In coagulation market, no need to break the budget

Anne Ford

Cost-consciousness is as strong as ever, and the cost of coagulation analyzers is no exception. "Laboratories today are dealing with more regulations and instrumental sophistication than ever before," says Michael Shiflett, American Labor president. "The cost of these two together oftentimes makes the choice of purchasing a new coagulation analyzer almost insurmountable." Some of the vendors with coagulation analyzers in this month's CAP TODAY instrument survey, however, have taken their customers' budgets into account by offering lower-cost options.

Take the STA-R Evolution, Diagnostica Stago's newest analyzer. Systems product manager Audrey Woodbeck calls it "innovative, yet affordable for the larger-volume laboratory." The analyzer uses the company's viscosity-based detection system technology, she says, "to ensure accuracy of results regardless of sample characteristics such as turbidity, icterus, or lipemia." Other features include software enhancements such as result traceability, password protection, and calibration data editing.

Of course, watching your budget doesn't just mean getting good deals on new purchases, but on making the most of the products you already have, as Woodbeck points out: "Manufacturers are always looking to optimize existing reagents with enhanced onboard stability and performance." To that end, Diagnostica Stago plans to introduce STA-Cephascreen, a liquid APTT reagent with up to 10-day onboard stability; STA-StaClot DRVV screen and confirm, for the detection of lupus anticoagulants; and STA-Liatest FM, an automated, quantitative assay for fibrin monomers (all pending FDA clearance). The company says that new research-use-only parameters, such as ELISA assays for thrombin activatable fibrinolysis inhibitor and antiphospholipid antibodies, are also forthcoming.

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In other cost-related news, Trinity Biotech recently made available its Amax Destiny Plus analyzer, which, says coagulation marketing manager Brooke McCutchan, MT(ASCP), offers quarter-volume testing for PT and APTT, "substantially reducing the reagent costs for the end user." The Amax Destiny Plus offers both optical and mechanical methodology and can perform all routine and specialty assays including automated D-dimer. The company is now introducing the Destiny Optical, with a throughput of 110 PTs per hour. And customers at this year's AACC meeting can look for the Destiny Max, which "will offer our customers the largest platform with the greatest throughput and capability of our Destiny platform offering," McCutchan says. The Destiny Max will feature cap piercing and laboratory automation system capability.

BioMérieux recently introduced the Coag-A-Mate MTX III, a medium-volume fully automated analyzer with a compact benchtop design. The MTX III supports the full line of BioMérieux coagulation reagents. The instrument features random access and batch or stat mode, and can accommodate up to 32 specimen tubes and eight assays per sample. "The MTX III offers many advanced capabilities usually only found in high-volume systems in a compact instrument perfect for the small- to medium-size labs," says Vince Tumminello, senior marketing manager. And here's that word again: "This system is a cost-effective option over larger systems."

Dade Behring, meanwhile, plans to launch the BCS XP, a high-speed analyzer aimed at high-volume and specialty coagulation laboratories. "The software and hardware refinements of the BCS XP were a direct result of our customers' wishes," says Jackie Hauser, marketing manager for coagulation instruments. "On the reagent side, we are very excited about introducing our research-use endogenous thrombin potential assay." The ETP assay, she adds, "is unique in that it is fully automated on a routine laboratory analyzer, the

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BCS." This year, the company also plans to offer connectivity of its Sysmex CA-7000 coagulation analyzer to the StreamLab analytical workcell.

It looks like a busy year ahead for Beckman Coulter, as the distributor of Instrumentation Laboratory's line of coagulation analyzers and reagents. Instrument development activities include the integration of 2-D kit bar codes for the high-volume instrumentation line, including the ACL TOP series. "These reagent bar codes contain all the relevant information about a particular kit's reagents," says Beckman Coulter hemostasis marketing manager Steve Edwards. This information is directly downloaded into the analyzer software. Furthermore, he adds, "We are launching new instruments this year, which include the ACL TOP CTS, a cap-piercing high-volume analyzer, and the ACL Elite series, developed for low- to moderate-volume laboratories. In addition, we are launching several innovative specialty assays expanding the diagnostic testing menu available to laboratories." The company recently launched the HemosIL D-dimer HS, a fifth-generation latex assay available on the ACL TOP instrument. "This new assay is not affected by interferences associated with rheumatoid factor," says Edwards, "and provides premium exclusion capabilities that improve patient diagnosis for deep vein thrombosis and pulmonary embolism, leading to reduced hospital costs."

Ah yes, costs. Diagnostica Stago's Woodbeck has a final reminder on those: "Customers are looking for a hemostasis partner that excels in areas that go beyond the features of the instrument such as price per milliliter of reagents or cents per cuvette," she says. "Critical requirements will include the service reputation and responsiveness of the provider, technical support availability, and continuing education for the technologists and physicians as new parameters and markers are developed. In other words, it is not price but rather the total value that the hemostasis partner can deliver."

CAP TODAY's survey of coagulation analyzers includes products from the manufacturers cited here and from Fisher Diagnostics and Helena Laboratories. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

Coagulation Analyzers

Part 1 of 12 *See accompanying article, page 22*	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	bioMérieux Inc. Vincent Tumminello vincent.tumminello@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2271 www.biomerieux-usa.com
Instrument name/first year sold	CD2000/1986	CoaLab/1991	Coag-A-Mate Max/1999
No. of units installed in U.S./Outside U.S.	>500/>1,000	—/—	>185 worldwide
No. of contracts signed between 1/1/05 and 12/31/05	30	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	batch, discrete	discrete, batch	random access
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	cuvette ring (automated)	2 rotors (31 positions each)
Model type	benchtop	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	15.3 x 40.2 x 28.3 in/134.5 lbs/8 sq ft, 11 w/ PC
FDA-cleared clotting-based tests	PT, PTT, fib., any citrated plasma clot-based assay	any clot-based detection, PT, APTT, TT, PT-based fibrinogen, Clauss fibrinogen, factor assays, protein C, protein S, LAC screen, LAC confirm, APCR-V	PT, APTT, TT, fib., PT & APTT factors
FDA-cleared chromogenic tests	none	none	AT III, hep. antifactor Xa
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	PT mix, APTT mix, lupus (dRVVT screen & confirm.), reptilase, proteins C & S (clotting), protein C (chromo.), APCR, LMWH (antifactor Xa)
Tests submitted for 510(k) clearance	none	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)	clotting, chromogenic 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	2 (PT, APTT)	30	10
No. of different assays programmed and calibrated at one time	1 (fib.)	30	40
No. of user-definable (open) channels	2	2	18
Of those defined, No. active simultaneously	2	varies with test-reagent combination	10
Factor assays require manual manipulation or dilutions	yes	no	no
No. of reag. containers onboard at one time/Tests per container	5 or more/ reag. mftr. dependent	10/varies	21 cooled, 16 for reagents, 5 for controls/15–160
Reagents refrigerated onboard	no	no	yes (18°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	no	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	laboratory dependent	18 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	no	32/30	62/232
Min. sample vol. aspirated precisely at one time	manual pipetting	5 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 50 µL/50 µL, min. 50 µL	50 µL, min. 50 µL/<50 µL, min. 50 µL	60 µL/10 µL
Disposables used/Price of each	500 microcuvette w/ mixers in trays/11.6¢ ea., bulk 11¢ ea.; 500 macrocuv. w/ mixers in trays/12¢ ea., bulk 10.6¢ ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3k tips bulk/3.9¢ ea.	sample cups, measurement cuvette rings/prices vary	cuvette racks, probe cleaner, predilution strips/prices available upon request
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes/no
Sample bar-code reading capability	no	yes	yes (2 internal bar-code scanners)
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	yes/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (3 sec)	yes (3 sec)	yes (PT: 9 sec, APTT: 15 sec)
Read time extended for prolonged clotting times	yes, up to 999 sec	yes (selectable on menus)	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	no/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/no	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	120 sec/user defined	4 min/140 specimens	<7 min/180 results
• PT, PTT	240 sec/user defined	8 min/140 specimens	<7 min/120–140 results
• Fibrinogen	300 sec/user defined	4 min/140 specimens	<7 min/140–180 results
• Factor VIII activity assay	300 sec/user defined	varies/varies	<7 min/120–140 results
Time delay from ordering stat to aspir. of sample	none—all preanalytical	15 sec	<3 min
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	yes (incl. QC: L-J plots)	yes (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	no	yes (additional cost)
Interfaces in active user sites for:	call technical support for inquiry	n/a	all commonly used LISs in North America
Bidirectional interface capability	no	no	yes
Results transferred to LIS as soon as test time complete	yes	no	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 30 sec; monthly: 5 min	daily: 10 min; weekly: 10 min; monthly: 5 min; biweekly: 5 min	daily: 5 min; weekly: 30 min; monthly: <5 min
Onboard maintenance records	no	yes	no
Training provided with purchase	videotape; on-site training extra	varies per site	3 days at vendor offices
Approx. No. of training hours needed per tech	2 h	varies	1–2 h/30 min or less for basic operation
List price	$900, special pricing avail. upon written request for quote	$25,000	$55,000
Ann. svc. contract cost (24/7)/Warranty with purchase	additional 1-yr initial contract $500 (optional)/1 yr, $300 renewal	various options available/1 yr	$6,300/1 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	• normalization of PT & APTT assays with other bioMérieux automated systems • workhorse analyzer for med- to high-vol. workload • easy operation & simple software means minimal training required

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Survey editor: Raymond D. Aller, MD

Coagulation Analyzers

Part 2 of 12 *See accompanying article, page 22*	bioMérieux Inc. Vincent Tumminello vincent.tumminello@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2271 www.biomerieux-usa.com	bioMérieux Inc. Vincent Tumminello vincent.tumminello@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2271 www.biomerieux-usa.com	bioMérieux Inc. Vincent Tumminello vincent.tumminello@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2271 www.biomerieux-usa.com
Instrument name/first year sold	Coag-A-Mate MTX III/2005 (sold as MTX since 1997)	Coag-A-Mate XM/1989	MDA II/1999
No. of units installed in U.S./Outside U.S.	>500 worldwide	>2,000 worldwide	>400 worldwide
No. of contracts signed between 1/1/05 and 12/31/05	—	—	—
Country where analyzer designed/Manufactured	Germany & U.S./Germany	U.S./U.S.	U.S./U.S.
Operational type	random access	discrete	continuous random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	rotor (32 positions)	manual pipetting into cuvette (4 wells at a time)	racks
Model type	benchtop	benchtop	floor standing
Dimensions (H x W x D)/Weight/Instrument footprint	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	58 x 75 x 31 in/840 lbs/18 sq ft w/PC
FDA-cleared clotting-based tests	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays	PT screening (moderate & low ISI), PT factors, quick%, APTT screening, APTT factors, PT mix, APTT mix, TT, fib.
FDA-cleared chromogenic tests	AT III, hep. antifactor Xa, protein C	none	hep. antifactor Xa, AT III, protein C, plasminogen, alpha-2 antiplasmin, lupus (dRVVT screen and confirm.), APCR
FDA-cleared immunologic tests	none (latex immunologic assay in development)	none (latex immunologic assay in development)	D-dimer (latex immunoassay)
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	alpha-2 antiplasmin, plasminogen, PT mix, APTT mix, LMWH (antifactor Xa)	none	clottable C & S, PNP, P & P (1 & 2), vWF, open assays—user definable for clotting, chrom. & microlatex assays
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	quantitative D-dimer immunoassay	—	none
Methodologies supported	clotting, chromogenic assays; photo-optical	clotting assays; photo-optical	clotting; chromogenic; immunoassay; 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	8	2	16
No. of different assays programmed and calibrated at one time	32	16	72
No. of user-definable (open) channels	up to 32	16	20
Of those defined, No. active simultaneously	8	2	16
Factor assays require manual manipulation or dilutions	no	yes	no
No. of reag. containers onboard at one time/Tests per container	16 cooled, 12 room temp. total 28/25–200	4/30–100	30/25–400
Reagents refrigerated onboard	yes (15°C)	no	yes (8-15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	no	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12–18 months	12–18 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	32/32	4/4	170/480
Min. sample vol. aspirated precisely at one time	2 µL	n/a	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/5 µL, min. 2 µL	100 µL/10 µL, min. 10 µL	50 µL/10 µL
Disposables used/Price of each	cuvette rings, pipettor wash solution, cleaning solution/prices available on request	cuvettes, stir bars, optional: printer & paper/prices available on request	cuvettes, bar-code labels, MDA probe cleaner/prices available on request
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	no/no	yes/yes
Sample bar-code reading capability	yes	no	yes (internal bar-code scanner)
Reagent bar-code reading capability	no	no	yes
Onboard test automatic inventory	yes	no	yes
Measures No. of tests remaining/Short sample detection	yes/no	no/no	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	yes/yes (detects bilirubin, corrects for lipemia)
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/Auto reflex testing capability	yes/no	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 3 sec, APTT: 5 sec)	yes (PT: 7 sec, APTT: 20 sec)	yes (PT: default 3 sec, APTT: default 5 sec)
Read time extended for prolonged clotting times	yes	yes	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	no/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	yes/yes
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	2 min/90 results	2 min/200 results (manual)	12 min/180 results
• PT, PTT	5 min/60 results	5 min/50 PTT results (manual)	12 min/180 results
• Fibrinogen	2 min/75 results	2–3 min/100 results (manual)	12 min/180 results
• Factor VIII activity assay	5 min/60 results	5 min/50 results (manual)	12 min/180 results
Time delay from ordering stat to aspir. of sample	30–60 sec	≤2 min	<1 min
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	yes (incl. QC: L-J plots)	no	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	yes (additional cost)	no	yes (additional cost)
Interfaces in active user sites for:	all commonly used LISs in North America	n/a	all commonly used LISs in North America
Bidirectional interface capability	yes	no	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	no	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	yes
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	daily: ~5 min; weekly: ~1 min; monthly: ~5 min	daily: none; weekly: ~5 min; monthly: none	daily: ~35 min; weekly: 45 min; monthly: 10 min
Onboard maintenance records	no	no	no
Training provided with purchase	3 days at vendor offices	1/2 day on site	3–5 days on site, 4 days at vendor offices
Approx. No. of training hours needed per tech	2–3 h	1–2 h	4–5 h
List price	$49,995	$5,198	$92,295
Ann. svc. contract cost (24/7)/Warranty with purchase	$7,300/1 yr	depot service (repair)/1 yr	$12,600/1 yr
Unique advantages (provided by vendors)	• 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	• 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

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SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 3 of 12 *See accompanying article, page 22*	**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	BFT II/U.S.: 1999	Sysmex CA-560/U.S.: 2003	Sysmex CA-1500/U.S.: 2000; worldwide: 1999
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/05 and 12/31/05	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Japan/Japan	Japan/Japan
Operational type	batch	batch, continuous random access	continuous random access
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually), optimized for Dade Behring instruments	open reagent system (lyoph., reconst. manually), optimized for Dade Behring instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	10-tube position sample rack	10-tube position sample rack × 5
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	3.9 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	20 x 31.2 x 31.2 in/186 lbs/6.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, reptilase time, protein C clot	PT, APTT, fibrinogen, TT, reptilase time, factor assays, dRVVT screen & confirm, factor V Leiden, protein C clot, protein S activity
FDA-cleared chromogenic tests	n/a	AT III, protein C chromo, heparin	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin
FDA-cleared immunologic tests	n/a	Advanced D-dimer	Advanced D-dimer
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	n/a	n/a
Tests submitted for 510(k) clearance	none	none	n/a
Tests in development but not yet submitted	none	n/a	—
Methodologies supported	turbodensitometric	clot detect., optical, turbidmetric; chromogen.; immunolog.	clot detection, optical, turbidmetric; chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	1	5	15
No. of different assays programmed and calibrated at one time	3	7	25
No. of user-definable (open) channels	n/a	7	25
Of those defined, No. active simultaneously	1	5	15
Factor assays require manual manipulation or dilutions	n/a	n/a	no
No. of reag. containers onboard at one time/Tests per container	4/up to 2,000	11/varies, up to 200	39/up to 200
Reagents refrigerated onboard	no	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	consumables yes, reagents no	some consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12 months	12 months	12 months
Walkaway capacity: No. of specimens/No. of tests	1/1	10/50	50/up to 1,000
Min. sample vol. aspirated precisely at one time	50 µL	10 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL	50 µL/n/a	50 µL/10 µL
Disposables used/Price of each	cuvettes, printer paper/price varies with volume	reaction tubes, CA clean I, thermal paper/price varies with volume	reaction tubes, sample plates, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/prices vary with volume
Supports direct-from-track sampling	no	no	yes (Sysmex CST series)
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (3–5 mL)/no	yes (3–5 mL)/yes
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	no	yes
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/yes	no/yes
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT: 5 sec, APTT: 15 sec)	yes (PT: <7 sec, PTT: <15 sec)	yes (PT: 7 sec, PTT: 15 sec)
Read time extended for prolonged clotting times	no	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	—/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	1 min/n/a manual	7 min/54 results	7 min/120 results
• PT, PTT	n/a manual	8 min/43 results	8 min/80 results
• Fibrinogen	<1 min/n/a manual	7 min/54 results	8 min/˜120 results
• Factor VIII activity assay	n/a	n/a/n/a	8 min/n/a
Time delay from ordering stat to aspir. of sample	n/a	2 min	2 min
Auto. transfer of QC results to LIS	no	yes	yes
Data management capability	no	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots & Westgard)
Interface supplied by instrument vendor	n/a	no	no
Interfaces in active user sites for:	n/a	Cerner, Misys (formerly Sunquest), others	Cerner, Misys (formerly Sunquest), others
Bidirectional interface capability	no	yes (host query)	yes (host query)
Results transferred to LIS as soon as test time complete	no	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	yes (Sysmex CST series)
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 1 min	daily: <5 min	daily: <5 min; weekly: <40 min; monthly: 1 min
Onboard maintenance records	no	no	no
Training provided with purchase	video	2 days on site	varies on site, 4 days at vendor offices plus self-directed online class
Approx. No. of training hours needed per tech	2 h	2 h	6 h
List price	$8,108	$44,470	$91,050 standard model; $103,200 cap-piercing model
Ann. svc. contract cost (24/7)/Warranty with purchase	depot service (repair)/1 yr	$4,652 (business hours)/—	$9,975 standard model; $11,225 cap-piercing/1 yr
Unique advantages (provided by vendors)	• 2-channel micro reagent volume clot-based technology • opto-mechanical detection accurate on lipemic, icteric samples • automatic INR calculation, curve storage, built-in thermal printer • perfect for low-volume testing/backup to larger systems	• 5-parameter true random access clotting/chromogenic • small footprint, complete automation, specialty assay capability • low-operating expense	• simultaneous curve calibrating & patient testing • ability to load multiple bottles or multiple lots of reagent

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

Coagulation Analyzers

Part 4 of 12

See accompanying article, page 22

	Dade Behring Inc. **Jackie Hauser** jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	Dade Behring Inc. **Jackie Hauser** jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	Diagnostica Stago Inc. **Audrey Woodbeck** audrey.woodbeck@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	**BCS/U.S.: 1998**	**Sysmex CA-7000/2002**	**STA-R Evolution Hemostasis System/2005**
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/05 and 12/31/05	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Japan/Japan	France/France
Operational type	batch, continuous random access	continuous random access	continuous random access
Reagent type	open reagent system (reconst. manually), optimized for Dade Behring instruments	open reagent system	open reagent system (lyoph., reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	rack	rack	rack with continuous specimen access
Model type	benchtop	benchtop	floor standing
Dimensions (H x W x D)/Weight/Instrument footprint	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	49.2 x 50.3 x 32.2 in/507 lbs/26.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, factor assays, reptilase time, dRVVT screen & confirm, factor V Leiden, protein C clot, protein S activity	PT, APTT, fib., TT, reptilase time, factor assays, dRVVT screen & confirm, factor V Leiden, protein C clot, protein S activity	PT, APTT, TT, fib., reptilase, intr. & extr. factor assays, proteins C & S, lupus anticoag. screen & confirm.
FDA-cleared chromogenic tests	AT III, alpha-2 antiplasmin, plasminogen, protein C chromo, heparin, factor VIII chromo	AT III, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin	heparin (UFH & LMWH), protein C, AT III, plasminogen, antiplasmin
FDA-cleared immunologic tests	Advanced D-dimer	Advanced D-dimer	D-dimer, vWF, protein S, free protein S, AT III antigen
Other FDA-cleared tests	BC von Willebrand-risto. cofactor assay (agglut. of fixed Plts.)	n/a	n/a
User-defined tests in clinical use	n/a	n/a	dRVVT screen & confirm assays, APCR, and other clotting-based, chromogenic, and immunological tests with user-defined applications
Tests submitted for 510(k) clearance	n/a	n/a	n/a
Tests in development but not yet submitted	ETP*	—	n/a
Methodologies supported	clot detect.: optical; xenon flasher lamp; chromogen.; immunol.	clot detection, optical, turbidimetric; chromogenic; immunol.	clot detection: mechanical; chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	28 tests/samples	20	up to 200
No. of different assays programmed and calibrated at one time	99	40	up to 200
No. of user-definable (open) channels	8,999 (Nos. 1–1,000 are factory set & unalterable)	40	200
Of those defined, No. active simultaneously	>100	20	200
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	86/—	58/varies up to 200	70/up to 83
Reagents refrigerated onboard	yes (<15°C)	yes (15°C)	yes (15–19°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12 months	12 months	18 months
Walkaway capacity: No. of specimens/No. of tests	110 samples/400 cuvettes	100/550 per hour PT and APTT, 300 per hour PT	215/32
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 100 µL (incl. dead vols.)/50 µL, min. 100 µL	50 µL/10 µL	50 µL/5 µL
Disposables used/Price of each	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	cuvette/—; wash-cleaner solution/—
Supports direct-from-track sampling	no	yes (custom automation solutions available)	yes (Beckman Coulter, Bayer LabCell, Roche CLAS)
Primary tube sampling supported/Pierces caps on primary tubes	yes (all up to 100 mm long, ext. diam. 10–16 mm)/no	yes (3–5 mL)/yes	yes/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes (avail. for user-defined tests)	yes	yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/yes	no/yes	no/no (not necessary for mechanical detection technology)
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	yes/no
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 7 sec)	yes (PT: 7 sec, PTT: 15 sec)	no
Read time extended for prolonged clotting times	no	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/no	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no (not necessary)/no (not necessary)
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	<5 min/~315 results (incl. abnormals)	7 min/280 results	<6 min/~300
• PT, PTT	<5 min/~285 results (incl. abnormals)	8 min/480 results	7 min/~150
• Fibrinogen	<5 min (if curve avail.)/~315 results	8 min/280 results	7 min/~180
• Factor VIII activity assay	<5 min (if curve avail.)/~280 results	8 min/300 results	7 min/~180
Time delay from ordering stat to aspir. of sample	varies by test in progress, approx. <5 min	2 min	<15 sec
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	limited	onboard (incl. QC: L-J plots & Westgard)	onboard (L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	Cerner, others in development	Cerner, Misys, Meditech, others
Bidirectional interface capability	yes (host query)	yes (host query)	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	Web site
Electronic interface available (or will be) to automated (or robotic) specimen handling system	possible future upgrade (not available)	custom automated connectivity with Stream Lab in development	yes (Beckman Coulter, Bayer LabCell, Roche CLAS)
Modem servicing	yes	no	yes
Time required for maintenance by lab personnel	daily: <5 min; weekly: <10 min; monthly: 15 min	per shift: <5 min; daily: <10 min; weekly: 1 min; quarterly: 5 min	daily: none; weekly: <30 min; monthly: <30 min
Onboard maintenance records	no	no	yes
Training provided with purchase	varies on site, 5 days at vendor offices for 2 operators (regular and advanced)	varies on site, 5 days at vendor offices for 2 operators	varies on site, 5 days at vendor offices
Approx. No. of training hours needed per tech	8 h on site	8 h on site	~3-5 h
List price	$139,600	$183,400	$161,900/1 yr
Ann. svc. contract cost (24/7)/Warranty with purchase	$16,875/1 yr	$16,100/1 yr	prices available upon request/1 yr
Unique advantages (provided by vendors)	• cont. 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	• viscosity-based detection system • connectivity to lab automation systems • exclusive software fo password protection and result traceability

*for research use only; not FDA-cleared for commercial use

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

SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 5 of 12 *See accompanying article, page 22*	**Diagnostica Stago Inc.** **Audrey Woodbeck** audrey.woodbeck@stago-us.com **5 Century Dr., Parsippany, NJ 07054** **800-222-COAG** www.stago-us.com	**Diagnostica Stago Inc.** **Audrey Woodbeck** audrey.woodbeck@stago-us.com **5 Century Dr., Parsippany, NJ 07054** **800-222-COAG** www.stago-us.com	**Diagnostica Stago Inc.** **Audrey Woodbeck** audrey.woodbeck@stago-us.com **5 Century Dr., Parsippany, NJ 07054** **800-222-COAG** www.stago-us.com
Instrument name/first year sold	**STA Compact Hemostasis System/1996**	**STA Compact CT/2001**	**Start 4/1998**
No. of units installed in U.S./Outside U.S.	—/—	—/—	—/—
No. of contracts signed between 1/1/05 and 12/31/05	—	—	—
Country where analyzer designed/Manufactured	France/France	France/France	France/France
Operational type	continuous random access	continuous random access	batch
Reagent type	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	continuous specimen access-primary tube	continuous specimen access—primary tube	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	25.2 x 38.8 x 25.8 in/351 lbs/25.6 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	heparin (UFH & LMWH), protein C, AT III, plasminogen, antiplasmin	n/a	none
FDA-cleared immunologic tests	D-dimer, vWF, protein S, free protein S, AT III antigen	n/a	none
Other FDA-cleared tests	n/a	n/a	n/a
User-defined tests in clinical use	dRVVT screen & confirm assays, APCR, other clotting-based chromogenic & immunological tests with user-defined applications	dRVVT screen & confirm. assays, APCR, other clotting-based tests can have user-defined applications	dRVVT screen & confirm assays, APCR, other clotting-based tests with user-defined applications
Tests submitted for 510(k) clearance	2	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clotting, chromogenic, & immunologic assays	clot detection, mechanical	clotting tests
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	up to 80	up to 80	1
No. of different assays programmed and calibrated at one time	up to 80	up to 80	20
No. of user-definable (open) channels	70	70	4
Of those defined, No. active simultaneously	70	70	1
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/Tests per container	45/varies, up to 83	45/varies, up to 83	4/varies, up to 100
Reagents refrigerated onboard	yes (15–19°C)	yes (15–19°C)	no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18 months	18 months	18 months
Walkaway capacity: No. of specimens/No. of tests	96/12 per sample	96/12 per specimen	4/1
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	25 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/5 µL	50 µL/5 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes, wash-cleaner solution/—	cuvettes, wash-cleaner solution/—	cuvettes, beads, ball/—
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/yes	no/no (n/a)
Sample bar-code reading capability	yes	yes	no
Reagent bar-code reading capability	yes	yes	no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	no/no
Clot detection as preanalytic variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	no
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for mechanical detection technology)	no/no (not necessary for mechanical detection technology)	no/no (not necessary for mechanical detection technology)
Dilution of patient samples onboard	yes	yes	no
Automatic rerun capability/Auto reflex testing capability	yes/no	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected	no	no	no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	no (not necessary)/no (not necessary)	no (not necessary)/no (not necessary)	no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	<6 min/150 specimens	<6 min/150 specimens	<1 min/up to 120 specimens
• PT, PTT	7 min/75 specimens	7 min/75 specimens	n/a/n/a
• Fibrinogen	7 min/75 specimens	7 min/75 specimens	<1 min/up to 120 specimens
• Factor VIII activity assay	7 min/70 specimens	7 min/70 specimens	varies/varies
Time delay from ordering stat to aspir. of sample	<15 sec	<15 sec	n/a
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots)	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others	n/a
Bidirectional interface capability	yes (host query)	yes (host query)	no
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <5 min; monthly: <5 min
Onboard maintenance records	yes	yes	no
Training provided with purchase	varies on site, 3 days at vendor offices	varies on site, 3 days at vendor office	1 day on site
Approx. No. of training hrs needed per tech	2 h basic	2 h basic	1 h
List price	$75,000	$50,000	$9,600
Ann. svc. contract cost (24/7)/Warranty with purchase	prices available on request/1 yr	prices available on request/1 yr	prices available on request/1 yr
Unique advantages (provided by vendors)	• viscosity-based detection system • walkaway testing for routine & specialty hemostasis assays • able to standardize with other STA analyzers	• viscosity-based detection system • walkaway testing for routine & specialty hemostasis assays • able to standardize with other STA systems	• viscosity-based detection system • excellent for low-volume testing or backup for optical system • programmable and preprogrammed assays with curve storage plus four independently timed incubation stations

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

Coagulation Analyzers

Part 6 of 12

See accompanying article, page 22

	Fisher Diagnostics **Ron Evancheck** ronald.evancheck@fishersci.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com	Fisher Diagnostics **Ron Evancheck** ronald.evancheck@fishersci.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com	Fisher Diagnostics **Ron Evancheck** ronald.evancheck@fishersci.com 8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com
Instrument name/first year sold	ThromboScreen 200/1994	ThromboScreen 400c/1996	ThromboScreen 1000/2003
No. of units installed in U.S./Outside U.S.	>50/>300	15/>150	>40/10
No. of contracts signed between 1/1/05 and 12/31/05	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	batch, discrete	batch, discrete	batch, random access
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually)	open reagent system (reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual	carousel
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	4 x 8 x 12 in/5 lbs/1 sq ft	5 x 12 x 12 in/10 lbs/1 sq ft	28 x 22 x 18 in/35 lbs/3 sq ft
FDA-cleared clotting-based tests	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance, proteins C&S	PT, APTT, fibrinogen
FDA-cleared chromogenic tests	none	AT III, heparin	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	n/a
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	thrombin time
Methodologies supported	clot detection, optical	clot detection, optical, chromogenic	optical turbodensitometry
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	2	3
No. of different assays programmed and calibrated at one time	14	18	3
No. of user-definable (open) channels	n/a	n/a	3
Of those defined, No. active simultaneously	1	1	3
Factor assays require manual manipulation or dilutions	yes	yes	n/a
No. of reag. containers onboard at one time/Tests per container	3/varies	3/varies	6/varies
Reagents refrigerated onboard	no	no	no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18–24 months	18–24 months	18–24 months
Walkaway capacity: No. of specimens/No. of tests	n/a/n/a	n/a/n/a	18/3
Min. sample vol. aspirated precisely at one time	25 µL	50 µL	10 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/—
Disposables used/Price of each	cuvettes & pipette tips/prices vary	cuvettes & pipette tips/prices vary	cuvette bars/prices vary
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	no/no	yes/no
Sample bar-code reading capability	no	no	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/no	no/yes
Clot detection as preanalytical variable in plasma sample	no	no	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	no/no
Lag time during which hypercoagulable samples will not be detected	no	no	yes (PT: 7 sec; PTT: 14 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/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	<1 min/120 specimens	<5 min/100 specimens
• PT, PTT	varies	varies	<5 min/50 specimens
• Fibrinogen	<1 min/120 specimens	<1 min/120 specimens	<5 min/80 specimens
• Factor VIII activity assay	n/a	n/a	n/a
Time delay from ordering stat to aspir. of sample	n/a	n/a	<3 min
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	no	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	n/a	n/a
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	no	no	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 5 min; weekly: 5 min; monthly: 5 min	daily: 5 min; weekly: 5 min; monthly: 5 min	daily: 5 min; weekly: 15 min; monthly: 15 min
Onboard maintenance records	no	no	no
Training provided with purchase	1 day on site	1 day on site	4 h on site
Approx. No. of training hours needed per tech	1 h	1 h	4 h
List price	$3,800	$6,100	$18,000
Ann. svc. contract cost (24/7)/Warranty with purchase	varies/1 yr	varies/1 yr	varies/1 yr
Unique advantages (provided by vendors)	• low volume or backup • small footprint—fits anywhere • simple to operate	• 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 • optional bar-code scanner

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

SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 7 of 12 *See accompanying article, page 22*	**Helena Laboratories** **Joe Golias** helena@helena.com **1530 Lindbergh Dr., Beaumont, TX 77704** **800-231-5663** www.helena.com	**Helena Laboratories** **Joe Golias** helena@helena.com **1530 Lindbergh Dr., Beaumont, TX 77704** **800-231-5663** www.helena.com	**Helena Laboratories** **Jim Campbell** jcampbell@helena.com **1530 Lindbergh Dr., Beaumont, TX 77704** **800-231-5663** www.helena.com
Instrument name/first year sold	**Cascade M/1991**	**Cascade M-4/1992**	**AggRAM/2005**
No. of units installed in U.S./Outside U.S.	**>150/—**	**>100/—**	**25+/50+**
No. of contracts signed between 1/1/05 and 12/31/05	**—**	**—**	**—**
Country where analyzer designed/Manufactured	**U.S./U.S.**	**U.S./U.S.**	**U.S./U.S.**
Operational type	**batch**	**random access**	**batch, random access**
Reagent type	**open reagent system**	**open reagent system**	**open reagent system**
Operates on whole blood or spun plasma	**spun plasma**	**spun plasma**	**spun plasma, PRP**
Sample handling system	**manual**	**manual**	**manual**
Model type	**benchtop**	**benchtop**	**benchtop**
Dimensions (H x W x D)/Weight/Instrument footprint	**8 x 15 x 13 in/25 lbs/1.4 sq ft**	**8 x 15 x 13 in/25 lbs/1.4 sq ft**	**6 x 10 x 17 in/15 lbs/—**
FDA-cleared clotting-based tests	**PT, APTT, fib., TCT, factor assays II, V, VII–XII**	**PT, APTT, fib., TCT, factor assays II, V, VII–XII**	**none**
FDA-cleared chromogenic tests	**none**	**none**	**none**
FDA-cleared immunologic tests	**none**	**none**	**none**
Other FDA-cleared tests	**none**	**none**	**ristocetin cofactor and platelet aggreg.**
User-defined tests in clinical use	**PT, APTT, fib., TCT, factor assays II, V, VII–XII**	**PT, APTT, fib., TCT, factor assays II, V, VII–XII**	**ristocetin cofactor, platelet aggreg.–ADP, EPI, COL, ristocetin, arach. acid**
Tests submitted for 510(k) clearance	**none**	**none**	**none**
Tests in development but not yet submitted	**dRVVT**	**dRVVT**	**none**
Methodologies supported	**clot detection, optical, turbidimetric**	**clot detection, optical, turbidimetric**	**ristocetin cofactor, platelet aggreg.**
Oper. must load sep. reag. pack for ea. specimen/Test run	**no/no**	**no/no**	**no/no**
No. of different measured assays onboard simultaneously	**1**	**4**	**4–8**
No. of different assays programmed and calibrated at one time	**1**	**4**	**4–8**
No. of user-definable (open) channels	**2**	**4**	**12**
Of those defined, No. active simultaneously	**1**	**2**	**4–8**
Factor assays require manual manipulation or dilutions	**yes**	**yes**	**yes**
No. of reag. containers onboard at one time/Tests per container	**—/—**	**0/n/a**	**n/a/n/a**
Reagents refrigerated onboard	**n/a**	**no**	**no**
Multiple reag. configurations supported	**n/a**	**no**	**no**
Reag., consumables loaded without interrupting testing	**no**	**no**	**no**
Same capabilities when 3rd-party reag. used	**yes**	**yes**	**n/a**
Max. time same lot No. of reag. can be used	**12 months**	**12 months**	**12 months**
Walkaway capacity: No. of specimens/No. of tests	**no**	**no**	**no**
Min. sample vol. aspirated precisely at one time	**manual-50 µL**	**manual-50 µL**	**n/a**
Standard specimen vol. required to run PT or PTT/Factor VIII activity	**100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)**	**100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)**	**Plt. aggreg.: 225 µL PRP, Risto cofactor: 50 µL**
Disposables used/Price of each	**cuvettes/500@$54; pipette tips/1,000@$82**	**cuvettes/500@$54; pipette tips/1,000@$82**	**cuvettes/200@$55.65; pipette tips/1,000@$82; stir bars/30@$62.25**
Supports direct-from-track sampling	**no**	**no**	**no**
Primary tube sampling supported/Pierces caps on primary tubes	**no**	**no**	**no**
Sample bar-code reading capability	**no**	**no**	**no**
Reagent bar-code reading capability	**no**	**no**	**no**
Onboard test automatic inventory	**no**	**no**	**no**
Measures No. of tests remaining/Short sample detection	**no/no**	**no/no**	**no/no**
Clot detection as preanalytical variable in plasma sample	**—**	**—**	**—**
Auto. detection of adequate reag. for aspir. & anal.	**no**	**no**	**no**
Hemolysis/Turbidity detection-quantitation	**no/no**	**no/no**	**no/no**
Dilution of patient samples onboard	**no**	**no**	**no**
Automatic rerun capability/Auto reflex testing capability	**no/no**	**no/no**	**no/no**
Lag time during which hypercoagulable samples will not be detected	**yes (PT: 4 sec, PTT: 14 sec)**	**yes (PT: 4 sec, PTT: 14 sec)**	**n/a**
Read time extended for prolonged clotting times	**yes (selectable on menus)**	**yes (selectable on menus)**	**n/a**
User can set different-than-standard:			
• Reag. volumes/Sample volumes	**yes/yes**	**yes/yes**	**yes/yes**
• No. and sources of reag.	**yes**	**yes**	**yes**
• Incub. times/Reading times	**yes/yes**	**yes/yes**	**yes/yes**
Autocalibration or autocalib. alert/Multipoint calibration supported	**no/yes**	**no/yes**	**no/yes**
Auto shutdown/Auto startup programmable	**no/no**	**no/no**	**no/no**
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	**3 min/120 specimens**	**3 min/140 specimens**	**—**
• PT, PTT	**7 min/50 specimens**	**7 min/80 specimens**	**—**
• Fibrinogen	**3 min/140 specimens**	**3 min/160 specimens**	**—**
• Factor VIII activity assay	**7 min/50 specimens**	**7 min/80 specimens**	**n/a**
Time delay from ordering stat to aspir. of sample	**n/a**	**n/a**	**n/a**
Auto. transfer of QC results to LIS	**no**	**yes**	**yes**
Data management capability	**no (incl. QC: L-J plots)**	**no (incl. QC: L-J plots)**	**onboard (incl. QC: L-J plots, Westgard)**
Interface supplied by instrument vendor	**no**	**no**	**no**
Interfaces in active user sites for:	**n/a**	**—**	**—**
Bidirectional interface capability	**no**	**no**	**no**
Results transferred to LIS as soon as test time complete	**no**	**yes**	**yes**
LOINC codes transmitted with all results	**no**	**no**	**no**
How labs get LOINC codes for reagent kits	**—**	**—**	**—**
Electronic interface available (or will be) to automated (or robotic) specimen handling system	**—**	**no**	**no**
Modem servicing	**no**	**no**	**—**
Time required for maintenance by lab personnel	**daily: 10 min; weekly: 10 min; monthly: 20 min**	**daily: 10 min; weekly: 10 min; monthly: 30 min**	**daily: 15 min; weekly: 15 min; monthly: 1 h**
Onboard maintenance records	**no**	**no**	**yes**
Training provided with purchase	**1 day on site**	**1 day on site**	**2 days on site**
Approx. No. of training hours needed per tech	**2–4 h**	**2 h**	**4–8 h**
List price	**$6,219**	**$8,403**	**$14,995**
Ann. svc. contract cost (24/7)/Warranty with purchase	**$714/1 yr**	**$966/1 yr**	**$1,800/1 yr**
Unique advantages (provided by vendors)	**• QC program onboard** **• curve storage** **• suitable for office lab or as backup analyzer**	**• 4-channel manual analyzer** **• QC program onboard** **• singles or duplicates**	**• specialized coag instrument intended for platelet aggreg. & ristocetin cofactor**

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

Coagulation Analyzers

Part 8 of 12

See accompanying article, page 22

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Instrument name/first year sold	ACL 100/1988	ACL 1000/1991	ACL 7000/1997
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)	4,000+ (all models combined)/8,000+ (all models combined)
No. of contracts signed between 1/1/05 and 12/31/05	158 worldwide	110	289
Country where analyzer designed/Manufactured	Italy/U.S.	Italy/U.S.	Italy/U.S.
Operational type	batch	batch	random programming
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray-IS sample cups	tray-IS primary tubes	tray-IS primary tubes
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	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. (PT-based), factor assays, proteins C & S (clottable), TT, lupus anticoag., APCR, Clauss fib.	PT, APTT, fib. (PT-based), factor assays, proteins C & S (clottable), TT, lupus anticoag., APCR-V, 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	none	none	antithrombin, heparin Xa, plasminogen, antiplasmin, protein C
FDA-cleared immunologic tests	none	none	D-dimer, vWF (activity & antigen)
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	—	—	—
Methodologies supported	clot detection, optical, nephelometric	clot detection, optical, nephelometric	clot detection, optical, nephelometric; 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	3	3	4
No. of different assays programmed and calibrated at one time	1	1	1
No. of user-definable (open) channels	0	0	10 (requires optional research package)
Of those defined, No. active simultaneously	n/a	n/a	1
Factor assays require manual manipulation or dilutions	yes	yes	no
No. of reag. containers onboard at one time/Tests per container	3/varies by test	3/varies by test	3/varies by test
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	no	no	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18 months	18 months	18 months
Walkaway capacity: No. of specimens/No. of tests	18/36	18/36	18/48
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	50 µL (PT)/40 µL	50 µL (PT)/40 µL	50 µL (PT)/40 µL
Disposables used/Price of each	sample cups/price varies; rotors/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	no/no	yes/no	yes/no
Sample bar-code reading capability	no	yes (optional)	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	no	no
Measures No. of tests remaining/Short sample detection	no/yes	no/yes	no/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 5.6 std, 6.7 ext)	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	yes	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	no/no	no/no	no/no
• No. and sources of reag.	no	no	no
• Incub. times/Reading times	no/yes	no/yes	no/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	not needed	not needed	not needed
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	5.5 min/110 specimens	5.5 min/110 specimens	5.5 min/175 specimens
• PT, PTT	8.5 min/80 specimens	8.5 min/80 specimens	8.5 min/110 specimens
• Fibrinogen	5.5 min/110 specimens	5.5 min/110 specimens	5.5 min/175 specimens
• Factor VIII activity assay	9.5 min/80 specimens	9.5 min/80 specimens	9.5 min/110 specimens
Time delay from ordering stat to aspir. of sample	15 sec	15 sec	15 sec
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	no	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major LIS vendors	most major LIS vendors	most major LIS vendors
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	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: 10 min; weekly: 15 min; monthly: 10 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	2 days on site	2 days on site	2 days on site
Approx. No. of training hrs needed per tech	2 h	6 h	12 h
List price	$16,000	$21,500	$45,000
Ann. svc. contract cost (24/7)/Warranty with purchase	various options available/1 yr	various options available/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	• 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	• part of ACL family, uses same consumables/reagents • quantitative D-dimer • positive displacement pipetting for low maintenance & high precision

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

Coagulation Analyzers

Part 9 of 12

See accompanying article, page 22

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Instrument name/first year sold	ACL 9000/2000	ACL Advance/2000	ACL 8000/2003
No. of units installed in U.S./Outside U.S.	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)
No. of contracts signed between 1/1/05 and 12/31/05	165	355	210
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	batch/random programming	random access	batch/random programming
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray-primary tubes	racks, continuous loading of primary tubes	tray-primary tubes
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	32.2 x 41 x 24.8 in/185 lbs/15 sq ft	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft
FDA-cleared clotting-based tests	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	PT, APTT, TT, PT-based fib., Clauss fib., factor assays, protein S & C, LAC screen, LAC confirm, APCR-V
FDA-cleared chromogenic tests	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin, factor VIII	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin	antithrombin, liquid antithrombin, factor VIII, heparin, plasmin inhibitor, plasminogen, protein C
FDA-cleared immunologic tests	D-dimer, vWF (activity and antigen), free protein S	D-dimer, vWF (activity and antigen), free protein S	D-dimer , vWF (activity and antigen), 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	none	—
Tests in development but not yet submitted	—	LA-silica clotting time, global protein C, factor XIII, homcyst.	LA-silica clotting time, global protein C pathway, homocyst.
Methodologies supported	clot detection, optical, nephelometric; chromogenic; immunologic	clot detection, optical; chromogenic; immunologic	clot detection, optical (nephelometric); chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	18	varies with test-reagent combination, limited only by No. of reag. positions	18
No. of different assays programmed and calibrated at one time	1	1	1
No. of user-definable (open) channels	total test capacity: 300 (IL test channels 120+ open)	total test capacity: 100 (IL test channels + open)	300 (IL test channels 120+ open)
Of those defined, No. active simultaneously	varies with test-reagent combination	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	18/varies by test	42/varies by test, container size	18/varies
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	no	yes	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18 months	18 months	18 months
Walkaway capacity: No. of specimens/No. of tests	40/260	120/variable	40/260
Min. sample vol. aspirated precisely at one time	5 µL	10 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/40 µL	50 µL /10 µL	PT: 60 µL/18 µL
Disposables used/Price of each	rotors/price varies	cuvettes/price varies	rotors/price varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/no	yes/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	yes	no	yes
Measures No. of tests remaining/Short sample detection	yes/yes	no/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/no	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 3 sec)	yes (PT: 7 sec., PTT: 10 sec)	yes (PT & PTT: 3 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	not needed	not needed	not needed
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	4 min/175 specimens	2.5 min/240 specimens	4 min/175 specimens
• PT, PTT	8 min/110 specimens	8 min/180 specimens	8 min/110 specimens
• Fibrinogen	4 min/175 specimens	2.5 min/240 specimens	4 min/175 specimens
• Factor VIII activity assay	8 min/110 specimens	8 min/180 specimens	8 min/110 specimens
Time delay from ordering stat to aspir. of sample	15 sec	20 sec	15 sec
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes	yes	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	most major LIS vendors	most major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	weekly: 10 min; monthly: 5 min; biweekly: 5 min	daily: 15 min; weekly: 15 min; monthly: 10 min	weekly: 10 min; monthly: 5 min; biweekly: 5 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	5 days at vendor offices in Miami	5 days at vendor offices in Miami	on site varies/5 days at vendor offices
Approx. No. of training hrs needed per tech	24 h	24 h	24 h
List price	$55,999	$79,500	$52,000
Ann. svc. contract cost (24/7)/Warranty with purchase	various options available/1 yr	various options available/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	• extensive menu of clotting, chromogenic, & immunologic assays in a small footprint • positive displacement pipetting for low maintenance & high precision	• extensive menu of clotting, chromogenic, & immunologic assays • high-end capabilities/small footprint • LED optics providing optimized results regardless of preanalytical variables	• PT-based fibrinogen, quantitative • extensive menu of clotting, chromogenic, & immunologic assays in a small footprint • positive displacement pipetting for low maintenance & high precision

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SURVEY OF INSTRUMENTS

Coagulation Analyzers

Part 10 of 12 *See accompanying article, page 22*	Instrumentation Laboratory/Beckman Coulter Inc. Steven Edwards sjedwards@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Steven Edwards sjedwards@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Trinity Biotech Brooke McCutchan brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100, Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	**ACL 10000/2003**	**ACL TOP/2004**	**MiniQuant D-dimer System/2002**
No. of units installed in U.S./Outside U.S.	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)	25/<25
No. of contracts signed between 1/1/05 and 12/31/05	125	210	3
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	Germany/Germany
Operational type	batch/random programming	continuous random access	discrete
Reagent type	open reagent system	open reagent sys., bar-coded reag.	uses MiniQuant D-dimer reagents
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray-primary tubes	rack, continuous loading of primary tubes	single cuvettes
Model type	benchtop	benchtop	handheld portable
Dimensions (H x W x D)/Weight/Instrument footprint	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	28.7 x 59.4 x 29.9 in/330.7 lbs/21 sq ft	4.3 x 7.9 x 8.9 in/2.75 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, Clauss fib., TT, APCR, LA screen & confirm	none
FDA-cleared chromogenic tests	antithrombin, liquid antithrombin, factor VIII, heparin, plasmin inhibitor, plasminogen, protein C	AT, protein C, heparin, plasminogen, plasmin inhibitor	none
FDA-cleared immunologic tests	D-dimer, vWF (activity & antigen), free protein S	D-dimer, vWF (antigen & activity), free protein S, high specificity D-dimer	D-dimer, quantitative microlatex
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	D-dimer
Tests submitted for 510(k) clearance	—	—	none
Tests in development but not yet submitted	LA-silica clotting time, global protein C pathway, homocyst.	LA-silica clotting time, global protein C pathway, homocyst., factor XIII	none
Methodologies supported	clot detection, optical (nephelometric); chromogenic; immunologic	clot detection, optical, chromogenic; immunologic	immunologic (quantitative microlatex)
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	22	500	1
No. of different assays programmed and calibrated at one time	1	500	1
No. of user-definable (open) channels	300 (IL test channels 120+ open)	250	—
Of those defined, No. active simultaneously	varies with test-reagent combination	varies with test-reagent combination	1
Factor assays require manual manipulation or dilutions	no	no	n/a
No. of reag. containers onboard at one time/Tests per container	22/varies	44/varies	—/50
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	no
Multiple reag. configurations supported	yes	yes	no
Reag., consumables loaded without interrupting testing	no	yes	no
Same capabilities when 3rd-party reag. used	yes	no	no
Max. time same lot No. of reag. can be used	18 months	18 months	n/a
Walkaway capacity: No. of specimens/No. of tests	40/260	120 (12 racks)/unlimited	n/a/n/a
Min. sample vol. aspirated precisely at one time	5 µL	4 µL	n/a
Standard specimen vol. required to run PT or PTT/Factor VIII activity	PT: 60 µL/18 µL	PT: 50 µL/25 µL	n/a/n/a
Disposables used/Price of each	rotors/price varies	varies	cuvettes/—
Supports direct-from-track sampling	no	yes (in development)	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/yes (in development)	no/no
Sample bar-code reading capability	yes	yes	no
Reagent bar-code reading capability	no	yes	no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining/Short sample detection	yes/yes	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/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/yes	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 3 sec)	no	n/a
Read time extended for prolonged clotting times	yes	yes	n/a
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	n/a
• No. and sources of reag.	yes	yes	n/a
• Incub. times/Reading times	yes/yes	yes/yes	n/a
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	yes/yes	n/a/yes
Auto shutdown/Auto startup programmable	not needed	yes/yes	n/a/n/a
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	4 min/175 specimens	<3 min/360 specimens	—/—
• PT, PTT	8 min/110 specimens	8 min/165 specimens	—/—
• Fibrinogen	4 min/175 specimens	<3 min/360 specimens	—/—
• Factor VIII activity assay	8 min/110 specimens	8 min/165 specimens	—/—
Time delay from ordering stat to aspir. of sample	15 sec	varies	—
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	yes	yes	no
Interface supplied by instrument vendor	no	no	—
Interfaces in active user sites for:	most major vendors	most major vendors	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)	no
Results transferred to LIS as soon as test time complete	yes	yes	no
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	yes	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	weekly: 10 min; monthly: 5 min; biweekly: 5 min	daily: <10 min; weekly: 10 min; no monthly maintenance	daily: 5 min
Onboard maintenance records	yes	yes	no
Training provided with purchase	on site varies/5 days at vendor offices	varies on site/5 days at vendor offices	1 day on site
Approx. No. of training hours needed per tech	24 h	24–40 h	2 h
List price	$59,995	$132,160 (base unit)	$5,150
Ann. svc. contract cost (24/7)/Warranty with purchase	various options available/1 yr	various options available/1 yr	—/1 yr
Unique advantages (provided by vendors)	• extensive menu of clotting, chromogenic, & immunologic assays in a small footprint • positive displacement pipetting for low maintenance and high precision	• state-of-the-art technology featuring clot signature curve analysis • robust system offering continuous operation without interruption to workflow • minimized operator intervention using intuitive Windows 2000 Professional software	• quantitative D-dimer • read time—5 minutes • easy to use

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Coagulation Analyzers

Part 11 of 12

See accompanying article, page 22

	Trinity Biotech **Brooke McCutchan** brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech **Brooke McCutchan** brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech **Brooke McCutchan** brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	Destiny Optical/2006	Amax Destiny/2003	AMAX Destiny Plus/2005
No. of units installed in U.S./Outside U.S.	—/—	>50/<50	—/—
No. of contracts signed between 1/1/05 and 12/31/05	—	40	—
Country where analyzer designed/Manufactured	US & Germany/Germany	Germany & U.S./Germany	Germany & U.S./Germany
Operational type	random access	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	50 positions/5 racks	50 positions/5 racks	50 positions/5 racks
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	22 x 33 x 27 in/165 lbs/150 sq ft	22 x 33 x 27 in/165 lbs/150 sq ft	22 x 33 x 27 in./165 lbs/150 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, XII	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, & XII	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, XII
FDA-cleared chromogenic tests	AT, heparin Xa	AT, heparin Xa	AT, heparin Xa
FDA-cleared immunologic tests	D-dimer	D-dimer	D-dimer
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	—
Methodologies supported	clot detection, optical (turbidimetric); chromogenic; immunologic	clot detect., mechanical; clot detect., optical (turbidimetric); chromogenic; immunologic	clot detection, mechanical & optical (turbidimetric); chromogenic; immunologic
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	10	10	10
No. of different assays programmed and calibrated at one time	unlimited	unlimited	unlimited
No. of user-definable (open) channels	unlimited	unlimited	unlimited
Of those defined, No. active simultaneously	10	10	10
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/Tests per container	30/varies	30/varies	30/varies
Reagents refrigerated onboard	yes (12–16°C)	yes (12–16°C)	yes (12-16°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	varies by reagent—routine reagents 12 months	varies by reagent	varies by reagent—routine reagents 12 months
Walkaway capacity: No. of specimens/No. of tests	50/240	50/240	50/240
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/10 µL	50 µL/10 µL	25 µL/10µL
Disposables used/Price of each	reaction trays, ProWash	reaction trays, ProWash/—	reaction trays, ProWash
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (standard, pediatric, micro)/no	yes (standard, pediatric, micro)/no	yes (all standard, pediatric, micro)/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	in development	in process	in development
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	yes	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no/yes	yes
Hemolysis/Turbidity detection-quantitation	not necessary	not necessary	not neccesary
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	no	0 sec	no
Read time extended for prolonged clotting times	yes	yes	yes
User can set different-than-standard:			
• Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	yes/yes	yes/yes	yes/yes
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	<3 min/110 tests	<3 min/100 tests	< 3 min/180 tests
• PT, PTT	—/60 tests	—/80	—/90 tests
• Fibrinogen	—/60 tests	—/100	—/105 tests
• Factor VIII activity assay	—/40 tests	n/a	—/58 tests
Time delay from ordering stat to aspir. of sample	varies by test	varies by test	varies by test
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots, Westgard)	onboard (incl. QC: L-J plots, Westgard)	onboard (incl. QC: LJ plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	all major LIS vendors	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	—	—	—
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	yes	yes	yes
Time required for maintenance by lab personnel	daily: <5 min; weekly: <30 min; monthly: <30 min	per shift: <5 min; weekly: <30 min; monthly: <5 min	daily: <5 min; weekly: <30 min; monthly: <30 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	2-4 days on site	2–4 days on site	2-4 days on site; 3 days at vendor offices
Approx. No. of training hours needed per tech	8 h	8 h	8 h
List price	$39,500	$49,000	$79,500
Ann. svc. contract cost (24/7)/Warranty with purchase	—/1 yr	—/1 yr	—/1 yr
Unique advantages (provided by vendors)	• small automated coag. analyzer capable of routine and specialty testing, including D-dimer • Windows-based icon-driven software easy to learn and retain • unlimited, any time stat access	• true clot detection • easy to use IntuiTouch software • expanded test menu to include D-dimer and heparin Xa	• one-quarter volume testing for PT & APTT • mechanical & optical clot detection in one platform • easy to learn & retain IntuiTouch software

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Coagulation Analyzers

Part 12 of 12

See accompanying article, page 22

	Trinity Biotech Brooke McCutchan brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech Brooke McCutchan brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com	Trinity Biotech Brooke McCutchan brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	KC1Δ/2001	KC4Δ/2001	Amax 200/2001
No. of units installed in U.S./Outside U.S.	>100/>100	>100/>100	>200/>200
No. of contracts signed between 1/1/05 and 12/31/05	30	15	39
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	semiautomatic, single channel	semiautomatic, 4 channels	random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual	60-position continuous addition sample rack
Model type	benchtop	benchtop	benchtop or floor standing
Dimensions (H x W x D)/Weight/Instrument footprint	3.25 x 5.5 x 8.25 in/2.5 lbs/<1 sq ft	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
FDA-cleared clotting-based tests	PT, APTT, fib.	PT, APTT, fib., TT, atroxin, intrinsic & extrinsic factors	APTT, atroxin, fib., PT, proteins C & S, TT, intrinsic & extrinsic factors, dRVVT
FDA-cleared chromogenic tests	n/a	n/a	antithrombin, plasminogen, heparin-Xa, protein C XII
FDA-cleared immunologic tests	n/a	n/a	D-dimer
Other FDA-cleared tests	n/a	n/a	none
User-defined tests in clinical use	n/a	n/a	PT & APTT mixing studies, Plt. neutralization, Kaolin clotting time, activated protein C resistance, protein S (immunol.), vWF assay (immunol.), thrombo test, heparin cofactor II, alpha-2 antiplasmin
Tests submitted for 510(k) clearance	n/a	n/a	none
Tests in development but not yet submitted	n/a	n/a	none
Methodologies supported	clot detection, mechanical	clot detection, mechanical	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	1	5	32
No. of different assays programmed and calibrated at one time	manual	1/1	32
No. of user-definable (open) channels	n/a	n/a	32
Of those defined, No. active simultaneously	n/a	up to 4	12
Factor assays require manual manipulation or dilutions	yes	yes	no
No. of reag. containers onboard at one time/Tests per container	1/varies for each assay	5/varies for test kit	24/varies with kit & operational mode
Reagents refrigerated onboard	no	no	yes (15°C)
Multiple reag. configurations supported	no	no	yes
Reag., consumables loaded without interrupting testing	n/a, manual	n/a, manual	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	12–18 months	12–18 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	n/a, manual	n/a, manual	60/450
Min. sample vol. aspirated precisely at one time	n/a	n/a	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/n/a	50 µL/10 µL	25 µL/10 µL
Disposables used/Price of each	cuvettes & ball dispenser/inquire	cuvettes & ball dispenser/inquire	cuvettes/—, probe decontaminate/—
Supports direct-from-track sampling	n/a	n/a	no
Primary tube sampling supported/Pierces caps on primary tubes	n/a	n/a	yes/no
Sample bar-code reading capability	n/a	n/a	yes
Reagent bar-code reading capability	n/a	n/a	no/yes
Onboard test automatic inventory	n/a	n/a	yes
Measures No. of tests remaining/Short sample detection	n/a	n/a	yes
Clot detection as preanalytical variable in plasma sample	n/a	n/a	no
Auto. detection of adequate reag. for aspir. & anal.	n/a	n/a	yes
Hemolysis/Turbidity detection-quantitation	n/a	n/a	not necessary
Dilution of patient samples onboard	n/a	n/a	yes
Automatic rerun capability/Auto reflex testing capability	n/a	n/a	yes/no
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 4.5 sec)	yes (PT & PTT: 4.5 sec)	0 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	no/no	yes/yes
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	75 sec/48 tests	75 sec/48 tests	<3 min/190 tests
• PT, PTT	350 sec/10 tests	350 sec/10 tests	300 sec/120 tests
• Fibrinogen	65 sec/55 tests	65 sec/55 tests	70 sec/115 tests
• Factor VIII activity assay	275 sec/13 tests	275 sec/13 tests	300 sec/120 tests
Time delay from ordering stat to aspir. of sample	n/a	n/a	varies by test
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes	yes	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
Bidirectional interface capability	n/a	n/a	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
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	n/a	n/a	no
Modem servicing	n/a	n/a	yes
Time required for maintenance by lab personnel	none	none	daily: <5 min; weekly: <30 min; monthly: <5 min
Onboard maintenance records	n/a	n/a	no
Training provided with purchase	as needed on site	as needed on site	5 days on site, 4 days at vendor office
Approx. No. of training hours needed per tech	2 h	2 h	16–24 h
List price	$2,100	$9,200	$81,000
Ann. svc. contract cost (24/7)/Warranty with purchase	$650 (M–F, 8–5)/1 yr	$936 (M–F, 8–5)/1 yr	—/1 yr
Unique advantages (provided by vendors)	• patented ball technology for extremely reproducible & reliable results • provides significant cost savings when used with Trinity's reagents & controls	• 4 test positions can be used simultaneously • patented ball method for extremely reproducible & reliable results • provides significant cost savings when used with Trinity's reagents & controls	• easy-to-use software monitors quality at all times • true clot detection (mechanical & optical) plus chromogenic & immunoturbidimetric detection • one-quarter volume usage for reagents & samples

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