In coagulation market, no need to break the budget

Anne Ford

ost-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

We listened

to you . . .

and we made

a good thing

even better.

TODAY instrument survey, however, have taken their customers' budgets into account by offering lowercost 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-useonly parameters, such as ELISA assays for thrombin activatable fibrinolysis inhibitor and antiphospholipid antibodies, are also forthcoming.

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," Mc-Cutchan 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 costeffective 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 researchuse 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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THE POWER OF 8

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Survey of Instruments

Coagulation Analyzers

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Circle No. 18 on reader service card

Coagulation

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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, tech-

nical 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."

CAPTODAY'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.

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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	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	bioMérieux Inc. Vincent Tumminello vincent.tumminello@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712
	www.americanlabor.org & www.labitec.de	www.americanlabor.org & www.labitec.de	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 Country where analyzer designed/Manufactured	30 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,	PT, APTT, TT, fib., PT & APTT factors
		protein S, LAC screen, LAC confirm, APCR-V	
FDA-cleared chromogenic tests	none	none	AT III, hep. antifactor Xa
FDA-cleared immunologic tests Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none none	none none	none PT mix, APTT mix, lupus (dRVVT screen & confirm.),
OSCI UCINICU (CSIS III CIIIICUI USC	none	none	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	clot detection, optical (tungsten, turbidimetric)	clotting, chromogenic assays; photo-optical
	mixing-optical detection	, , , , , , , , , , , , , , , , , , , ,	
Oper. must load sep. reag. pack for ea. specimen/Test run No. of different measured assays onboard simultaneously	0/10 2 (PT, APTT)	no/no 30	no/no 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 Max. time same lot No. of reag. can be used	yes laboratory dependent	yes 18 months	yes 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	5μL	5 μL
Standard specimen vol. required to run PT or PTT/Factor VIII activity		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¢	sample cups, measurement cuvette rings/prices vary	cuvette racks, probe cleaner, predilution strips/prices
	ea.; 500 macrocuv. w/ mixers in trays/12¢ ea., bulk 10.6¢		available upon request
	ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3k tips bulk/3.9¢ ea.		
Supports direct-from-track sampling	no.	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no 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	110	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 Dilution of patient samples onboard	no/no no	no/no yes	no/no 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 (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. Insula disease (Booding disease)	yes	yes	yes
Incub. times/Reading times Autocalibration or outcoalib clart/Multingint calibration cunnerted.	yes/yes	yes/yes	no/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	no/no 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 Time delay from ordering stat to assir of sample.	300 sec/user defined	varies/varies	<7 min/120–140 results
Time delay from ordering stat to aspir. of sample Auto, transfer of QC results to LIS	none—all preanalytical no	15 sec no	<3 min
Data management capability	no no	yes (incl. QC: L-J plots)	yes yes (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	100 post (moi. qo. e-5 piots)	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	00 daily 20 aga waakky 20 aga manthiy E min	no doile 10 min weekly 10 min monthly 5 min, historikly 5 min	no doily E min weekly 20 min monthly 45 min
Time required for maintenance by lab personnel Onboard maintenance records	daily: 30 sec; weekly: 30 sec; monthly: 5 min no	daily: 10 min; weekly: 10 min; monthly: 5 min; biweekly: 5 min yes	daily: 5 min; weekly: 30 min; monthly: <5 min 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		varies	1–2 h/30 min or less for basic operation
ripproxition of training hours housed per teem	2h	Valles	1 E 1//00 IIIII OI 1000 IOI BUOIO OPOI UUOII
	2h		·
List price	2 h \$900, special pricing avail. upon written request for quote	\$25,000	\$55,000
	2 h \$900, special pricing avail. upon written request for quote additional 1-yr initial contract \$500 (optional)/1 yr,		·
List price	2 h \$900, special pricing avail. upon written request for quote	\$25,000	\$55,000
List price	2 h \$900, special pricing avail. upon written request for quote additional 1-yr initial contract \$500 (optional)/1 yr,	\$25,000	\$55,000
List price Ann. svc. contract cost (24/7)/Warranty with purchase	2 h \$900, special pricing avail. upon written request for quote additional 1-yr initial contract \$500 (optional)/1 yr, \$300 renewal • smaller clinic; office, private, vet labs • low acquisition & service cost, low maintenance	\$25,000 various options available/1 yr • clot code electronic signatures available for each assay run, visualization, and printouts	\$55,000 \$6,300/1 yr • normalization of PT & APTT assays with other bioMérieux automated systems
List price Ann. svc. contract cost (24/7)/Warranty with purchase	2 h \$900, special pricing avail. upon written request for quote additional 1-yr initial contract \$500 (optional)/1 yr, \$300 renewal • smaller clinic; office, private, vet labs • low acquisition & service cost, low maintenance • refurbished units available at reduced prices	\$25,000 various options available/1 yr • clot code electronic signatures available for each assay run, visualization, and printouts • extensive menu of clotting	\$55,000 \$6,300/1 yr • normalization of PT & APTT assays with other bioMérieux automated systems • workhorse analyzer for med- to high-vol. workload
List price Ann. svc. contract cost (24/7)/Warranty with purchase	2 h \$900, special pricing avail. upon written request for quote additional 1-yr initial contract \$500 (optional)/1 yr, \$300 renewal • smaller clinic; office, private, vet labs • low acquisition & service cost, low maintenance	\$25,000 various options available/1 yr • clot code electronic signatures available for each assay run, visualization, and printouts • extensive menu of clotting • positive displacement pipetting for low maintenance and	\$55,000 \$6,300/1 yr • normalization of PT & APTT assays with other bioMérieux automated systems • workhorse analyzer for med- to high-vol. workload • easy operation & simple software means minimal
List price Ann. svc. contract cost (24/7)/Warranty with purchase	2 h \$900, special pricing avail. upon written request for quote additional 1-yr initial contract \$500 (optional)/1 yr, \$300 renewal • smaller clinic; office, private, vet labs • low acquisition & service cost, low maintenance • refurbished units available at reduced prices	\$25,000 various options available/1 yr • clot code electronic signatures available for each assay run, visualization, and printouts • extensive menu of clotting	\$55,000 \$6,300/1 yr • normalization of PT & APTT assays with other bioMérieux automated systems • workhorse analyzer for med- to high-vol. workload

Part 2 of 12			
FAIL Z VI 12	bioMérieux Inc.	bioMérieux Inc.	bioMérieux Inc.
	Vincent Tumminello	Vincent Tumminello	Vincent Tumminello
	vincent.tumminello@na.biomerieux.com	vincent.tumminello@na.biomerieux.com	vincent.tumminello@na.biomerieux.com
See accompanying article, page 22	100 Rodolphe St., Durham, NC 27712	100 Rodolphe St., Durham, NC 27712	100 Rodolphe St., Durham, NC 27712
See accompanying article, page 22	919-620-2271 www.biomerieux-usa.com	919-620-2271 www.biomerieux-usa.com	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 with installed in H.C. (Outside H.C.	. 500	. 0.000	. 400
No. of units installed in U.S./Outside U.S. No. of contracts signed between 1/1/05 and 12/31/05	>500 worldwide	>2,000 worldwide	>400 worldwide
Country where analyzer designed/Manufactured	Germany & U.S./Germany		 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 cleaned clatting based tests	DT ADTT TT (ib. DT 9 ADTT foster coorse	DT ADTT TT 5th DT 9 ADTT factor coccus	DT covering (madewate 9 levelCl) DT feature guidle/
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%, APIT screening, APIT factors, PT mix, APIT mix, TT, fib.
FDA-cleared chromogenic tests	AT III, hep. antifactor Xa, protein C	none	hep. antifactor Xa, AT III, protein C, plasminogen,
TDA dicarca cinoniogenio tests	AT III, Hop. untiluctor Au, protoin o	none	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,	none	clottable C & S, PNP, P & P (1 & 2), vWF, open assays—
	LMWH (antifactor Xa)		user definable for clotting, chrom. & microlatex assays
Tests submitted for 510(k) clearance Tests in development but not yet submitted	none quantitative D-dimer immunoassay	none 	none none
resis in development but not yet submitted	quantitative D-uniter infinitioassay	_	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		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 No.	yes (8-15°C)
Multiple reag. configurations supported Reag., consumables loaded without interrupting testing	yes no	yes yes	yes consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	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	cuvettes, stir bars, optional: printer & paper/prices	cuvettes, bar-code labels, MDA probe cleaner/prices
	solution/prices available on request	available on request	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	10	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	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no ,	yes
Hemolysis/Turbidity detection-quantitation Dilution of patient samples onboard	no/no	no/no no	yes/yes (detects bilirubin, corrects for lipemia)
Automatic rerun capability/Auto reflex testing capability	yes yes/no	no/no	yes 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	
Incub. times/Reading times	yes/yes	yes/yes	yes
			no/yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	yes/yes	no/yes yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable	yes/yes no/no		no/yes
Auto shutdown/Auto startup programmable		yes/yes	no/yes yes/yes
		yes/yes	no/yes yes/yes
Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for:	no/no	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual)	no/yes yes/yes yes/yes
Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen	2 min/90 results 5 min/60 results 2 min/75 results	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2–3 min/100 results (manual)	no/yes yes/yes yes/yes 12 min/180 results 12 min/180 results 12 min/180 results
Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone • PT, PTT • Fibrinogen • Factor VIII activity assay	2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2–3 min/100 results (manual) 5 min/50 results (manual)	no/yes yes/yes yes/yes 12 min/180 results 12 min/180 results 12 min/180 results 12 min/180 results
Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone • PT, PTT • Fibrinogen • Factor VIII activity assay Time delay from ordering stat to aspir. of sample	2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2–3 min/100 results (manual) 5 min/50 results (manual) ≤2 min	no/yes yes/yes yes/yes 12 min/180 results 12 min/180 results 12 min/180 results 12 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results
Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone • PT, PTT • Fibrinogen • Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS	2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2–3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no	no/yes yes/yes yes/yes 12 min/180 results 12 min/180 results 12 min/180 results 12 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results
Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone • PT, PTT • Fibrinogen • Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability	2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes yes (incl. QC: L-J plots)	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2–3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no no	no/yes yes/yes yes/yes 12 min/180 results 12 min/180 results 12 min/180 results 12 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results
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Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone • PT, PTT • Fibrinogen • Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability	2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes yes (incl. QC: L-J plots)	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2–3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no no	no/yes yes/yes yes/yes 12 min/180 results 12 min/180 results 12 min/180 results 12 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results
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Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor Interfaces in active user sites for: Bidirectional interface capability Results transferred to LIS as soon as test time complete 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 Modem servicing Time required for maintenance by lab personnel Onboard maintenance records Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase	no/no 2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a no no daily: ~5 min; weekly: ~1 min; monthly: ~5 min no 3 days at vendor offices 2-3 h \$49,995 \$7,300/1 yr	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2-3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no no no no no no no no 1/2 day on site 1-2 h \$5,198 depot service (repair)/1 yr • simple to operate: clot detection starts automatically on addition of start reagent	no/yes yes/yes yes/yes 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 12 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 11 min/180 results 12 min/1
Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor Interfaces in active user sites for: Bidirectional interface capability Results transferred to LIS as soon as test time complete 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 Modem servicing Time required for maintenance by lab personnel Onboard maintenance records Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase	no/no 2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a no no daily: ~5 min; weekly: ~1 min; monthly: ~5 min no 3 days at vendor offices 2–3 h \$49,995 \$7,300/1 yr • normalization of PT & APTT results between bioMérieux automated systems • stat results within 2–5 min	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2-3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no no no no no no no no no 1/2 day on site 1-2 h \$5,198 depot service (repair)/1 yr • simple to operate: clot detection starts automatically on addition of start reagent • flexibility; test params. can be modified to	no/yes yes/yes yes/yes yes/yes 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 14 min/180 results 12 min/180 results
Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor Interfaces in active user sites for: Bidirectional interface capability Results transferred to LIS as soon as test time complete 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 Modem servicing Time required for maintenance by lab personnel Onboard maintenance records Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase	no/no 2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a no no daily: ~5 min; weekly: ~1 min; monthly: ~5 min no 3 days at vendor offices 2–3 h \$49,995 \$7,300/1 yr • normalization of PT & APTT results between bioMérieux automated systems • stat results within 2–5 min • flexibility; MTX can support new assays easily	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2-3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no no no no no no no no 1/2 day on site 1-2 h \$5,198 depot service (repair)/1 yr • simple to operate: clot detection starts automatically on addition of start reagent	no/yes yes/yes yes/yes 12 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 18 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 10 min/1
Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor Interfaces in active user sites for: Bidirectional interface capability Results transferred to LIS as soon as test time complete 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 Modem servicing Time required for maintenance by lab personnel Onboard maintenance records Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase	no/no 2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no no daily: ~5 min; weekly: ~1 min; monthly: ~5 min no 3 days at vendor offices 2–3 h \$49,995 \$7,300/1 yr • 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	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2-3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no no no no no no no no 1/2 day on site 1-2 h \$5,198 depot service (repair)/1 yr • simple to operate: clot detection starts automatically on addition of start reagent • flexibility; test params. can be modified to	no/yes yes/yes yes/yes 12 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 10 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 10 min/1
Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor Interfaces in active user sites for: Bidirectional interface capability Results transferred to LIS as soon as test time complete 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 Modem servicing Time required for maintenance by lab personnel Onboard maintenance records Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase	no/no 2 min/90 results 5 min/60 results 2 min/75 results 5 min/60 results 30–60 sec yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a no no daily: ~5 min; weekly: ~1 min; monthly: ~5 min no 3 days at vendor offices 2–3 h \$49,995 \$7,300/1 yr • normalization of PT & APTT results between bioMérieux automated systems • stat results within 2–5 min • flexibility; MTX can support new assays easily	yes/yes no/no 2 min/200 results (manual) 5 min/50 PTT results (manual) 2-3 min/100 results (manual) 5 min/50 results (manual) ≤2 min no no no no no no no no 1/2 day on site 1-2 h \$5,198 depot service (repair)/1 yr • simple to operate: clot detection starts automatically on addition of start reagent • flexibility; test params. can be modified to	no/yes yes/yes yes/yes 12 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 10 min/180 results 11 min/180 results 12 min/180 results 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/180 results 16 min/180 results 17 min/180 results 18 min/180 results 18 min/180 results 18 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 19 min/180 results 10 min/1

Part 3 of 12	Dade Behring Inc.	Dade Behring Inc.	Dade Behring Inc.
Fail 3 01 12	Jackie Hauser jackie_hauser@dadebehring.com	Jackie Hauser jackie_hauser@dadebehring.com	Jackie Hauser jackie_hauser@dadebehring.com
See accompanying article, page 22	1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com
nstrument name/first year sold	BFT II/U.S.: 1999	Sysmex CA-560/U.S.: 2003	Sysmex CA-1500/U.S.: 2000; worldwide: 1999
lo. of units installed in U.S./Outside U.S.	-/-	-/-	-/-
No. of contracts signed between 1/1/05 and 12/31/05		— Japan/Japan	— James / James
Country where analyzer designed/Manufactured Operational type	Germany/Germany batch	batch, continuous random access	Japan/Japan continuous random access
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually), optimized	open reagent system (lyoph., reconst. manually),
• •		for Dade Behring instruments	optimized for Dade Behring instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system Model type	manual benchtop	10-tube position sample rack benchtop	10-tube position sample rack × 5 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
	·	<u>`</u>	<u>·</u>
DA-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 clo
FDA-cleared chromogenic tests	n/a	AT III, protein C chromo, heparin	protein S activity AT III, plasminogen, factor VIII chromo, alpha-2
EDA algored immunologie teete	n/o	Advanced D. dimer	antiplasmin, protein C chromo, heparin Advanced D-dimer
FDA-cleared immunologic tests Other FDA-cleared tests	n/a none	Advanced D-dimer none	none
Jser-defined tests in clinical use	none	n/a	n/a
Tests submitted for 510(k) clearance	none	none	n/a
ests in development but not yet submitted	none	n/a	-
Nethodologies supported	turbodensitometric	clot detect., optical, turbidmetric; chromogen.; immunolog.	clot detection, optical, turbidmetric; chromogenic;
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	immunologic 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
lo. of user-definable (open) channels	n/a	7	25
Of those defined, No. active simultaneously	1	5 n/a	15
actor assays require manual manipulation or dilutions lo. of reag. containers onboard at one time/Tests per container	n/a 4/up to 2,000	n/a 11/varies, up to 200	no 39/up to 200
leagents refrigerated onboard	no	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
eag., consumables loaded without interrupting testing	yes	consumables yes, reagents no	some consumables yes, reagents no
ame capabilities when 3rd-party reag. used lax. time same lot No. of reag. can be used	yes 12 months	yes 12 months	yes 12 months
Valkaway capacity: No. of specimens/No. of tests	12 monais 1/1	12 monus 10/50	50/up to 1,000
Ain. sample vol. aspirated precisely at one time	50 µL	10 uL	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	reaction tubes, sample plates, CA clean I & II, system
		with volume	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 no/no	yes	yes
Measures No. of tests remaining/Short sample detection Clot detection as preanalytical variable in plasma sample	no/no	yes/yes	yes/yes no
Auto. detection of adequate reag. for aspir. & anal.	no no	no yes	yes
lemolysis/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
ag 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)
lead time extended for prolonged clotting times lser can set different-than-standard:	no	yes (selectable on menus)	yes (selectable on menus)
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
uto shutdown/Auto startup programmable	no/no	no/no	no/no
tat 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 PFibrinogen	n/a manual <1 min/n/a manual	8 min/43 results 7 min/54 results	8 min/80 results 8 min/120 results
Factor VIII activity assay	n/a	7 mm/34 results n/a/n/a	8 min/n/a
ime delay from ordering stat to aspir. of sample	n/a	2 min	2 min
auto. transfer of QC results to LIS	no	yes	yes
ata management capability	no "/a	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots & Westgard)
nterface supplied by instrument vendor nterfaces in active user sites for:	n/a n/a	no Cerner, Misys (formerly Sunquest), others	no Cerner, Misys (formerly Sunquest), others
interfaces in active user sites for: Bidirectional interface capability	no	yes (host query)	yes (host query)
lesults transferred to LIS as soon as test time complete	no	yes	yes
OINC codes transmitted with all results	no	no .	no
low 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
Fime 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 video	no 2 days on site	no
Training provided with purchase		·	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
.ist price Ann. svc. contract cost (24/7)/Warranty with purchase	\$8,108 depot service (repair)/1 yr	\$44,470 \$4,652 (business hours)/—	\$91,050 standard model; \$103,200 cap-piercing mode \$9,975 standard model; \$11,225 cap-piercing/1 yr
Unique advantages (provided by vendors)	• 2-channel micro reagent volume clot-based technology	• 5-parameter true random access	 simultaneous curve calibrating & patient testing
Unique advantages (provided by vendors)	opto-mechanical detection accurate on lipemic,	clotting/chromogenic	ability to load multiple bottles or multiple lots of
Inique advantages (provided by vendors)	opto-mechanical detection accurate on lipemic, icteric samples	clotting/chromogenic • small footprint, complete automation, specialty	• • • • • • • • • • • • • • • • • • • •
Inique advantages (provided by vendors)	opto-mechanical detection accurate on lipemic,	clotting/chromogenic	ability to load multiple bottles or multiple lots of

Part 4 of 12	Dade Behring Inc.	Dade Behring Inc.	Diagnostica Stago Inc.
1 4 11 4 01 12	Jackie Hauser jackie_hauser@dadebehring.com	Jackie Hauser jackie_hauser@dadebehring.com	Audrey Woodbeck audrey.woodbeck@stago-us.com
See accompanying article, page 22	1717 Deerfield Rd., Deerfield, IL 60015	1717 Deerfield Rd., Deerfield, IL 60015	5 Century Dr., Parsippany, NJ 07054
	847-267-5383 www.dadebehring.com	847-267-5383 www.dadebehring.com	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	open reagent system	open reagent system (lyoph., reconst. manually)
	Dade Behring instruments		
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system Model type	rack benchtop	rack benchtop	rack with continuous specimen access 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	PT, APTT, fib., TT, reptilase time, factor assays, dRVVT screen	PT, APTT, TT, fib., reptilase, intr. & extr. factor assays,
FDA alasmed shummanis toots	& confirm, factor V Leiden, protein C clot, protein S activity	& confirm, factor V Leiden, protein C clot, protein S activity	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 clottin
			based, chromogenic, and immunological tests with user
Tests submitted for 510(k) clearance	n/a	n/a	defined applications
Tests in development but not yet submitted	n/a ETP*	_	n/a 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 No. of different assays programmed and calibrated at one time	28 tests/samples 99	20 40	up to 200 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 oc/	NO	110
No. of reag. containers onboard at one time/Tests per container Reagents refrigerated onboard	86/— ves (<15°C)	58/varies up to 200	70/up to 83
Multiple reag. configurations supported	yes (<15°C) yes	yes (15°C) yes	yes (15–19°C) 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 Min. sample vol. aspirated precisely at one time	110 samples/400 cuvettes 5 µL	100/550 per hour PT and APTT, 300 per hour PT 5 μL	215/32 5 μL
Standard specimen vol. required to run PT or PTT/Factor VIII activity		50 μL/10 μL	50 μL/5 μL
Disposables used/Price of each	cuvette rotors, washing solution, terralin disinfectant, BC	reaction tubes, CA clean I & II, system buffer, halogen	cuvette/—; wash-cleaner solution/—
	validation kit/price varies with volume	lamp, closed container sample replacement	
		needles/prices vary with volume	
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 Maggires No. of tests remaining/Short comple detection	yes voo/voo	yes	yes
Measures No. of tests remaining/Short sample detection Clot detection as preanalytical variable in plasma sample	yes/yes no	yes/yes no	yes/yes 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 Lag time during which hypercoagulable samples will not be detected	yes/yes yes (PT & PTT: 7 sec)	yes/yes yes (PT: 7 sec, PTT: 15 sec)	yes/no no
Read time extended for prolonged clotting times	yes (ΓΙ α ΓΙΙ. 7 sec) No	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:		, co (co.co.u.z.c cc.,	jes (constitute on monus)
Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
No. and sources of reag. Insula disease (Booding disease)	yes	yes	yes
Incub. times/Reading times Autocalibration or autocalib. alert/Multipoint calibration supported	yes/no yes/yes	yes/yes no/yes	yes/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:		T 1 /000	0.14.000
PT alone PT, PTT	<5 min/~315 results (incl. abnormals) <5 min/~285 results (incl. abnormals)	7 min/280 results 8 min/480 results	<6 min/~300 7 min/~150
• Fibrinogen	<5 min (if curve avail.)/~315 results	8 min/280 results	7 min/~150 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 limited	yes	yes
Data management capability Interface supplied by instrument vendor	limited no	onboard (incl. QC: L-J plots & Westgard) no	onboard (L-J plots) 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 How labs get LOINC codes for reagent kits	no n/a	no n/a	no Web site
Electronic interface available (or will be) to automated	possible future upgrade (not available)	custom automated connectivity with Stream Lab	yes (Beckman Coulter, Bayer LabCell, Roche CLAS)
(or robotic) specimen handling system	, , , , , , ,	in development	, , , , , ,
Modern comission			
Modem servicing Time required for maintenance by lab personnel	yes daily: <5 min; weekly: <10 min; monthly: 15 min	no per shift: <5 min; daily: <10 min; weekly: 1 min; quarterly: 5 min	yes 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	varies on site, 5 days at vendor offices for 2 operators	varies on site, 5 days at vendor offices
	(regular and advanced)		0.51
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
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Unique advantages (provided by vendors)	cont. loading of bar-coded reagent & samples multilat multicurus reagent management	fastest throughput available for routine testing; PT APTT results every 7 see.	viscosity-based detection system connectivity to lab automation systems
	multilot, multicurve reagent management PT/APTT/fib./AT III/D-dimer in <10 min	PT, APTT results every 7 sec continuous loading of reagents, consumables, & patient	connectivity to iab automation systems exclusive software fo password protection and result
	• simultaneous curve calibration & patient testing	samples without interruption	traceability
	•		
	*for research use only; not FDA-cleared for commercial use		

Part 5 of 12	Diagnostica Stago Inc.	Diagnostica Stago Inc.	Diagnostica Stago Inc.
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See accompanying article, page 22	800-222-COAG	800-222-COAG	800-222-COAG
	www.stago-us.com	www.stago-us.com	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 Operational type	France/France continuous random access	France/France continuous random access	France/France 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 Sample handling system	spun plasma continuous specimen access-primary tube	spun plasma continuous specimen access—primary tube	spun plasma 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,	PT, APTT, TT, fib., reptilase, intr. & extr. factors,	PT, APTT, TT, fib., reptilase, intr. & extr. factors,
FDA-cleared chromogenic tests	proteins C & S, lupus anticoag. screen & confirm. heparin (UFH & LMWH), protein C, AT III, plasminogen,	proteins C & S, lupus anticoag. screen & confirm n/a	proteins C & S, lupus anticoag. screen & confirm. none
•	antiplasmin	-1-	
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	dRVVT screen & confirm. assays, APCR, other clotting-based tests can have user-defined	dRVVT screen & confirm assays, APCR, other clotting- based tests with user-defined applications
	user-defined applications	applications	
Tests submitted for 510(k) clearance Tests in development but not yet submitted	2 none	none none	none none
. ,			
Methodologies supported Oper. must load sep. reag. pack for ea. specimen/Test run	clotting, chromogenic, & immunologic assays no/no	clot detection, mechanical no/no	clotting tests 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 No. of user-definable (open) channels	up to 80 70	up to 80 70	20 4
Of those defined, No. active simultaneously	70 70	70 70	1
Factor assays require manual manipulation or dilutions	NO	NO AE/varios un to 92	yes
No. of reag. containers onboard at one time/Tests per container Reagents refrigerated onboard	45/varies, up to 83 yes (15–19°C)	45/varies, up to 83 yes (15–19°C)	4/varies, up to 100 no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing Same capabilities when 3rd-party reag. used	yes yes	yes yes	no 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 Min. sample vol. aspirated precisely at one time	96/12 per sample 5 µL	96/12 per specimen 5 μL	4/1 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 Sample bar-code reading capability	yes/yes yes	yes/yes yes	no/no (n/a) no
Reagent bar-code reading capability	yes	yes	no
Onboard test automatic inventory Measures No. of tests remaining/Short sample detection	yes yes/yes	yes yes/yes	no no/no
Clot detection as preanalytic variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal. Hemolysis/Turbidity detection-quantitation	yes no/no (not necessary for mechanical detection	yes no/no (not necessary for mechanical detection	no no/no (not necessary for mechanical detection
, , ,	technology)	technology)	technology)
Dilution of patient samples onboard Automatic rerun capability/Auto reflex testing capability	yes yes/no	yes yes/no	no no/no
Lag time during which hypercoagulable samples will not be detected	no	no	no
Read time extended for prolonged clotting times User can set different-than-standard:	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
No. and sources of reag. Incub. times/Reading times	yes yes/yes	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 PT, PTT	<6 min/150 specimens	<6 min/150 specimens	<1 min/up to 120 specimens
• Fibrinogen	7 min/75 specimens 7 min/75 specimens	7 min/75 specimens 7 min/75 specimens	n/a/n/a <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 Auto. transfer of QC results to LIS	<15 sec yes	<15 sec yes	n/a no
Data management capability	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots)	no
Interface supplied by instrument vendor Interfaces in active user sites for:	no Cerner, Misys, Meditech, others	no Cerner, Misys, Meditech, others	no n/a
Bidirectional interface capability	yes (host query)	yes (host query)	no
Results transferred to LIS as soon as test time complete LOINC codes transmitted with all results	yes no	yes no	yes 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
	ma.	70	
Modem servicing Time required for maintenance by lab personnel	no daily: none; weekly: <30 min; monthly: <30 min	no daily: none; weekly: <30 min; monthly: <30 min	no daily: none; weekly: <5 min; monthly: <5 min
Onboard maintenance records	yes	yes	no
Training provided with purchase Approx. No. of training hrs needed per tech	varies on site, 3 days at vendor offices 2 h basic	varies on site, 3 days at vendor office 2 h basic	1 day on site 1 h
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$75,000 prices available on request/1 yr	\$50,000 prices available on request/1 yr	\$9,600 prices available on request/1 yr
	• • • • • • • • • • • • • • • • • • • •		· · · · · ·
Unique advantages (provided by vendors)	 viscosity-based detection system walkaway testing for routine & specialty 	viscosity-based detection systemwalkaway testing for routine & specialty	 viscosity-based detection system excellent for low-volume testing or backup for
	hemostasis assays • able to standardize with other STA analyzers	hemostasis assays • able to standardize with other STA systems	optical system • programmable and preprogrammed assays with
	- anie to standaruize with Dulet STA diidiyzets	- anie to standaruize with dulet STA Systems	programmable and preprogrammed assays with curve storage plus four independently timed
			incubation stations

Part 6 of 12	Fisher Diagnostics	Fisher Diagnostics	Fisher Diagnostics
	Ron Evancheck ronald.evancheck@fishersci.com 8365 Valley Pike, Middletown, VA 22645	Ron Evancheck ronald.evancheck@fishersci.com 8365 Valley Pike, Middletown, VA 22645	Ron Evancheck ronald.evancheck@fishersci.com 8365 Valley Pike, Middletown, VA 22645
San accompanying article page 22	540-869-8224	540-869-8224	540-869-8224
See accompanying article, page 22	www.fisherdiagnostics.com	www.fisherdiagnostics.com	www.fisherdiagnostics.com
Instrument name/first year sold	ThromboScreen 200/1994	ThromboScreen 400c/1996	ThromboScreen 1000/2003
mstrument name/mst year sour	THIOTHUGGETECH 200/ 1994	THIOTHIDOSCICCH 400C/ 1550	Hildiliposciecii 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 Dimensions (H x W x D)/Weight/Instrument footprint	benchtop 4 x 8 x 12 in/5 lbs/1 sq ft	benchtop 5 x 12 x 12 in/10 lbs/1 sq ft	benchtop 28 x 22 x 18 in/35 lbs/3 sq ft
			DT 4077 (1)
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,	PT, APTT, fibrinogen
	,,,,,	proteins C&S	
FDA-cleared chromogenic tests	none	AT III, heparin	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests User-defined tests in clinical use	none n/a	none n/a	none n/a
user-definied tests in chinical use	II/d	iva	n/a
Tests submitted for E10((a) electrones	none	nana	none
Tests submitted for 510(k) clearance Tests in development but not yet submitted	none none	none none	none thrombin time
Mathadalariae cunnerted	olat datastian entical	elet detection enticel observacionis	antical turbodonoitameter
Methodologies supported Oper. must load sep. reag. pack for ea. specimen/Test run	clot detection, optical no/no	clot detection, optical, chromogenic no/no	optical turbodensitometry 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 2/uprice	yes 2/uorioo	n/a
No. of reag. containers onboard at one time/Tests per container Reagents refrigerated onboard	3/varies no	3/varies	6/varies
Multiple reag. configurations supported	yes	no yes	no yes
Reag., consumables loaded without interrupting testing	yes	yes	100
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 Standard specimen vol. required to run PT or PTT/Factor VIII activity	25 μL 50 μL, min. 50 μL/—	50 μL 50 μL, min. 50 μL/—	10 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 Clot detection as preanalytical variable in plasma sample	no/no no	no/no no	no/yes 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 User can set different-than-standard:	yes (selectable on menus)	yes	yes (selectable on menus)
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 Factor VIII activity assay	<1 min/120 specimens n/a	<1 min/120 specimens n/a	<5 min/80 specimens n/a
Time delay from ordering stat to aspir. of sample	n/a n/a	n/a	11/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 Results transferred to LIS as soon as test time complete	no no	no 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	no	no	no
(or robotic) specimen handling system			
Modem servicing	no doity 5 min. wookly 5 min. monthly 5 min	no dojiya 5 mina waakkiya 5 mina manthiya 5 min	NO
Time required for maintenance by lab personnel Onboard maintenance records	daily: 5 min; weekly: 5 min; monthly: 5 min no	daily: 5 min; weekly: 5 min; monthly: 5 min no	daily: 5 min; weekly: 15 min; monthly: 15 min no
Training provided with purchase	1 day on site	1 day on site	4 h on site
	1 h	1 h	4 h
Approx. No. of training hours needed per tech	\$3,800	\$6,100	\$18,000
	70,000	varies/1 yr	varies/1 yr
List price Ann. svc. contract cost (24/7)/Warranty with purchase	varies/1 yr		
List price	• low volume or backup	• small footprint—fits anywhere	•
List price Ann. svc. contract cost (24/7)/Warranty with purchase	low volume or backup small footprint—fits anywhere	chromogenic assay capability	instrument
List price Ann. svc. contract cost (24/7)/Warranty with purchase	• low volume or backup		instrument • low cost, fully automated analyzer for routine
List price Ann. svc. contract cost (24/7)/Warranty with purchase	low volume or backup small footprint—fits anywhere	chromogenic assay capability	fibrinogen curve provided for reagents used of instrument low cost, fully automated analyzer for routine coagulation tests simple to operate
List price Ann. svc. contract cost (24/7)/Warranty with purchase	low volume or backup small footprint—fits anywhere	chromogenic assay capability	instrument • low cost, fully automated analyzer for routin coagulation tests

Part 7 of 12	Helena Laboratories Joe Golias helena@helena.com	Helena Laboratories Joe Golias helena@helena.com	Helena Laboratories Jim Campbell jcampbell@helena.com
	1530 Lindbergh Dr., Beaumont, TX 77704	1530 Lindbergh Dr., Beaumont, TX 77704	1530 Lindbergh Dr., Beaumont, TX 77704
See accompanying article, page 22	800-231-5663	800-231-5663	800-231-5663
	www.helena.com	www.helena.com	www.helena.com
nstrument 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 Operational type	U.S./U.S. batch	U.S./U.S. random access	U.S./U.S. 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 Model type	manual benchtop	manual benchtop	manual 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
DA-cleared chromogenic tests	none	none	none
FDA-cleared immunologic tests Other FDA-cleared tests	none none	none none	none ristocetin cofactor and platelet aggreg.
Jser-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, C
			ristocetin, arach. acid
Fests submitted for 510(k) clearance Fests in development but not yet submitted	none dRVVT	none dRVVT	none 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. of different measured assays onboard simultaneously	no/no 1	no/no 4	no/no 4–8
No. of different assays programmed and calibrated at one time	1	4	4–6 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 No. of reag. containers onboard at one time/Tests per container	yes —/—	yes O/n/a	yes 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 Same capabilities when 3rd-party reag. used	no ves	no vas	no n/a
Max. time same lot No. of reag. can be used	yes 12 months	yes 12 months	12 months
Nalkaway capacity: No. of specimens/No. of tests	no	no	no
Min. sample vol. aspirated precisely at one time Standard specimen vol. required to run PT or PTT/Factor VIII activity	manual-50 μL 100 μL, min. 50 μL/100 μL (dil.), min. 50 μL (dil.)	manual-50 μL 100 μL, min. 50 μL/100 μL (dil.), min. 50 μL (dil.)	n/a 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; s 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 Reagent bar-code reading capability	no no	no 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
lemolysis/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
ag time during which hypercoagulable samples will not be detected. Read time extended for prolonged clotting times	yes (PT: 4 sec, PTT: 14 sec) yes (selectable on menus)	yes (PT: 4 sec, PTT: 14 sec) yes (selectable on menus)	n/a n/a
Jser can set different-than-standard:	, oo (oo oo aa oo o	,	
Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
No. and sources of reag. Incub. times/Reading times	yes	yes	yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes no/yes	yes/yes no/yes	yes/yes no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
PT alone	3 min/120 specimens	3 min/140 specimens	_
• PT, PTT • Fibrinogen	7 min/50 specimens 3 min/140 specimens	7 min/80 specimens 3 min/160 specimens	_ _
Practor VIII activity assay	7 min/50 specimens	7 min/80 specimens	m/a
Fime 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 nterface supplied by instrument vendor	no (incl. QC: L-J plots) no	no (incl. QC: L-J plots) no	onboard (incl. QC: L-J plots, Westgard) no
nterfaces in active user sites for:	n/a	——————————————————————————————————————	——————————————————————————————————————
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	no no	yes	yes
.OINC codes transmitted with all results low labs get LOINC codes for reagent kits	no 	<u>no</u>	no —
Electronic interface available (or will be) to automated	-	no	no
(or robotic) specimen handling system			
Modem servicing Fime required for maintenance by lab personnel	no daily: 10 min; weekly: 10 min; monthly: 20 min	no 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 Approx. No. of training hours needed per tech	1 day on site 2–4 h	1 day on site 2 h	2 days on site 4–8 h
ist price	\$6,219	\$8,403	\$14,995
•	\$714/1 yr	\$966/1 yr	\$1,800/1 yr
Ann. svc. contract cost (24/7)/Warranty with purchase	• OC program ophoard	• A-channel manual analyzor	• energalized coan instrument intended for also
•	QC program onboard curve storage	4-channel manual analyzer QC program onboard	specialized coag instrument intended for plate aggreg. & ristocetin cofactor

Part 8 of 12	Instrumentation Laboratory/Beckman Coulter Inc. Steven Edwards sjedwards@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822	Instrumentation Laboratory/Beckman Coulter Inc. Steven Edwards sjedwards@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822	Instrumentation Laboratory/Beckman Coulter Inc. Steven Edwards sjedwards@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822
See accompanying article, page 22	714-961-4556 www.beckmancoulter.com	714-961-4556 www.beckmancoulter.com	714-961-4556 www.beckmancoulter.com
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
No. of contracts signed between 1/1/05 and 12/31/05 Country where analyzer designed/Manufactured Operational type Reagent type Operates on whole blood or spun plasma	toninned) 158 worldwide Italy/U.S. batch open reagent system spun plasma	tonibilieu) 110 Italy/U.S. batch open reagent system spun plasma	combined) 289 Italy/U.S. random programming open reagent system spun plasma
Sample handling system Model type Dimensions (H x W x D)/Weight/Instrument footprint	tray-IS sample cups benchtop 17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	tray-IS primary tubes benchtop 17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	tray-IS primary tubes benchtop 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 a intrinsic), proteins C & S (clottable), TT, lupus anticoaq., APCR-V, Clauss fib.
FDA-cleared chromogenic tests	none	none	antithrombin, heparin Xa, plasminogen, antiplasmi protein C
FDA-cleared immunologic tests	none	none	D-dimer, vWF (activity & antigen)
Other FDA-cleared tests User-defined tests in clinical use	none none	none none	none none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	_	_	_
Methodologies supported Oper. must load sep. reag. pack for ea. specimen/Test run	clot detection, optical, nephelometric no/no	clot detection, optical, nephelometric no/no	clot detection, optical, nephelometric; chromogenic immunologic (optical, latex enhanced immunoassa no/no
No. of different measured assays onboard simultaneously No. of different assays programmed and calibrated at one time	3 1	3 1	4 1
No. of user-definable (open) channels	0	0	10 (requires optional research package)
Of those defined, No. active simultaneously Factor assays require manual manipulation or dilutions	n/a yes	n/a yes	1 no
No. of reag. containers onboard at one time/Tests per container Reagents refrigerated onboard	3/varies by test	3/varies by test	3/varies by test yes (15°C)
Multiple reag. configurations supported	yes (15°C) yes	yes (15°C) yes	yes (15 6)
Reag., consumables loaded without interrupting testing Same capabilities when 3rd-party reag. used	no yes	no yes	no 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 Min. sample vol. aspirated precisely at one time	18/36 10 μL	18/36 10 μL	18/48 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 Primary tube sampling supported/Pierces caps on primary tubes Sample bar-code reading capability	no no/no no	no yes/no yes (optional)	no yes/no yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory Measures No. of tests remaining/Short sample detection	no no/yes	no no/yes	no no/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal. Hemolysis/Turbidity detection-quantitation	yes no/no	yes no/no	yes no/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times	no/no yes (PT & PTT: 5.6 std, 6.7 ext) yes	no/no yes (PT & PTT: 5.6 std, 6.7 ext) yes	no/no yes (PT & PTT: 5.6 std, 6.7 ext) yes
User can set different-than-standard: • Reag. volumes/Sample volumes	no/no	no/no	no/no
No. and sources of reag. Incub. times/Reading times	no no/yes	no no/yes	no 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 Factor VIII activity assay	5.5 min/110 specimens 9.5 min/80 specimens	5.5 min/110 specimens 9.5 min/80 specimens	5.5 min/175 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 Data management capability	no no	no no	yes yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for: Bidirectional interface capability	most major LIS vendors no	most major LIS vendors no	most major LIS vendors yes (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	no —	no —	no —
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing Time required for maintenance by lab personnel	no daily: 10 min; weekly: 15 min; monthly: 10 min	no daily: 10 min; weekly: 15 min; monthly: 10 min	no daily: 10 min; weekly: 15 min; monthly: 10 min
Onboard maintenance records Training provided with purchase	yes 2 days on site	yes 2 days on site	yes 2 days on site
Approx. No. of training hrs needed per tech	2 h	6 h	12 h
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$16,000 various options available/1 yr	\$21,500 various options available/1 yr	\$45,000 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

Part 9 of 12 See accompanying article, page 22			
See accompanying article, page 22	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckman Coulter Inc
See accompanying article, page 22	Steven Edwards sjedwards@beckman.com	Steven Edwards sjedwards@beckman.com	Steven Edwards sjedwards@beckman.com
coo accompanying armore, page ==	200 S. Kraemer Blvd., Brea, CA 92822	200 S. Kraemer Blvd., Brea, CA 92822	200 S. Kraemer Blvd., Brea, CA 92822
	714-961-4556 www.beckmancoulter.com	714-961-4556 www.beckmancoulter.com	714-961-4556 www.beckmancoulter.com
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.
•	batch/random programming	random access	batch/random programming
Operational type			, ,
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
Dimensions (if X w x b)/ weight/instrument tootprint	23.0 X 30.2 X 23.0 III/ 130.0 ID3/0 34 It	32.2 X 41 X 24.0 III/ 103 Ib3/ 13 34 It	23.0 X 30.2 X 23.0 III/ 130.0 IBS/0 Sq It
FDA-cleared clotting-based tests	DT ADTT DT-based file Clause file TT factor assays	PT, APTT, PT-based fib., Clauss fib., TT, factor	PT, APTT, TT, PT-based fib., Clauss fib., factor assa
FDA-Cleared Clothing-Dased lesis	PT, APTT, PT-based fib., Clauss fib., TT, factor assays, proteins C & S, LAC screen, LAC confirm, APCR-V		
	• • • • • • • • • • • • • • • • • • • •	assays, protein C, LAC screen, LAC confirm, APCR-V	protein S & C, LAC screen, LAC confirm, APCR-V
FDA-cleared chromogenic tests	antithrombin, heparin, protein C, plasminogen,	antithrombin, heparin, protein C, plasminogen,	antithrombin, liquid antithrombin, factor VIII,
	plasmin inhibitor, liquid antithrombin, factor VIII	plasmin inhibitor, liquid antithrombin	heparin, plasmin inhibitor, plasminogen, protein
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
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	none
Tests submitted for 510(k) clearance	none	none	_
			Assilies clotting time global protein C nothers
Tests in development but not yet submitted	_	LA-silica clotting time, global protein C, factor XIII,	LA-silica clotting time, global protein C pathway,
		homcyst.	homocyst.
Methodologies supported	clot detection antical numbalametria chromosocie	clot detection, optical; chromogenic; immunologic	clot detection, optical (nephelometric); chromoge
πιστισμοιοχίσο συμμοίτου	clot detection, optical, nephelometric; chromogenic;	olot uetection, optical, chromogenic, miniunologic	, , , , , , , ,
	immunologic	,	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	18
		by No. of reag. positions	
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 NO.	yes	no voo
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 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
a Inquis times /Donding times	yes/yes	yes/yes	yes/yes
• Incub. times/Reading times	no/yes	no lugo	mo higo
Autocalibration or autocalib. alert/Multipoint calibration supported		no/yes	no/yes
<u> </u>	not needed	not needed	not needed
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable		•	•
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for:	not needed	not needed	not needed
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone	not needed 4 min/175 specimens	not needed 2.5 min/240 specimens	not needed 4 min/175 specimens
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for:	not needed	not needed	not needed
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT	not needed 4 min/175 specimens 8 min/110 specimens	not needed 2.5 min/240 specimens 8 min/180 specimens	4 min/175 specimens 8 min/110 specimens
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen	not needed 4 min/175 specimens 8 min/110 specimens 4 min/175 specimens	2.5 min/240 specimens 8 min/180 specimens 2.5 min/240 specimens	4 min/175 specimens 8 min/110 specimens 4 min/175 specimens
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone • PT, PTT • Fibrinogen • Factor VIII activity assay	not needed 4 min/175 specimens 8 min/110 specimens 4 min/175 specimens 8 min/110 specimens	2.5 min/240 specimens 8 min/180 specimens 2.5 min/240 specimens 8 min/180 specimens	4 min/175 specimens 8 min/110 specimens 4 min/175 specimens 8 min/110 specimens
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Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: • PT alone • PT, PTT • Fibrinogen • Factor VIII activity assay Time delay from ordering stat to aspir. of sample	not needed 4 min/175 specimens 8 min/110 specimens 4 min/175 specimens 8 min/110 specimens 15 sec	2.5 min/240 specimens 8 min/180 specimens 2.5 min/240 specimens 8 min/180 specimens 20 sec	4 min/175 specimens 8 min/110 specimens 4 min/175 specimens 8 min/110 specimens 15 sec
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Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor Interfaces in active user sites for: Bidirectional interface capability Results transferred to LIS as soon as test time complete 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 Modem servicing Time required for maintenance by lab personnel Onboard maintenance records Training provided with purchase	4 min/175 specimens 8 min/110 specimens 4 min/175 specimens 8 min/110 specimens 15 sec yes yes no — yes (broadcast download & host query) yes no — no no weekly: 10 min; monthly: 5 min; biweekly: 5 min	2.5 min/240 specimens 8 min/180 specimens 2.5 min/240 specimens 8 min/180 specimens 20 sec yes yes no most major LIS vendors yes (broadcast download) yes no no	A min/175 specimens 8 min/110 specimens 4 min/175 specimens 8 min/110 specimens 15 sec yes yes no most major LIS vendors yes (broadcast download & host query) yes no — no
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Part 10 of 12	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckman Coulter Inc.	Trinity Biotech
FAIL IU UI 12	Steven Edwards sjedwards@beckman.com	Steven Edwards sjedwards@beckman.com	Brooke McCutchan brooke.mccutchan@trinityusa.com
See accompanying article, page 22	200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.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 Operational type	U.S./U.S. batch/random programming	U.S./U.S. continuous random access	Germany/Germany 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 Dimensions (H x W x D)/Weight/Instrument footprint	benchtop 23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	benchtop 28.7 x 59.4 x 29.9 in/330.7 lbs/21 sq ft	handheld portable 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,	PT, APTT, Clauss fib., TT, APCR, LA screen & confirm	none
FDA-cleared chromogenic tests	protein S & C, LAC screen, LAC confirm, APCR-V antithrombin, liquid antithrombin, factor VIII, heparin,	AT, protein C, heparin, plasminogen, plasmin inhibitor	none
FDA-cleared immunologic tests	plasmin inhibitor, plasminogen, protein C D-dimer, vWF (activity & antigen), free protein S	D-dimer, vWF (antigen & activity), free protein S, high	D-dimer, quantitative microlatex
Other FDA-cleared tests	none	specificity D-dimer none	none
User-defined tests in clinical use Tests submitted for 510(k) clearance	none —	none —	D-dimer none
Tests in development but not yet submitted	LA-silica clotting time, global protein C pathway,	LA-silica clotting time, global protein C pathway,	none
Methodologica gunnarted	homocyst.	homocyst., factor XIII	immunologio (quantitativa migraletav)
Methodologies supported Oner must load son read nack for ea specimen/Test run	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. of different measured assays onboard simultaneously	no/no 22	no/no 500	no/no 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 Factor assays require manual manipulation or dilutions	varies with test-reagent combination	varies with test-reagent combination	1 n/a
No. of reag. containers onboard at one time/Tests per container	no 22/varies	no 44/varies	n/a —/50
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	no
Multiple reag. configurations supported	yes	yes	no
Reag., consumables loaded without interrupting testing Same capabilities when 3rd-party reag. used	no yes	yes no	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 Primary tube sampling supported/Pierces caps on primary tubes	no voc/no	yes (in development)	no no/no
Sample bar-code reading capability	yes/no yes	yes/yes (in development) yes	no/no no
Reagent bar-code reading capability	no	yes	no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining/Short sample detection Clot detection as preanalytical variable in plasma sample	yes/yes no	yes/yes 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 Automatic rerun capability/Auto reflex testing capability	yes yes/yes	yes yes/yes	no 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 No. and sources of reag. 	yes/yes yes	yes/yes yes	n/a 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 Time delay from ordering stat to aspir. of sample	8 min/110 specimens 15 sec	8 min/165 specimens varies	—/— —
Auto. transfer of QC results to LIS	yes	varies yes	no
Data management capability	yes	yes	no
Interface supplied by instrument vendor	no most major vandova	no most major vandova	_
Interfaces in active user sites for: Bidirectional interface capability	most major vendors yes (broadcast download & host query)	most major vendors yes (broadcast download & host query)	no
Results transferred to LIS as soon as test time complete	yes (broadcast download & host query)	yes (broadcast download & host query)	no
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	— no	yes	n/a no
(or robotic) specimen handling system	110	,	
Modem servicing Time required for maintenance by lab personnel	no weekly: 10 min; monthly: 5 min; biweekly: 5 min	no daily: <10 min; weekly: 10 min; no monthly maintenance	no daily: 5 min
Onboard maintenance records	yes	yes	no
Training provided with purchase Approx. No. of training hours needed per tech	on site varies/5 days at vendor offices 24 h	varies on site/5 days at vendor offices 24–40 h	1 day on site 2 h
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$59,995 various options available/1 yr	\$132,160 (base unit) various options available/1 yr	\$5,150 —/1 yr
· · · · · ·	extensive menu of clotting, chromogenic, &	· · · · · · · · · · · · · · · · · · ·	• quantitative D-dimer
Unique advantages (provided by vendors)	extensive menu or 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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brokument name/first year sold Durding Optical 2009 Annu Durding 2005 Annu Durding 200	ermany em ks 5 lbs/150 sq ft
Instrument name/first year sold And of units installed in U.S. Philaded IU.S. And of context signal behaviors (17.05 and 17.25 for Country where analyzer designed-fish standard units of Country where analyzer designed-fish standard units of Country and U.S. Germany & U.S. G	ermany em ks 5 lbs/150 sq ft
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Operation on whole blood or group plasma Sample hamming system Rhodel types Semple hamming system Special	ks 5 lbs/150 sq ft
Sample handling system Model type Dimensions (9 x W x 10)Weight/horstrument footprint FDA-cleared deliting-based tests FDA-cleared deliting-based tests FDA-cleared deliting-based tests FDA-cleared chromogenic tests FDA-cleared instein sets FDA-cleared tests FDA-cleared instein sets FDA-cleared i	5 lbs/150 sq ft
Model type Demonstrating 19 xt 33 x27 x17 first Ser150 up 11 2 x 33 x27 x17 fits	5 lbs/150 sq ft
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FDA-cleared chromogenic tests AT, Ingent 7a AT, I	atroxin, factors II, V, VII, VIII, IX,
FDA-cleared chromogenic tests AT, Inspar Ta AT, I	atroxin, factors II, V, VII, VIII, IX,
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User -defined tests in clinical use	
Tests submitted for 510(b) clearance Tests in development four noty est submitted ——————————————————————————————————	
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Reagents refrigerated onboard yes (12-16°C) yes (12-16°C) yes (12-16°C) yes ye	
Multiple reag. configurations supported yes yes yes yes yes yes Reago, consimples loaded without interrupting testing yes yes yes yes yes Amax. time same lot No. of reag. can be used yes waries by reagent—routine reagents 12 months yearies by reagent waries by reagent waries by reagent waries by reagent waries by reagent yes	
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Max. time same to No. of reag. can be used varies by reagent—outline reagents 12 months varies by reagent varies by reagent varies by reagent walk away capacity: No. of reag. can be used S0/240 S0/2	
Walkaway capacity: No. of specimens/No. of tests 50/240 50/2	-routine reagents 12 months
Min. sample vol. aspirated precisely at one time Standard specimen vol. required to run PT or PTT/Factor VIII activity Disposables used/Price of each no	vageto 12 months
Standard speciment vol. required to run PT or PTT/Factor VIII activity 50 µL/10 µL reaction trays, ProWash reaction trays, ProWash/— reaction trays, ProWash/— reaction trays, ProWash reaction trays, ProWash/— reaction trays, ProWash/	
Disposables used/Price of each reaction trays, ProWash no no no primary tube sampling supported/Pierces caps on primary tubes Sample bar-code reading capability yes Reagent bar-code reading capability no development no process in development yes yes yes yes Neasures No. of tests remaining/Short sample detection yes/yes yes yes yes yes yes yes	
Supports direct-from-track sampling Primary tube sampling supported/Pierces caps on primary tubes Supports direct-from-track sampling Primary tube sampling supported/Pierces caps on primary tubes Sample bar-code reading capability in development in process in development in process in development Onboard test automatic inventory yes Measures No. of tests remaining/Short sample detection Clot detection of adequate reag, for aspir. & anal. Hemolysis/Turbidity detection-quantitation no yes In on yes No Auto. detection of adequate reag, for aspir. & anal. Hemolysis/Turbidity detection-quantitation not necessary yes yes yes yes yes yes yes yes yes ye	Wash
Primary tube sampling supported/Pierces caps on primary tubes Sample bar-code reading capability Sample bar-code reading capability In development In process In development In process In development In process In development In process In development Onboard test automatic inventory Wes Measures No. of tests remaining/Short sample detection Clot detection as preanalytical variable in plasma sample No. of tests remaining/Short sample detection No. of tests remaining/Short sample on no. No. of tests remaining/Short sample sample no. No. of tests remaining/Short sample of tests are no. No. of tests remaining/Short sample of tests in on no. No. no. of sec.	
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Reagent bar-code reading capability in development per detautomatic inventory yes yes yes yes yes yes yes yes yes ye	
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Clot detection as preanalytical variable in plasma sample Auto. detection of adequate reag, for aspir. & anal. yes no/yes nolyes yes nolyes yes nolyes yes nolyes yes yes yes yes yes yes Automatic rerun capability/Auto reflex testing capability yes/yes yes/yes 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 • No. and sources of reag. • Incub. times/Reading times Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable yes/yes Stat time to completion of all analytes/Throughput per hour for: • PT alone • FT	
Auto. detection of adequate reag. for aspir. & anal. Hemolysis/Turbidity detection-quantitation not necessary not necesary not necesary not necessary not necessary not necessary	
Hemolysis/Turbidity detection-quantitation not necessary n	
Dilution of patient samples onboard yes yes/yes yes yes yes yes yes yes yes yes yes	
Automatic rerun capability/Auto reflex testing capability Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times User can set different-than-standard: Reag. volumes/Sample volumes No. and sources of reag. No. and sourcesources of reag. No. and sources of reag. No. and sources of reag.	
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Read time extended for prolonged clotting times User can set different-than-standard: Reag. volumes/Sample volumes No. and sources of reag. No. and N	
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Reag. volumes/Sample volumes No. and sources of reag. No. solves No. and No.	
No. and sources of reag. yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes Autocalibration or autocalib. alert/Multipoint calibration supported no/yes Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: PT alone Sa min/110 tests Sa min/100	
Incub. times/Reading times Autocalibration or autocalib. alert/Multipoint calibration supported no/yes Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: PT alone PT alone PT, PTT -/60 tests Pibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor yes/yes yes/yes yes/yes no/yes no/yes no/yes yes/yes yes/yes no/yes no/yes yes/yes yes/yes yes/yes no/yes yes/yes yes/ye	
Auto shutdown/Auto startup programmable Stat time to completion of all analytes/Throughput per hour for: PT alone PT, PTT Fibrinogen Factor VIII activity assay Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability Individual calibration supported no/yes yes/yes No/yes No/yes yes/yes No/yes No/ye	
Auto shutdown/Auto startup programmable yes/yes yes	
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• 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: L-J plots, Westgard) no no	
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Data management capability onboard (incl. QC: L-J plots, Westgard) onboard (incl. QC:	
Interface supplied by instrument vendor no no no	LJ plots, Westgard)
	. ,
Interfaces in active user sites for: all major LIS vendors all major LIS vendors all major LIS vendors all major LIS vendors	ors
	vnload & 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 no no	
(or robotic) specimen handling system	
Modem servicing yes yes yes	
	kly: <30 min; monthly: <30 min
Onboard maintenance records yes yes yes	down ad 1 to
	days at vendor offices
Approx. No. of training hours needed per tech 8 h 8 h	
List wise \$20,500 \$40,000 \$70,500	
List price \$39,500 \$49,000 \$79,500 Ann. svc. contract cost (24/7)/Warranty with purchase —/1 yr —/1 yr —/1 yr	
—/1 yr —/1 yr —/1 yr	
Unique advantages (provided by vendors) • small automated coag. analyzer capable of • true clot detection • one-quarter volu	
	me testing for PT & APTT
	me testing for PT & APTT
and retain heparin Xa	tical clot detection in one platfo
• unlimited, any time stat access	•
uninnious un sunt successione	tical clot detection in one platfo

Part 12 of 12	Trinity Biotech	Trinity Biotech	Trinity Biotech
See accompanying article, page 22	Brooke McCutchan brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922	Brooke McCutchan brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922	Brooke McCutchan brooke.mccutchan@trinityusa.com 4 Connell Dr., Ste. 7100 Berkeley Heights, NJ 07922
Instrument name/first year sold	800-325-3424 www.trinitybiotech.com KC1△/2001	800-325-3424 www.trinitybiotech.com KC4\\(^2\)2001	800-325-3424 www.trinitybiotech.com Amax 200/2001
<u> </u>			
No. of units installed in U.S./Outside U.S. No. of contracts signed between 1/1/05 and 12/31/05	>100/>100 30	>100/>100 15	>200/>200 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 Sample handling system	spun plasma manual	spun plasma manual	spun plasma 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 User-defined tests in clinical use	n/a n/a	n/a n/a	none PT & APTT mixing studies, Plt. neutralization, Kaolin
Osci-uciliicu tests iii ciliilodi use	ii/a	II/ a	clotting time, activated protein C resistance, protein S
			(immunol.), vWF assay (immunol.), thrombo test, heparin
Tooks submitted for F10//s) alcohomos	n la	l.a	cofactor II, alpha-2 antiplasmin
Tests submitted for 510(k) clearance Tests in development but not yet submitted	n/a n/a	n/a n/a	none none
Methodologies supported	clot detection, mechanical	clot detection, mechanical	clot detect., mechanical; clot detect., optical (tungsten, tur-
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	bidimetric); chromogenic; immunologic (microparticles) 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 Factor assays require manual manipulation or dilutions	n/a yes	up to 4 yes	12 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 Reag., consumables loaded without interrupting testing	no n/a, manual	no n/a, manual	yes yes
Same capabilities when 3rd-party reag. used	yes	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 E ul
Min. sample vol. aspirated precisely at one time Standard specimen vol. required to run PT or PTT/Factor VIII activity	n/a 50 µL/n/a	n/a 50 μL/10 μL	5 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 Reagent bar-code reading capability	n/a n/a	n/a n/a	yes 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 Auto. detection of adequate reag. for aspir. & anal.	n/a n/a	n/a n/a	no 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 Lag time during which hypercoagulable samples will not be detected	n/a ves (PT & PTT: 4 5 sec)	n/a yes (PT & PTT: 4.5 sec)	yes/no O sec
Read time extended for prolonged clotting times	yes	yes	yes
User can set different-than-standard:			
Reag. volumes/Sample volumes No. and sources of reag.	yes/yes	yes/yes	yes/yes
No. and sources of reag. Incub. times/Reading times	yes yes/yes	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 • Fibrinogen	350 sec/10 tests 65 sec/55 tests	350 sec/10 tests 65 sec/55 tests	300 sec/120 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 onboard (incl. OC: L. Lolots, Westgard)
Data management capability Interface supplied by instrument vendor	yes no	yes no	onboard (incl. QC: L-J plots, Westgard) 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 LOINC codes transmitted with all results	yes —	yes —	yes yes
How labs get LOINC codes for reagent kits	-	_	_
Electronic interface available (or will be) to automated (or robotic) specimen handling system	n/a	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 Approx. No. of training hours needed per tech	as needed on site 2 h	as needed on site 2 h	5 days on site, 4 days at vendor office 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