmex CA-560/U.S.: 2003**
No. of units installed in U.S./outside U.S.	**>400 worldwide**	**—/—**	**—/—**
Country where analyzer designed/manufactured	**U.S./U.S.**	**Germany/Germany**	**Japan/Japan**
Operational type	**continuous random access**	**batch**	**batch, continuous random access**
Reagent type	**open reagent system**	**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	**racks**	**manual**	**10-tube position sample rack**
Model type	**floor standing**	**benchtop**	**benchtop**
Dimensions (H x W x D)/weight/instrument footprint	**58 x 75 x 31 in/840 lbs/18 sq ft w/PC**	**3.9 x 7.9 x 11.8 in/8.4 lbs/1.5 sq ft**	**19 x 21 x 18.5 in/99 lbs/9 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.**	**PT, APTT, fib.**	**PT, APTT, fib., TT, factor assays, reptilase time, protein C**
FDA-cleared chromogenic tests	**hep. antifactor Xa, AT III, protein C, plasminogen, alpha-2 antiplasmin, lupus (dRVVT screen and confirm.), APCR**	**none**	**AT III, protein C chromo., heparin**
FDA-cleared immunologic tests	**D-dimer (latex immunoassay)**	**none**	**D-dimer**
Other FDA-cleared tests	**none**	**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**	**none**	**n/a**
Tests submitted for 510(k) clearance	**none**	**none**	**none**
Tests in development but not yet submitted	**none**	**none**	**n/a**
Methodologies supported	**clotting; chromogenic; immunoassay; photo-optical**	**clot detection, opto-mechanical**	**clot detect.: optical light scat., chromogen., 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**	**5**
No. of different assays programmed and calibrated at one time	**72**	**3**	**7**
No. of user-definable (open) channels	**20**	**n/a**	**7**
Of those defined, No. active simultaneously	**16**	**1**	**5**
Factor assays require manual manipulation or dilutions	**no**	**n/a**	**n/a**
No. of reag. containers onboard at one time/tests per container	**30/25–400**	**4/up to 2,000**	**11/varies, up to 200**
Reagents refrigerated onboard	**yes (8-15˚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 number of reag. can be used	**12–18 mos**	**12 mos**	**12 mos**
Walkaway capacity: No. of specimens/No. of tests	**170/480**	**1/1**	**10/50**
Min. sample vol. aspirated precisely at one time	**5 µL**	**50 µL**	**10 µL**
Standard specimen vol. required to run PT or PTT/factor VIII activity	**50 µL/10 µL**	**50 µL**	**50 µL/n/a**
Disposables used/price of each	**cuvettes, bar-code labels, MDA probe cleaner/prices available on request**	**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/yes**	**no**	**yes (3–5 mL)/no**
Sample bar-code reading capability	**yes (internal bar-code scanner)**	**no**	**yes**
Reagent bar-code reading capability	**yes**	**no**	**no**
Onboard test automatic inventory	**yes**	**no**	**yes**
Measures No. of tests remaining	**yes**	**no**	**yes**
Short sample detection	**yes**	**no**	**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**	**no/yes**
Dilution of patient samples onboard	**yes**	**no**	**yes**
Automatic rerun capability/auto reflex testing capability	**no/no**	**no/yes**	**no/no**
Lag time during which hypercoagulable samples will not be detected	**yes (PT: default 3 sec, APTT: default 5 sec)**	**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	**no/yes**	**yes/yes**	**yes/yes**
Autocalibration or autocalib. alert/multipoint calibration supported	**yes/yes**	**yes/yes**	**—/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	**12 min/180 results**	**1 min/n/a manual**	**7 min/60 results**
• PT, PTT	**12 min/180 results**	**n/a manual**	**8 min/41 results**
• Fibrinogen	**12 min/180 results**	**<1 min/n/a manual**	**7 min/60 results**
• Factor VIII activity assay	**12 min/180 results**	**n/a**	**n/a/n/a**
Time delay from ordering stat to aspir. of sample	**<1 min**	**n/a**	**2 min**
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)**
Interface supplied by instrument vendor	**yes (additional cost)**	**n/a**	**no**
Interfaces in active user sites for:	**all commonly used LISs in North America**	**n/a**	**Cerner, Sunquest, others**
Bidirectional interface capability	**yes (broadcast download & 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**	**—**	**—**
Electronic interface available (or will be) to automated (or robotic) specimen handling system	**yes**	**no**	**no**
Modem servicing	**yes**	**no**	**no**
Time required for maintenance by lab personnel	**daily: ~35 min; weekly: 45 min; monthly: 10 min**	**daily: 1 min**	**daily: <5 min**
Onboard maintenance records	**no**	**no**	**no**
Training provided with purchase	**3–5 days on site, 4 days at vendor offices**	**video**	**2 days on site**
Approx. No. of training hours needed per tech	**4–5 h**	**2 h**	**2 h**
List price	**$92,295**	**$8,037**	**$44,100**
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	**$12,600/1 yr**	**depot service (repair)/1 yr**	**$4,350 (business hours)/—**
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**	**• 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-vol. testing/backup to larger systems**	**• 5-parameter true random access clotting/chromogenic • small footprint, complete automation, specialty assay capability • low-operating expense**

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

Coagulation Analyzers

Part 4 of 13 *See accompanying article, page 56*	**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	**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	**Sysmex CA-1500/U.S.: 2000; worldwide: 1999**	**BCS/U.S.: 1998**	**Sysmex CA-7000/2002**
No. of units installed in U.S./outside U.S.	—/—	—/—	—/—
Country where analyzer designed/manufactured	Japan/Japan	Germany/Germany	Japan/Japan
Operational type	continuous random access	batch, continuous random access	continuous random access
Reagent type	open reagent system (lyoph., reconst. manually), optimized for Dade Behring instruments	open reagent system (reconst. manually), optimized for Dade Behring instruments	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack x 5	rack	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	20 x 31.2 x 31.2 in/186 lbs/6.8 sq ft	37 x 49 x 25 in/330 lbs/14 sq ft	24.8 x 42 x 43.8 in/345.4 lbs/12.78 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., factor assays, reptilase time, thrombin time, protein C clotting	PT, APTT, fib., TT, factor assays, reptilase time, dRVVT screen & confirm., factor V Leiden, protein C clotting	PT, APTT, fib., factor assays, protein C clotting, TT, Lupus, dRVVT, batroxobin
FDA-cleared chromogenic tests	protein S activity, AT III, plasminogen, factor VIII chromo., alpha-2 antiplasmin, protein C chromo., heparin	AT III, alpha-2 antiplasmin, plasminogen, protein C chromo., heparin, protein S activity, factor VIII	protein S activity, heparin AT III, factor VIII chromogenic, plasminogen, alpha-2 antiplasmin, protein C chromogenic
FDA-cleared immunologic tests	advanced D-dimer	advanced D-dimer	D-dimer
Other FDA-cleared tests	none	BC von Willebrand-ristocetin cofactor assay (agglut. of fixed Plts.)	n/a
User-defined tests in clinical use	n/a	n/a	n/a
Tests submitted for 510(k) clearance	n/a	n/a	n/a
Tests in development but not yet submitted	dRVVT screen and confirm, factor V Leiden	n/a	factor V Leiden assay
Methodologies supported	clot detection, optical, turbidmetric; chromogenic; immunologic (latex agglutination)	clot detection: optical; xenon flasher lamp; chromogenic; immunologic (ristocetin cofactor)	clot detection, optical, turbidimetric; chromogenic; immunologic (latex, transmitted light)
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 tests/sample (theoretically 9,999)	20
No. of different assays programmed and calibrated at one time	25	99	40
No. of user-definable (open) channels	25	8,999 (Nos. 1–1,000 are factory set & unalterable)	40
Of those defined, No. active simultaneously	15	>100	20
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	18–78/varies for micro volume assay format	58/varies up to 200
Reagents refrigerated onboard	yes (15˚C)	yes (<15˚C)	yes (15˚C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	some consumables yes, reagents no	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12 mos	12 mos	12 mos
Walkaway capacity: No. of specimens/No. of tests	50/up to 1,000	110 samples/400 cuvettes	100/550 per hour PT and APTT, 300 per hour PT
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, min. 100 µL (incl. dead vols.)/50 µL, min. 100 µL	50 µL/10 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	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/price varies with volume	reaction tubes, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/prices vary with volume
Supports direct-from-track sampling	yes (Sysmex CST series)	no	yes (custom automation solutions available)
Primary tube sampling supported/pierces caps on primary tubes	yes (3–5 mL)/yes	yes (all up to 100 mm long, ext. diam. 10–16 mm)/no	yes (3–5 mL)/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	yes (avail. for user-defined tests)	yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining	yes	yes	yes
Short sample detection	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	yes/yes	no/yes
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/auto reflex testing capability	yes/yes	yes/yes	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT: 7 sec, PTT: 15 sec)	yes (PT & PTT: 7 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/yes	yes/no	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/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	7 min/80 results	<5 min/~300 results (incl. abnormals)	7 min/280 results
• PT, PTT	8 min/120 results	<5 min/~270 results (incl. abnormals)	8 min/550 results
• Fibrinogen	8 min/80 results	<5 min (if curve avail.)/~300 results	8 min/280 results
• Factor VIII activity assay	8 min/n/a	<5 min (if curve avail.)/~280 results	8 min/300 results
Time delay from ordering stat to aspir. of sample	2 min	varies by test in progress, approx. <5 min	2 min
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots & Westgard)	limited	onboard (incl. QC: L-J plots & Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Sunquest, others	Cerner, Sunquest, Meditech, others	Cerner, others in development
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	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes (Sysmex CST series)	possible future upgrade (not avail.)	yes (custom automation solutions avail.)
Modem servicing	no	yes	no
Time required for maintenance by lab personnel	daily: <5 min; weekly: <40 min; monthly: 1 min	daily: <5 min; weekly: <10 min; monthly: 15 min	per shift: <5 min; daily: <10 min; weekly: 1 min; quarterly: 5 min
Onboard maintenance records	no	no	no
Training provided with purchase	varies on site, 4 days at vendor offices	varies on site, 5 days at vendor offices	varies on site, 5 days at vendor offices
Approx. No. of training hours needed per tech	6 h	8 h on site	8 h on site
List price	$90,295 standard model; $102,334 cap-piercing model	$138,452	$165,375 standard; $181,913 with cap piercer
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$13,000 standard model; $14,000 cap-piercing/1 yr	$19,050/1 yr	$18,500/1 yr
Unique advantages (provided by vendors)	• simultaneous curve calibrating & patient testing • ability to load multiple bottles or multiple lots of reagent	• continuous loading of bar-coded reagent & samples • multilot, multicurve reagent management • PT/APTT/fib./AT III/D-dimer in <10 min • simultaneous curve calibration & patient testing	• fastest throughput available for routine testing; PT, APTT results every 7 sec • continuous loading of reagents, consumables, & patient samples without interruption

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SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 5 of 13

See accompanying article, page 56

	Diagnostica Stago Inc. **Pascal Boulanger** pascal.boulanger@stago-us.com **5 Century Dr., Parsippany, NJ 07054** **800-222-COAG** www.stago-us.com	**Diagnostica Stago Inc.** **Pascal Boulanger** pascal.boulanger@stago-us.com **5 Century Dr., Parsippany, NJ 07054** **800-222-COAG** www.stago-us.com	**Diagnostica Stago Inc.** **Pascal Boulanger** pascal.boulanger@stago-us.com **5 Century Dr., Parsippany, NJ 07054** **800-222-COAG** www.stago-us.com
Instrument name/first year sold	**STA-R Hemostasis System/1998**	**STA Compact Hemostasis System/1996**	**Start 4/1998**
No. of units installed in U.S./outside U.S.	193/1,128	993/4,217	683/7,498
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	rack with continuous specimen access	continuous specimen access-primary tube	manual
Model type	floor standing	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	49.2 x 47.6 x 32.2 in/441 lbs/26.8 sq ft	25.2 x 38.8 x 25.8 in/351 lbs/25.6 sq ft	4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.
FDA-cleared chromogenic tests	unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin	unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin	
FDA-cleared immunologic tests	D-dimer, vWF, protein S antigen & AT III antigen (microlatex agglut.)	D-dimer, vWF antigen, protein S antigen & AT III antigen (microlatex agglut.)	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVVT screen & confirm assays & activated protein C resistance	all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVVT screen & confirm assay & activated protein C resistance	same as clotting-based tests above & dRVVT screen & confirm assays & activated protein C resistance
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clotting, chromogenic, & immunological assays	clotting, chromogenic, & immunological assays	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 200	up to 80	1
No. of different assays programmed and calibrated at one time	up to 200	up to 80	20
No. of user-definable (open) channels	200	70	4
Of those defined, No. active simultaneously	200	70	1
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/tests per container	70/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 number of reag. can be used	18 mos	18 mos	18 mos
Walkaway capacity: No. of specimens/No. of tests	215/32 per specimen	96/12 per sample	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, min. 50 µL/50 µL, min. 50 µL	50 µL, min. 50 µL/50 µL, min. 50 µL	50 µL, min. 50 µL/50 µL, min. 50 µL
Disposables used/price of each	cuvettes, wash-cleaner solution/—	cuvettes, wash-cleaner solution/—	cuvettes, beads, ball/—
Supports direct-from-track sampling	yes	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes/optional	yes (5 & 2.5 mL tube sizes)/optional	no/no (n/a)
Sample bar-code reading capability	yes	yes	no
Reagent bar-code reading capability	yes (not for user-defined tests)	yes (not for user-defined tests)	no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining	yes	yes	no
Short sample detection	yes	yes	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	yes/yes	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/no (not needed)	no/no (not needed)	no
Stat time to completion of all analytes/throughput per hour for:			
• PT alone	<6 min/300 specimens	<6 min/150 specimens	<1 min/up to 120 specimens
• PT, PTT	7 min/150 specimens	7 min/75 specimens	n/a/n/a
• Fibrinogen	7 min/180 specimens	7 min/75 specimens	<1 min/up to 120 specimens
• Factor VIII activity assay	7 min/180 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:	contact marketing for updated list	contact marketing for updated list	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	yes (contact marketing for list of systems)	no	no
Modem servicing	yes	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: <5 min; 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 offices	1 day on site
Approx. No. of training hours needed per tech	2 h basic, 24 h system training at training center	2 h basic, 24 h system training at training center	1 h
List price	$149,995	$75,000	$9,600
Ann. svc. contract cost (24 h/7 d)/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)	• walkaway testing with robotics-capable interface to automated lines for high-volume testing, with touch-screen software & cap piercing option • continuous random access for up to 200 test selections with no carryover • able to standardize with other STA family of analyzers • viscosity-based detection system	• walkaway testing for routine & specialty hemostasis assays with 45 reag. positions, 96 sample pos., up to 1,000 disposable cuvettes • continuous random access for up to 80 test selections with no carryover • able to standardize with other STA analyzers • viscosity-based detection system	• excellent for low-volume testing or as backup to optical system • programmable and preprogrammed assays with curve storage, 4 independently timed incubation stations, electronically linked multiple pipettor, 40-character display and internal thermal printer • lightweight and compact

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Coagulation Analyzers

Part 6 of 13

See accompanying article, page 56

	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Fisher Diagnostics Paul Gee paul.gee@fishersci.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com
Instrument name/first year sold	Start 8/1999	STA Compact CT/2001	ThromboScreen 200/1994
No. of units installed in U.S./outside U.S.	>20/673	62/337	>25/>250
Country where analyzer designed/manufactured	France/France	France/France	Germany/Germany
Operational type	batch	continuous random access	batch, discrete
Reagent type	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)	open reagent system (reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	continuous specimen access—primary tube	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft	25.2 x 38.8 x 25.8 in/351 lbs/25.6 sq ft	4 x 8 x 12 in/5 lbs/1 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance
FDA-cleared chromogenic tests	none	n/a	none
FDA-cleared immunologic tests	none	n/a	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	same as clotting-based tests above & dRVVT screen & confirm. assays & activated protein C resistance	all clotting-based tests can have user-def. applications, dRVVT screen & confirm. assays & activated protein C resistance	n/a
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clotting tests	clot detection, mechanical	clot detection, optical
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	1	up to 80	2
No. of different assays programmed and calibrated at one time	20	up to 80	14
No. of user-definable (open) channels	4	70	n/a
Of those defined, No. active simultaneously	1	70	1
Factor assays require manual manipulation or dilutions	yes	no	yes
No. of reag. containers onboard at one time/tests per container	4/varies, up to 100	45/varies, up to 83	3/varies
Reagents refrigerated onboard	no	yes (15–19°C)	no
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 number of reag. can be used	18 mos	18 mos	18–24 mos
Walkaway capacity: No. of specimens/No. of tests	4/1	96/12 per specimen	n/a/n/a
Min. sample vol. aspirated precisely at one time	25 µL	5 µL	25 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/5 µL, min. 5 µL	50 µL, min. 50 µL/—
Disposables used/price of each	cuvettes, beads, ball/—	cuvettes, wash-cleaner solution/—	cuvettes & pipette tips/prices vary
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	no/no (n/a)	yes (5 x 2.5 mL)/yes (optional)	no/no
Sample bar-code reading capability	no	yes	no
Reagent bar-code reading capability	no	yes (not for user-defined tests)	no
Onboard test automatic inventory	no	yes	no
Measures No. of tests remaining	no	yes	no
Short sample detection	no	yes	no
Clot detection as preanalytic variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	no
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	yes	no
Automatic rerun capability/auto reflex testing capability	no/no	yes/no	no/no
Lag time during which hypercoagulable 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	no/yes	yes/yes	no/yes
Auto shutdown/auto startup programmable	no	no/not needed	no/no
Stat time to completion of all analytes/throughput per hour for:			
• PT alone	<1 min/up to 120 specimens	<6 min/150 specimens	<1 min/120 specimens
• PT, PTT	n/a/n/a	7 min/75 specimens	varies
• Fibrinogen	<1 min/up to 120 specimens	7 min/75 specimens	<1 min/120 specimens
• Factor VIII activity assay	varies/varies	7 min/70 specimens	n/a
Time delay from ordering stat to aspir. of sample	n/a	<15 sec	n/a
Auto. transfer of QC results to LIS	no	yes	no
Data management capability	no	onboard (incl. QC: L-J plots)	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	n/a	contact marketing for updated list	—
Bidirectional interface capability	no	yes (host query)	no
Results transferred to LIS as soon as test time complete	yes	yes	no
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	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: <5 min; monthly: <5 min	weekly: <30 min; monthly: <30 min	daily: 5 min; weekly: 5 min; monthly: 5 min
Onboard maintenance records	no	yes	no
Training provided with purchase	1 day on site	varies on site, 3 days at vendor office	1 day on site
Approx. No. of training hrs needed per tech	1 h	2 h basic, 24 h system training at training ctr.	1 h
List price	$12,500	$50,000	$3,800
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	prices available on request/1 yr	prices available on request/1 yr	varies/1 yr
Unique advantages (provided by vendors)	• excellent for low- & mid-volume testing or backup • 32 incubation positions for samples, 8 measurement channels, 4 independent built-in timers for incubation; results in seconds and in various units (% ratio, INR, g/L, mg/dL, IU/mL), RS-232 interface • lightweight and compact • viscosity-based detection system	• walkaway testing for routine hemostasis assays • viscosity-based detection system • able to standardize with other STA analyzers	• low volume or backup • small footprint—fits anywhere • simple to operate

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SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 7 of 13

See accompanying article, page 56

	Fisher Diagnostics Paul Gee paul.gee@fishersci.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com	Fisher Diagnostics Paul Gee paul.gee@fishersci.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com
Instrument name/first year sold	ThromboScreen 400/1996	ThromboScreen 1000/2003	Cascade M/1991
No. of units installed in U.S./outside U.S.	—/>150	—/—	>150/—
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	U.S./U.S.
Operational type	batch, discrete	batch, random access	batch
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	carousel	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	5 x 12 x 12 in/10 lbs/1 sq ft	28 x 22 x 18 in/35 lbs/3 sq ft	8 x 15 x 13 in/25 lbs/1.4 sq ft
FDA-cleared clotting-based tests	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance, proteins C&S	PT, APTT, fibrinogen	PT, APTT, fib., TCT, factor assays II, V, VII–XII
FDA-cleared chromogenic tests	AT III, heparin	none	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	n/a	n/a	PT, APTT, fib., TCT, factor assays II, V, VII–XII
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	thrombin time	dRVVT
Methodologies supported	clot detection, optical, chromogenic	optical turbodensitometry	clot detection, optical, turbidimetric
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	2	3	1
No. of different assays programmed and calibrated at one time	18	3	1
No. of user-definable (open) channels	n/a	3	2
Of those defined, No. active simultaneously	1	3	1
Factor assays require manual manipulation or dilutions	yes	n/a	yes
No. of reag. containers onboard at one time/tests per container	3/varies	6/varies	—/—
Reagents refrigerated onboard	no	no	n/a
Multiple reag. configurations supported	yes	yes	n/a
Reag., consumables loaded without interrupting testing	yes	no	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	18–24 mos	18–24 mos	12 mos
Walkaway capacity: No. of specimens/No. of tests	n/a/n/a	18/3	no
Min. sample vol. aspirated precisely at one time	50 µL	10 µL	manual–50 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 50 µL/—	50 µL, min. 50 µL/—	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)
Disposables used/price of each	cuvettes & pipette tips/prices vary	cuvette bars/prices vary	cuvettes/500@$54; pipette tips/1,000@$82
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	no/no	yes/no	no
Sample bar-code reading capability	no	yes	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	no	no
Measures No. of tests remaining	no	no	no
Short sample detection	no	yes	no
Clot detection as preanalytical variable in plasma sample	no	no	—
Auto. detection of adequate reag. for aspir. & anal.	no	yes	no
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	yes	no
Automatic rerun capability/auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	no	yes (PT: 7 sec; PTT: 14 sec)	yes (PT: 4 sec, PTT: 14 sec)
Read time extended for prolonged clotting times	yes	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	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/120 specimens	<5 min/100 specimens	3 min/120 specimens
• PT, PTT	varies	<5 min/50 specimens	7 min/50 specimens
• Fibrinogen	<1 min/120 specimens	<5 min/80 specimens	3 min/140 specimens
• Factor VIII activity assay	n/a	n/a	7 min/50 specimens
Time delay from ordering stat to aspir. of sample	n/a	<3 min	n/a
Auto. transfer of QC results to LIS	no	yes	no
Data management capability	no	no	no (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	n/a	n/a	n/a
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	no	yes	no
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	—
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 5 min; weekly: 5 min; monthly: 5 min	daily: 5 min; weekly: 15 min; monthly: 15 min	daily: 10 min; weekly: 10 min; monthly: 20 min
Onboard maintenance records	no	no	no
Training provided with purchase	1 day on site	4 h on site	1 day on site
Approx. No. of training hours needed per tech	1 h	4 h	2–4 h
List price	$6,100	$18,000	$6,219
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	varies/1 yr	varies/1 yr	$714/1 yr
Unique advantages (provided by vendors)	• small footprint—fits anywhere • chromogenic assay capability • performs kinetic & endpoint determination	• fibrinogen curve provided for reagents used on instrument • low cost, fully automated analyzer for routine coagulation tests • simple to operate	• QC program onboard • curve storage • suitable for office lab or as backup analyzer

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

Coagulation Analyzers

Part 8 of 13

See accompanying article, page 56

	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	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com
Instrument name/first year sold	Cascade M-4/1992	Packs-4/1991	Electra 1400C/1995
No. of units installed in U.S./outside U.S.	>100/—	150/180	—/—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	random access	random access	continuous random access
Reagent type	open reagent system	open reagent system	open reagent system (reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual	automatic pipetting from tray
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	8 x 15 x 13 in/25 lbs/1.4 sq ft	10 x 22 x 23 in/70 lbs/3.5 sq ft	19.7 x 41 x 27.2 in/198 lbs/7.74 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TCT, factor assays II, V, VII–XII	none	PT, APTT, fib. (Clauss), TT, factor assays, Pfib (PT assay-based fib.), protein S
FDA-cleared chromogenic tests	none	AT III, F-VIII:C, heparin, plasminogen, protein C	plasminogen, factor VIII, antithrombin, protein C, heparin
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	ristocetin cofactor and platelet aggreg.	none
User-defined tests in clinical use	PT, APTT, fib., TCT, factor assays II, V, VII–XII	chrom: AT III, F-VIII:C, hep., plasmin., protein C, ristocetin cofactor, platelet aggreg.–ADP, EPI, COL, ristocetin, arach. acid	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	dRVVT	none	none
Methodologies supported	clot detection, optical, turbidimetric	chromogenic, ristocetin cofactor, platelet aggreg.	clot detection, optical, tungsten; 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	4	4	11
No. of different assays programmed and calibrated at one time	4	4	11
No. of user-definable (open) channels	4	12	4
Of those defined, No. active simultaneously	2	4	4
Factor assays require manual manipulation or dilutions	yes	yes	no
No. of reag. containers onboard at one time/tests per container	0/n/a	n/a/n/a	4/varies
Reagents refrigerated onboard	no	no	yes (8°C ±4)
Multiple reag. configurations supported	no	no	yes
Reag., consumables loaded without interrupting testing	no	no	yes
Same capabilities when 3rd-party reag. used	yes	n/a	yes
Max. time same lot number of reag. can be used	12 mos	12 mos	12 mos recommended
Walkaway capacity: No. of specimens/No. of tests	no	no	35/4
Min. sample vol. aspirated precisely at one time	manual-50 µL	n/a	10 µL
Standard specimen vol. required to run PT or PTT/factor VIII activity	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)	chromogenics: 75 µL, Plt. aggreg.: 225 µL PRP, Risto cofactor: 50 µL	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)
Disposables used/price of each	cuvettes/500@$54; pipette tips/1,000@$82	cuvettes/200@$55.65; pipette tips/1,000@$82; stir bars/30@$62.25	cuvette, dual well, 560 pk/prices vary; heat exchanger, 10 pk/prices vary
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	no	no	yes (13x75, 13x100, 10x85, 10x65, 12x91 mm Sarstedt)/no
Sample bar-code reading capability	no	no	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	no	yes
Measures No. of tests remaining	no	no	yes
Short sample detection	no	no	yes
Clot detection as preanalytical variable in plasma sample	—	—	no
Auto. detection of adequate reag. for aspir. & anal.	no	no	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	no	yes
Automatic rerun capability/auto reflex testing capability	no/no	no/no	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT: 4 sec, PTT: 14 sec)	n/a	yes (PT: 7 sec, PTT: 14 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	n/a	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/no
Stat time to completion of all analytes/throughput per hour for:			
• PT alone	3 min/140 specimens	—	approx. 3 min/200 specimens
• PT, PTT	7 min/80 specimens	—	approx. 7 min/136 specimens
• Fibrinogen	3 min/160 specimens	—	approx. 3 min/160 specimens
• Factor VIII activity assay	7 min/80 specimens	20–24 specimens for any test	approx. 7 min/136 specimens
Time delay from ordering stat to aspir. of sample	n/a	n/a	none
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	no (incl. QC: L-J plots)	onboard (incl. QC: L-J plots, Westgard)	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	Sunquest, Cerner, HBOC, Meditech, Dawning, Antrim, Soft Computer, others
Bidirectional interface capability	no	no	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	—	—	in development
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	—	no
Time required for maintenance by lab personnel	daily: 10 min; weekly: 10 min; monthly: 30 min	daily: 15 min; weekly: 15 min; monthly: 1 h	daily: 5 min; weekly: 15 min; monthly: 15 min
Onboard maintenance records	no	yes	no
Training provided with purchase	1 day on site	2 days on site	up to 3 days on site
Approx. No. of training hours needed per tech	2 h	4–8 h	up to 24 h
List price	$8,403	$16,650	$41,194
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$966/1 yr	$2,079/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	• 4-channel manual analyzer • QC program onboard • singles or duplicates	• specialized coag instrument intended for platelet aggreg., ristocetin cofactor, & chromogenics	• integral bar-code reader • standardized test results

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

SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 9 of 13 *See accompanying article, page 56*	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com
Instrument name/first year sold	Electra 1800C/1997	ACL 100/1988	ACL 1000/1991
No. of units installed in U.S./outside U.S.	—/—	4,000+ (all models combined)/8,000+ (all models combined)	4,000+ (all models combined)/8,000+ (all models combined)
Country where analyzer designed/manufactured	U.S./U.S.	Italy/U.S.	Italy/U.S.
Operational type	continuous random access	batch	batch
Reagent type	open reagent system (reconst. manually)	open reagent system, guarantee only IL products	open reagent system, guarantee only IL products
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	auto pipetting, rack	tray	tray
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	25 x 48 x 30.4 in/283 lbs/10.13 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (Clauss), TT, factor assays, Pfib (PT assay-based fib.), protein S	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR, Clauss fib.	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.
FDA-cleared chromogenic tests	plasminogen, factor VIII, antithrombin, protein C, heparin	none	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clot detection, optical, tungsten; chromogenic	clot detection, optical, nephelometric	clot detection, optical, nephelometric
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	12	3	3
No. of different assays programmed and calibrated at one time	12	1	1
No. of user-definable (open) channels	4	0	0
Of those defined, No. active simultaneously	4	0	0
Factor assays require manual manipulation or dilutions	no	yes	yes
No. of reag. containers onboard at one time/tests per container	6/varies	3/varies by test	3/varies by test
Reagents refrigerated onboard	yes (8°C ±4)	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	no	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12 mos recommended	18 mos	18 mos
Walkaway capacity: No. of specimens/No. of tests	100/4	18/36	18/36
Min. sample vol. aspirated precisely at one time	10 µL	10 µL	10 µL
Standard specimen vol. required to run PT or PTT/factor VIII activity	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)	50 µL (PT), 53 µL (PTT)/40 µL	50 µL (PT), 53 µL (PTT)/40 µL
Disposables used/price of each	cuvette, single well, 2,000 pk/price varies; heat exchanger, 10 pk/price varies	sample cups/price varies; rotors/price varies	rotors/price varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes [13x75, 13x100 (closed & open tubes), 10x85,10x65, 12x91 Sarstedt (open)]/yes	no/no	yes (13 x 75 mm)/no
Sample bar-code reading capability	yes	no	yes (optional)
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	yes	no	no
Measures No. of tests remaining	yes	no	no
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/auto reflex testing capability	yes/yes	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 7 sec, PTT: 14 sec)	yes (PT & PTT: 5.6 std, 6.7 ext)	yes (PT & PTT: 5.6 std, 6.7 ext)
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	no/no	no/no
• No. and sources of reag.	yes	no	no
• Incub. times/reading times	yes/yes	no/yes	no/yes
Autocalibration or autocalib. alert/multipoint calibration supported	yes/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	approx. 3 min/228 specimens	5.5 min/110 specimens	5.5 min/110 specimens
• PT, PTT	approx. 7 min/120 specimens	8.5 min/80 specimens	8.5 min/80 specimens
• Fibrinogen	approx. 7 min/146 specimens	5.5 min/110 specimens	5.5 min/110 specimens
• Factor VIII activity assay	approx. 7 min/120 specimens	9.5 min/80 specimens	9.5 min/80 specimens
Time delay from ordering stat to aspir. of sample	none	15 sec	15 sec
Auto. transfer of QC results to LIS	yes	no	no
Data management capability	onboard (incl. QC: L-J plots, Westgard)	no	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Sunquest, Cerner, HBOC, Meditech, Dawning, Antrim, Soft Computer, others	most major LIS vendors	most major LIS vendors
Bidirectional interface capability	yes (host query)	no	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	in development	in development	in development
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: 25 min; monthly: 30 min	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: 10 min; weekly: 15 min; monthly: 10 min
Onboard maintenance records	no	yes	yes
Training provided with purchase	up to 3 days on site	2 days on site	2 days on site
Approx. No. of training hrs needed per tech	24 h max.	2 h	6 h
List price	$73,645	$16,000	$21,500
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	various options available/1 yr	various options available/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	• cap piercing • standardized test results • automatic sample predilution, including parallelism function	• part of the ACL family, uses same consumables/reagents • quantitative PT-based fib. • positive displacement pipetting for low maintenance & high precision	• part of ACL family, uses same consumables/reagents • quantitative PT-based fib. • positive displacement pipetting for low maintenance & high precision

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

Coagulation Analyzers

Part 10 of 13

See accompanying article, page 56

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Instrument name/first year sold	ACL 7000/1997	ACL 9000/2000	ACL Advance/2000
No. of units installed in U.S./outside U.S.	4,000+ (all models combined)/8,000+ (all models combined)	300+/600+	500+/1,000+
Country where analyzer designed/manufactured	Italy/U.S.	Italy/U.S.	U.S./U.S.
Operational type	random programming	random access	random access
Reagent type	open reagent system, guarantee only IL products	open reagent system	open reagent system, guarantee only IL products
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray	tray	racks, up to 12
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	32.2 x 41 x 24.8 in/185 lbs/15 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.	PT, APTT, PT-based fib., Clauss fib., TT, factor assays, proteins C & S, LAC screen, LAC confirm, APCR-V	PT, APTT, PT-based fib., Clauss fib., TT, factor assays, protein C, LAC screen, LAC confirm, APCR-V
FDA-cleared chromogenic tests	antithrombin, heparin Xa, plasminogen, antiplasmin, protein C	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin, factor VIII	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin
FDA-cleared immunologic tests	D-dimer (latex enhanced immunoassay), vWF	D-dimer (latex enhanced immunoassay), vWF (latex enhanced immunoassay), free protein S	D-dimer (latex enhanced immunoassay), vWF, free protein S
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	none
Tests submitted for 510(k) clearance	none	HS-CRP	HS-CRP, protein S
Tests in development but not yet submitted	none	vWF activity	vWF activity
Methodologies supported	clot detection, optical, nephelometric; chromogenic; immunologic (optical, latex enhanced immunoassay)	clot detection, optical, nephelometric; chromogenic; immunologic	clot detection, optical; chromogenic; immunologic (optical, latex enhanced immunoassay)
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	18	varies with test-reagent combination, limited only by No. of reag. positions
No. of different assays programmed and calibrated at one time	1	1	1
No. of user-definable (open) channels	10 (requires optional research package)	total test capacity: 300 (IL test channels 120+ open)	total test capacity: 100 (IL test channels + open)
Of those defined, No. active simultaneously	1	varies with test-reagent combination	varies with test-reagent combination
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/tests per container	3/varies by test	18/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	no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	18 mos	18 mos	18 mos
Walkaway capacity: No. of specimens/No. of tests	18/36	40/260	120/variable
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), 53 µL (PTT)/40 µL	50 µL/40 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 (13 x 75 mm)/no	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	no
Measures No. of tests remaining	no	yes	no
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	yes/yes
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 std, 6.7 ext)	yes (PT & PTT: 3 sec)	yes (PT: 7 sec., PTT: 10 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	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	no/no	no/no	no/no
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/110 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	varies/110 specimens	2.5 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	onboard (incl. QC: L-J plots)	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 LIS 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	in development	in development	in development
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	weekly: 10 min; monthly: 5 min; biweekly: 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 in Miami	5 days at vendor offices in Miami
Approx. No. of training hrs needed per tech	12 h	varies	24 h
List price	$45,000	$61,950	$79,500
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	various options available/1 yr	various options available/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	• part of ACL family, uses same consumables/reagents • quantitative PT-based fib. • positive displacement pipetting for low maintenance & high precision	• robotic transport arm • extensive menu of clotting, chromogenic, & immunological assays in a small footprint • positive displacement pipetting for low maintenance & high precision	• extensive menu of clotting, chromogenic, & immunologic assays • high throughput • positive displacement pipetting for low maintenance & high precision

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

SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 11 of 13

See accompanying article, page 56

	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	ACL 8000/2003	ACL 10000/2003	KC1Δ/2001
No. of units installed in U.S./outside U.S.	—/—	—/—	>100/>100
Country where analyzer designed/manufactured	Italy/U.S.	Italy/U.S.	Germany/Germany
Operational type	batch	batch	semiautomatic, single channel
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray	tray	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	3.25 x 5.5 x 8.25 in/2.5 lbs/<1 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, PT-based fib., Clauss fib., factor assays, protein S & C, LAC screen, LAC confirm, APCR-V	PT, APTT, TT, PT-based fib., Clauss fib., factor assays, protein S & C, LAC screen, LAC confirm, APCR-V	PT, APTT, fib., TT, instrinsic & extrinsic factors
FDA-cleared chromogenic tests	antithrombin, liquid antithrombin, factor VIII, heparin, plasmin inhibitor, plasminogen, protein C	antithrombin, liquid antithrombin, factor VIII, heparin, plasmin inhibitor, plasminogen, protein C	n/a
FDA-cleared immunologic tests	D-dimer (latex-enhanced immunoassay), vWF (latex-enhanced immunoassay), free protein S (latex turbidimetric ligand immunoassay)	D-dimer (latex-enhanced immunoassay), vWF (latex-enhanced immunoassay), free protein S (latex turbidimetric ligand immunoassay)	n/a
Other FDA-cleared tests	none	none	n/a
User-defined tests in clinical use	none	none	n/a
Tests submitted for 510(k) clearance	vWF activity, HS-CRP	vWF activity, HS-CRP	n/a
Tests in development but not yet submitted	silica clotting time, global protein C pathway, homocyst.	silica clotting time, global protein C pathway, homocyst.	n/a
Methodologies supported	clot detection, optical (tungsten, nephelometric); chromogenic; immunologic	clot detection, optical (tungsten, nephelometric); chromogenic; immunologic	clot detection, mechanical
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	18	22	1
No. of different assays programmed and calibrated at one time	1	1	manual
No. of user-definable (open) channels	300 (IL test channels 120+ open)	300 (IL test channels 120+ open)	n/a
Of those defined, No. active simultaneously	varies with test-reagent combination	varies with test-reagent combination	n/a
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/tests per container	18/varies	22/varies	1/varies for each assay
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	no
Multiple reag. configurations supported	yes	yes	no
Reag., consumables loaded without interrupting testing	no	no	n/a, manual
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	18 mos	18 mos	12–18 mos
Walkaway capacity: No. of specimens/No. of tests	40/260	40/260	n/a, manual
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	n/a
Standard specimen vol. required to run PT or PTT/factor VIII activity	PT: 60 µL, min. 160; PTT: 63 µL, min. 163/18 µL, min. 118 µL	PT: 60 µL, min. 160; PTT: 63 µL, min. 163/18 µL, min. 118 µL	50 µL/10 µL
Disposables used/price of each	rotors/price varies	rotors/price varies	cuvettes & ball dispenser/inquire
Supports direct-from-track sampling	no	no	n/a
Primary tube sampling supported/pierces caps on primary tubes	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	n/a
Sample bar-code reading capability	yes	yes	n/a
Reagent bar-code reading capability	no	no	n/a
Onboard test automatic inventory	yes	yes	n/a
Measures No. of tests remaining	yes	yes	n/a
Short sample detection	yes	yes	n/a
Clot detection as preanalytical variable in plasma sample	no	no	n/a
Auto. detection of adequate reag. for aspir. & anal.	no	no	n/a
Hemolysis/turbidity detection-quantitation	no/no	no/no	n/a
Dilution of patient samples onboard	yes	yes	n/a
Automatic rerun capability/auto reflex testing capability	yes/yes	yes/yes	n/a
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 3 sec)	yes (PT & PTT: 3 sec)	yes (PT & PTT: 4.5 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	yes/yes	yes/yes	yes/yes
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	4 min/175 specimens	4 min/175 specimens	75 sec/48 tests
• PT, PTT	8 min/110 specimens	8 min/110 specimens	350 sec/10 tests
• Fibrinogen	4 min/175 specimens	4 min/175 specimens	65 sec/55 tests
• Factor VIII activity assay	varies/110 specimens	varies/110 specimens	275 sec/13 tests
Time delay from ordering stat to aspir. of sample	15 sec	15 sec	n/a
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots)	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	n/a	n/a	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)	n/a
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	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	n/a
Modem servicing	no	no	n/a
Time required for maintenance by lab personnel	weekly: 10 min; monthly: 5 min; biweekly: 5 min	weekly: 10 min; monthly: 5 min; biweekly: 5 min	none
Onboard maintenance records	yes	yes	n/a
Training provided with purchase	on site varies/5 days at vendor offices	on site varies/5 days at vendor offices	as needed on site
Approx. No. of training hours needed per tech	varies	varies	2 h
List price	$52,000	$59,995	$2,100
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	various options available/1 yr	various options available/1 yr	$364 (M–F, 8–5)/1 yr
Unique advantages (provided by vendors)	• PT-based fibrinogen, quantitative • extensive menu of clotting, chromogenic, & immunologic assays in a small footprint • positive displacement pipetting for low maintenance & high precision	• robotic transport arm • extensive menu of clotting, chromogenic, & immunologic assays in a small footprint • positive displacement pipetting for low maintenance & high precision	• half volume PT & APTT testing for significant reagent savings • patented ball technology for extremely reproducible & reliable results

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

Coagulation Analyzers

Part 12 of 13

See accompanying article, page 56

	Trinity Biotech **Venita Shirley** shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com	Trinity Biotech **Venita Shirley** shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com	Trinity Biotech **Venita Shirley** shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	KC4Δ/2001	Amax 200/2001	Amax 400/1997
No. of units installed in U.S./outside U.S.	>100/>100	>200/>200	<50/<50
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	semiautomatic, 4 channels	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	manual	60-position continuous addition sample rack	continuous feed sample chain
Model type	benchtop	benchtop or floor standing	floor standing
Dimensions (H x W x D)/weight/instrument footprint	4.7 x 13.9 x 17.7 in/14 lbs/1.7 sq ft	BT: 25 x 32.75 x 28.75 in/286 lbs/6.5 sq ft FS: 53.25 x 32.75 x 28.75 in/451 lbs/6.5 sq ft	52 x 56 x 27 in/803 lbs/10.5 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, intrinsic & extrinsic factors	APTT, atroxin, fib., PT, proteins C & S, TT, intrinsic & extrinsic factors, dRVVT	PT, APTT, fib., TT, intrinsic & extrinsic factors, proteins C & S, dRVVT
FDA-cleared chromogenic tests	n/a	antithrombin, plasminogen, heparin-Xa, protein C	heparin-Xa, antithrombin, plasminogen, protein C
FDA-cleared immunologic tests	n/a	D-dimer	D-dimer
Other FDA-cleared tests	n/a	none	none
User-defined tests in clinical use	n/a	PT & APTT mixing studies, Plt. neutralization, Kaolin clotting time, activated protein C resistance, protein S (immunol.), vWF assay (immunol.), thrombotest, heparin cofactor II, alpha-2 antiplasmin	PT & APTT mixing studies, Plt. neutralization, Kaolin clotting time, protein S (immunol.), vWF assay (immunol.), thrombo test, heparin cofactor II, alpha-2 antiplasmin
Tests submitted for 510(k) clearance	n/a	none	activated protein C resistance
Tests in development but not yet submitted	n/a	none	none
Methodologies supported	clot detection, mechanical	clot detect., mechanical; clot detect., optical (tungsten, turbidimetric); chromogenic; immunologic (microparticles)	clot detect., mechanical; clot detect., optical (tungsten, turbidimetric); chromogenic; immunologic (microparticles)
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	32	40
No. of different assays programmed and calibrated at one time	1/1	32	40
No. of user-definable (open) channels	n/a	32	40
Of those defined, No. active simultaneously	up to 4	12	40
Factor assays require manual manipulation or dilutions	yes	no	no
No. of reag. containers onboard at one time/tests per container	5/varies for test kit	24/varies with kit & operational mode	24/varies with assay & operational mode
Reagents refrigerated onboard	no	yes (15˚C)	yes (15˚C)
Multiple reag. configurations supported	no	yes	yes
Reag., consumables loaded without interrupting testing	n/a, manual	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12–18 mos	12–18 mos	12–18 mos
Walkaway capacity: No. of specimens/No. of tests	n/a, manual	60/450	1,250/450
Min. sample vol. aspirated precisely at one time	n/a	5 µL	3 µL
Standard specimen vol. required to run PT or PTT/factor VIII activity	50 µL/10 µL	25 µL/10 µL	25 µL/10 µL
Disposables used/price of each	cuvettes & ball dispenser/inquire	cuvettes/—, probe decontaminate/—	cuvettes/—, probe decontaminate/—, tubing/—
Supports direct-from-track sampling	n/a	no	no
Primary tube sampling supported/pierces caps on primary tubes	n/a	yes/no	yes/no
Sample bar-code reading capability	n/a	yes	yes
Reagent bar-code reading capability	n/a	no	no
Onboard test automatic inventory	n/a	yes	yes
Measures No. of tests remaining	n/a	yes	yes
Short sample detection	n/a	yes	yes
Clot detection as preanalytical variable in plasma sample	n/a	no	no
Auto. detection of adequate reag. for aspir. & anal.	n/a	yes	yes
Hemolysis/turbidity detection-quantitation	n/a	not necessary	not necessary
Dilution of patient samples onboard	n/a	yes	yes
Automatic rerun capability/auto reflex testing capability	n/a	yes/no	yes/yes (out of test)
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 4.5 sec)	yes (4.5 sec)	yes (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	no/no	yes/yes	yes/yes
Stat time to completion of all analytes/throughput per hour for:			
• PT alone	75 sec/48 tests	90 sec/190 tests	90 sec/325 tests
• PT, PTT	350 sec/10 tests	300 sec/120 tests	300 sec/480 tests
• Fibrinogen	65 sec/55 tests	70 sec/115 tests	70 sec/212 tests
• Factor VIII activity assay	275 sec/13 tests	300 sec/120 tests	300 sec/200 tests
Time delay from ordering stat to aspir. of sample	n/a	varies by test	varies by test
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes	onboard (incl. QC: L-J plots, Westgard)	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	n/a	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	—	yes	yes
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	n/a	no	yes
Modem servicing	n/a	yes	yes
Time required for maintenance by lab personnel	none	daily: <2 min; weekly: <35 min; monthly: <5 min	daily: <10 min; weekly: <30 min; monthly: <5 min
Onboard maintenance records	n/a	no	yes
Training provided with purchase	as needed on site	5 days on site, 4 days at vendor office	5 days on site, 5 days at vendor office
Approx. No. of training hours needed per tech	2 h	16–24 h	48–72 h
List price	$9,200	$81,000	$132,000
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$936 (M–F, 8–5)/1 yr	—/1 yr	—/1 yr
Unique advantages (provided by vendors)	• uses half volume for PT & APTT, reduced volume for all other tests • 4 test positions can be used simultaneously • patented ball method for extremely reproducible & reliable results	• quarter volume PT & APTT (half volume other tests) • easy-to-use software monitors quality at all times • true clot detection (mechanical & optical) plus chromogenic & immunoturbidimetric detection	• true clot detection • high throughput • quarter volume reagent usage

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Coagulation Analyzers

Part 13 of 13

See accompanying article, page 56

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Instrument name/first year sold	Amax Destiny/2003	MiniQuant D-dimer System/2002
No. of units installed in U.S./outside U.S.	<50/<50	25/<25
Country where analyzer designed/manufactured	Germany & U.S./Germany	Germany/Germany
Operational type	random access	discrete
Reagent type	open reagent system	uses MiniQuant D-dimer reagents
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	50 positions/5 racks	single cuvettes
Model type	benchtop	handheld-portable
Dimensions (H x W x D)/weight/instrument footprint	22 x 33 x 27 in/165 lbs/150 sq ft	4.3 x 7.9 x 8.9 in/2.75 lbs/1 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, & XII	none
FDA-cleared chromogenic tests	AT	none
FDA-cleared immunologic tests	D-dimer	D-dimer, quantitative microlatex
Other FDA-cleared tests	—	none
User-defined tests in clinical use	—	D-dimer
Tests submitted for 510(k) clearance	—	none
Tests in development but not yet submitted	—	none
Methodologies supported	clot detect., mechanical; clot detect., optical (turbidimetric); chromogenic; immunologic	immunologic (quantitative microlatex)
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	1
No. of user-definable (open) channels	unlimited	—
Of those defined, No. active simultaneously	10	1
Factor assays require manual manipulation or dilutions	no	n/a
No. of reag. containers onboard at one time/tests per container	30/varies	—/50
Reagents refrigerated onboard	yes (12–16°C)	no
Multiple reag. configurations supported	yes	no
Reag., consumables loaded without interrupting testing	yes	no
Same capabilities when 3rd-party reag. used	yes	no
Max. time same lot number of reag. can be used	varies by reagent	n/a
Walkaway capacity: No. of specimens/No. of tests	50/240	n/a/n/a
Min. sample vol. aspirated precisely at one time	5 µL	n/a
Standard specimen vol. required to run PT or PTT/factor VIII activity	50 µL/10 µL	n/a/n/a
Disposables used/price of each	reaction trays, ProWash/—	cuvettes/—
Supports direct-from-track sampling	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes (standard, pediatric, micro)/no	no/no
Sample bar-code reading capability	yes	no
Reagent bar-code reading capability	no	no
Onboard test automatic inventory	yes	no
Measures No. of tests remaining	yes	no
Short sample detection	yes	no
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no
Hemolysis/turbidity detection-quantitation	not necessary	no/no
Dilution of patient samples onboard	yes	no
Automatic rerun capability/auto reflex testing capability	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (3 sec)	n/a
Read time extended for prolonged clotting times	yes	n/a
User can set different-than-standard:		
• Reag. volumes/sample volumes	yes/yes	n/a
• No. and sources of reag.	yes	n/a
• Incub. times/reading times	yes/yes	n/a
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	n/a/yes
Auto shutdown/auto startup programmable	yes/yes	n/a/n/a
Stat time to completion of all analytes/throughput per hour for:		
• PT alone	<3 min/90 tests	—/—
• PT, PTT	—/—	—/—
• Fibrinogen	—/—	—/—
• Factor VIII activity assay	—/—	—/—
Time delay from ordering stat to aspir. of sample	varies by test	—
Auto. transfer of QC results to LIS	yes	no
Data management capability	onboard (incl. QC: L-J plots, Westgard)	no
Interface supplied by instrument vendor	no	—
Interfaces in active user sites for:	all major LIS vendors	—
Bidirectional interface capability	yes (broadcast download & host query)	no
Results transferred to LIS as soon as test time complete	yes	no
LOINC codes transmitted with all results	yes	no
How labs get LOINC codes for reagent kits	—	n/a
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	per shift: <2 min; weekly: <30 min; monthly: <5 min	daily: 5 min
Onboard maintenance records	yes	no
Training provided with purchase	2 days on site	1 day on site
Approx. No. of training hours needed per tech	8 h	2 h
List price	$49,000	$5,150
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	—/1 yr	—/1 yr
Unique advantages (provided by vendors)	• true clot detection • IntuiTouch software • expanded test menu (D-dimer)	• quantitative D-dimer • read time—5 minutes • easy to use

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