Balancing cost and capabilities of coag analyzers

Anne Ford

ome coagulation analyzer vendors are trying to ring in the new year with a bang -the most bang for their buck, that is. Trinity Biotech's hemostasis

marketing manager, Venita Shirley, rates cost-effectiveness as one of the most important features of any coagulation analyzer, including her company's Amax 200. It's "the only analyzer on the market that offers quarter-volume testing," she says. "For example, PT testing on the Amax 200 uses 25 µL of sample and 50 µL of reagent as compared to $50 \,\mu\text{L}$ and $100 \,\mu\text{L}$, respectively, for other analyzers. This reduced-volume testing may reduce laboratory reagent costs up to 50 percent." Furthermore, she adds, for labs that receive micro plasma volumes, such as those in pediatric hospitals, "quarter-volume testing means less precious blood required."

American Labor president Michael Shiflett agrees that cost-effectiveness is a leading concern. "I still feel there's a continuing need in the marketplace for basic coagulation equipment that is simple to use and inexpensive to operate," he says. "We are amazed each year to hear from small physicians' offices, clinics, and vet labs that their needs could be met with a basic coagulometer. They oftentimes question whether the expense of all the new bells and whistles is worth it."

Paul Gee, of Fisher Diagnostics, cites his company's ThromboScreen 1000, introduced in June 2003, as an example of a low-cost analyzer for lower-volume labs. The company is considering adding D-dimer capabilities to the product. "This was designed for laboratories that are looking to do the basic coagulation tests," he says, echoing Shiflett's assertion that most analyzers provide more features than small labs require.

Yet other vendors, particularly those that market both higher-volume analyzers and smaller systems, say that on the contrary, their customers are attracted to instruments with a wider range of assays and features. "There is a definite trend or upward movement to more sophisticated coagulation systems," says Steve Edwards, hemostasis marketing manager for Instrumentation Laboratory/Beckman Coulter. "Analyzers that are easy to use but provide extensive data-management capabilities and advanced technol-

ogy, such as clot curve analysis, PT-based fibrinogen, and optics

with autoranging capabilities to minimize sample interference, are in increasing demand." Instrumentation Laboratory/Beckman Coulter launched three analyzers in 2004the ACL 8000, ACL 10000, and ACL TOP—of which, the ACL TOP is designed for higher volume laboratories. All three offer a complete test menu, including a D-dimer assay and clot curve analysis technology.

But what about small or midsize laboratories that don't need extensive coagulation testing capabilities but are looking for a bit more than the basics? At least a few vendors are launching analyzers for this market segment in 2005. BioMérieux expects to release its new mid-range analyzer, the MTX III, in the United States this April. The company spent two years developing the analyzer, which will offer automated latex immunoassay D-dimer capability. To create the MTX III, "we've added a second wavelength to the [existing] MTX II platform that will enable the instrument to perform additional assays," says hemostasis marketing manager Susan Taylor.

Also scheduled for release in 2005 is Diagnostica Stago's STA Satellite, a small automated benchtop analyzer. The STA Satellite will

A side-by-side look at what's

on the market, pages 22-43

feature D-dimer, fibrinogen, and antithrombin. The analyzer is "suit-

able for low-volume testing laboratories who require automation and a few specialty assays," says Laura Worfolk, PhD, MT(ASCP), Diagnostica Stago scientific manager. Alternatively, she says, "it is an ideal backup analyzer for the larger analyzers, the STA Compact and the STA-R."

CAP TODAY's survey of coagulation analyzers on pages 22-43 includes products from the aforementioned manufacturers as well as from Dade Behring and Helena Laboratories. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the features and capabilities stated.

Anne Ford is a writer in Chicago.

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January Page 20 & PROOF—1004-6 FILE—0504-20

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	Coagulation	Analyzers	
Part 1 of 13	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org	bioMérieux Inc. Susan Tavlor susan tavlor@na.biomerieu
See accompanying article, page 20	1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de	1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de	100 Rodolphe St., Durham, NC 27712 919-620-2000 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
Country where analyzer designed/Manufactured Operational type	Germany/Germany batch, discrete	Germany/Germany discrete, batch	Germany/Germany random access
Reagent type Operates on whole blood or snun plasma	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)	open reagent system
Sample handling system	cuvette, semiautomated	cuvette ring (automated)	2 rotors (31 positions each)
Model type Dimensions (H x W x D)/Weight/Instrument footprint	benchtop 5 x 12 x 8.5 in/9.2 lbs/1 sq ft	benchtop 14 x 18 x 41 in/138.6 lbs/6 sq ft	benchtop 15.3 x 40.2 x 28.3 in/134.5 lbs/8 sq ft, 11
EDA_cleared clottinn-based tests	DT PTT fib any citrated plasma clot-based assay	any clot-based detection. PT. APTT. TT. PT-based	PT APTT TT fib. PT & APTT factors
	F1, F11, IIV., ally vivated plasma over susce avour	fibrinogen, Clauss fibrinogen, factor assays, protein C, protein S, LAC screen, LAC confirm, APCR-V	
FDA-cleared chromogenic tests FDA-cleared immunologic tests	none	none	AT III, hep. anthactor xa none
Other FDA-cleared tests	none	none	NONE PT miv ADTT miv Junus (dRVVT screen)
User-weinited for 510/k) plagrance			reptilase, proteins C & S (clotting), protei APCR, LMWH (antifactor Xa)
Tests in development but not yet submitted	none	none	none
Methodologies supported	clot detection, optical; turbodensitometry stir bar	clot detection, optical (tungsten, turbidimetric)	clotting, chromogenic assays; photo-opt
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	2 (PT, APTT) 1 (fib.)	30 30	10 40
No. of user-definable (open) channels	2	2 2	18
Factor assays require manual manipulation or dilutions	yes	Varies with test-reagent compination NO	no
No. of reag. containers onboard at one time/Tests per container Reagents refrigerated onboard	5 or more/ reag. mftr. dependent no	10/varies no	21 cooled, 16 for reagents, 5 for controls ves (18°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing Same capabilities when 3rd-party reag. used	yes yes	no yes	Consumables yes, reagents no yes
Max. time same lot No. of reag. can be used Walkaway canacity: No. of specimens/No. of tests	laboratory dependent	18 months 32/30	12–18 months 62/232
Min. sample vol. aspirated precisely at one time	manual pipetting	52/00 5 µL	5 µL
Standard specimen vol. required to full FT of FTT/Factor vill activity Disposables used/Price of each	50 µL, min. 50 µL/50 µL, min. 50 µL 500 microcuvette w/ mixers in trays/11.6¢ ea., bulk 11¢ ea.; 500 macrocuv. w/ mixers in trays/12¢ ea., bulk 10.6¢ ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3k tips bulk/3.9¢ ea.	50 μL, min. 50 μL/<30 μL, min. 30 μL sample cups, measurement cuvette rings/prices vary	60 µL/ 10 µL cuvette racks, probe cleaner, predilutior available upon request
Supports direct-from-track sampling Primary tube sampling supported/Pierces caps on primary tubes	no no/no	no yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	no yes/no
Sample bar-code reading capability Reagent bar-code reading capability	no	yes no	yes (2 internal bar-code scanners) no
Onboard test automatic inventory	no	yes	yes
Short sample detection	no	yes yes	yes no
Clot detection as preanalytical variable in plasma sample Auto, detection of adequate reag, for aspir, & anal.	10 no	no Ves	no ves
Herolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard Automatic rerun capability/Auto reflex testing capability	no no/no	yes yes/no	yes yes/yes
Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times	yes (3 sec)	yes (3 sec) yes (selectable on menus)	yes (PT: 9 sec, APTT: 15 sec)
User can set different han-standard:	, , , , , , , , , , , , , , , , , , ,		yes .
Reag. volumes/Sample volumes No. and sources of reag.	yes/yes ves	yes/yes ves	yes/yes yes
Incub. times/Reading times Autocalibration or autocalib, alert/Multipoint calibration supported	yes/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 PT, PTT	120 sec/user defined 240 sec/user defined	4 min/140 specimens 8 min/140 specimens	min/180 results<br <7 min/120–140 results
• Fibrinogen • Factor VIII activity assay	300 sec/user defined 200 sec/user defined	4 min/140 specimens varies/varies	<7 min/140–180 results <7 min/120–140 results
Time delay from ordering stat to aspir. of sample	none—all preanalytical	15 sec	<3 min
Auto. transfer of QC results to LIS Data management capability	no	no ves (incl. QC: L-J plots)	yes ves (incl. QC: L-J plots)
Interface supplied by instrument vendor	NO call technical sunnort for inquiry	n No	yes (additional cost)
Bidirectional interface capability	Call technical support for inquiry NO	n/a no	an community used Liss in North Among Yes
Results transferred to LIS as soon as test time complete LOINC codes transmitted with all results	yes no	no no	yes no
How labs get LOINC codes for reagent kits	n/a	n/a	n/a
(or robotic) specimen handling system	yes	10	no
Modem servicing Time required for maintenance by lab personnel	no daily: 30 sec; weekly: 30 sec; monthly: 5 min	no daily: 10 min; weekly: 10 min; monthly: 5 min; biweekly: 5 min	no daily: 5 min; weekly: 30 min; monthly: <
Onboard maintenance records Training provided with purchase Approx. No. of training hours needed per tech	no videotape; on-site training extra 2 h	yes varies per site varies	no 3 days at vendor offices 1–2 h/30 min or less for basic operation
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$900, special pricing avail. upon written request for quote additional 1-yr initial contract \$500 (optional)/1 yr,	\$25,000 various options available/1 yr	\$55,000 \$6,300/1 yr
	\$300 renewal		
Unique advantages (provided by vendors)	 smaller clinic; office, private, vet labs low acquisition & service cost, low maintenance refurbished units available at reduced prices able to handle turbid/colored samples 	 clot code electronic signatures available for each assay run, visualization, and printouts extensive menu of clotting positive displacement pipetting for low maintenance and kick available 	normalization of PT & APTT assays wi bioMérieux automated systems workhorse analyzer for med- to high- easy operation & simple software met training required

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Survey editor: Raymond D. Aller, MD

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Part 2 of 13	bioMérieux Inc. Susan Taylor susan taylor@na biomerieux com	bioMérieux Inc. Susan Taylor susan taylor@na biomerieux.com	bioMérieux Inc. Susan Taylor susan taylor@na biomerieu
	100 Rodolphe St., Durham, NC 27712	100 Rodolphe St., Durham, NC 27712	100 Rodolphe St., Durham, NC 27712
See accompanying article, page 20	919-620-2000 www.biomerieux-usa.com	919-620-2000 www.biomerieux-usa.com	919-620-2000 www.biomerieux-usa.com
Instrument name/first year sold	Coag-A-Mate MTX II/1999 (sold as MTX since 1997)	Coag-A-Mate XM/1989	MDA II/1999
No. of units installed in U.S./Outside U.S.	>500 worldwide	>2,000 worldwide	>400 worldwide
Country where analyzer designed/Manufactured	Germany & U.S./Germany	U.S./U.S.	U.S./U.S.
Operational type Reagent type	onen reagent system	onen reagent system	continuous random access 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 floor standing
Dimensions (H x W x D)/Weight/Instrument footprint	19.7 x 30.7 x 21.3 in/100 lbs/5 sq ft, 8 w/ PC	4.6 x 14.7 x 20 in/20 lbs/2 sq ft	58 x 75 x 31 in/840 lbs/18 sq ft w/PC
FDA-cleared clotting-based tests	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays	PT screening (moderate & low ISI), PT facto
FDA-cleared chromogenic tests	AT III hen antifactor Xa protein C	none	APTT screening, APTT factors, PT mix, APTT ben antifactor Xa, AT III, protein C, plasm
			alpha-2 antiplasmin, lupus (dRVVT screen
FDA-cleared immunologic tests	none (latex immunologic assay in development)	none (latex immunologic assay in development)	contirm.), APCR D-dimer (latex immunoassav)
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	alpha-2 antiplasmin, plasminogen, PT mix, APTT mix, LMWH (antifactor Xa)	none	clottable C & S, PNP, P & P (1 & 2), vWF, assays—user definable for clotting, chro
Tests submitted for 510(k) clearance	none	none	microlatex assays none
Tests in development but not yet submitted	quantitative D-dimer immunoassay	—	none
Methodologies supported	clotting, chromogenic assays; photo-optical	clotting assays; photo-optical	clotting; chromogenic; immunoassay; pl
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no 16
No. of different assays programmed and calibrated at one time	o 32	2 16	72
No. of user-definable (open) channels	up to 32	16	20
Of those defined, No. active simultaneously	8	2	16
Factor assays require manual manipulation or dilutions	10 16 cooled 12 room temp. total 28/25_200	yes 4/30_100	NO 30/25_400
Reagents refrigerated onboard	yes (15°C)	no	yes (8-15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing	no	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag, used Max, time same lot No, of reag, can be used	yes 12-18 months	yes 12-18 months	yes 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 useu/Price of each	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	no	yes (internal bar-code scanner)
Onboard test automatic inventory	Ves	no	ves
Measures No. of tests remaining	yes	no	yes
Short sample detection	no	no	yes
Ciot detection as preanalytical variable in plasma sample	no ves	no	no ves
Hemolysis/Turbidity detection-quantitation	no/no	no/no	ycə ves/ves (detects biliruhin, corrects for liv
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/Auto reflex testing capability	yes/no	no/no	no/no
Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times	yes (P1: 3 sec, APTT: 5 sec) yes	yes (P1: 7 sec, APTT: 20 sec) yes	yes (P1: default 3 sec, APTT: default 5 se yes (selectable on menus)
user can set different-than-standard: • Read, volumes/Sample volumes	ves/ves	ves/ves	ves/ves
• No. and sources of reag.	yes	yes	yes
Incub. times/Reading times	yes/yes	yes/yes	no/yes
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable	yes/yes no/no	yes/yes no/no	yes/yes yes/yes
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	2 min/90 results	2 min/200 results (manual)	12 min/180 results
• PT, PTT	5 min/60 results	5 min/50 PTT results (manual)	12 min/180 results
 runnogen Factor VIII activity assay 	2 min/75 results 5 min/60 results	z−3 mm/ 100 results (manual) 5 min/50 results (manual)	12 MIN/ 180 FESUITS 12 min/180 results
Time delay from ordering stat to aspir. of sample	30–60 sec	2 min	<1 min
Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS	30–60 sec yes	2 min no	<1 min yes

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	yes (authonia cost) all commonly used LISs in North America yes no n/a no	n/a no no no n/a no	all commonly used LISs in North America yes (broadcast download & host query) yes no n/a yes
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	daily: ~5 min; weekly: ~1 min; monthly: ~5 min	daily: none; weekly: ~5 min; monthly: none	daily: ~35 min; weekly: 45 min; monthly: 10 min
Onboard maintenance records	no	no	no
Training provided with purchase	3 days at vendor offices	1/2 day on site	3–5 days on site, 4 days at vendor offices
Approx. No. of training hours needed per tech	2–3 h	1–2 h	4–5 h
List price	\$49,995	\$5,198	\$92,295
Ann. svc. contract cost (24/7)/Warranty with purchase	\$7,300/1 yr	depot service (repair)/1 yr	\$12,600/1 yr
Unique advantages (provided by vendors)	 normalization of PT & APTT results between bioMérieux automated systems stat results within 2–5 min flexibility; MTX can support new assays easily through user-programmable method files internal bar-code reader for sample & test identification 	 simple to operate: clot detection starts automatically on addition of start reagent flexibility; test params. can be modified to accommodate various reagent systems 	 patented waveform analysis technology with flags for identifying abnormal waveforms (e.g. biphasic samples) sensitive quantitative D-dimer assay for use in diagnosis of VTE dyes in routine reagents for volume delivery check throughput remains the same regardless of test mix

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Part 3 of 13	Dade Behring Inc.	Dade Behring Inc.	Dade Behring Inc.
	Jackie Hauser jackie_hauser@dadebehring.com	Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Bd., Deerfield, II, 60015	Jackie Hauser jackie_hauser@dadebehring 1717 Deerfield Bd., Deerfield, II 60015
See accompanying article, page 20	847-267-5383	847-267-5383	847-267-5383
	www.dadebenring.com	www.dadebenring.com	www.dadebenring.com
Instrument name/first year sold	BFT II/U.S.: 1999	Sysmex CA-560/U.S.: 2003	Sysmex CA-1500/U.S.: 2000; worldwide: 1
No. of units installed in U.S./Outside U.S. Country where analyzer designed/Manufactured	—/— Germanv/Germanv	—/— Japan/Japan	—/— Japan/Japan
Operational type	batch	batch, continuous random access	continuous random access
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually), optimized for Dade Behring instruments	open reagent system (lyopn., reconst. man optimized for Dade Behring instruments
Operates on whole blood or spun plasma Sample handling system	spun plasma manual	spun plasma 10-tube position sample rack	spun plasma 10-tube position sample rack $ imes 5$
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	3.9 x 7.9 x 11.8 in/8.4 lbs/1.5 sq ft	19 x 21 x 18.5 in/99 lbs/9 sq ft	20 x 31.2 x 31.2 in/186 lbs/6.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib.	PT, APTT, fib., TT, factor assays, reptilase time,	dRVVT screen and confirm, factor V Leiden,
FDA-cleared chromogenic tests	none	AT III, protein C chromo., heparin	protein S activity, AT III, plasminogen, factor V
EDA-cleared immunologic tects	none	D-dimer	alpha-2 antiplasmin, protein C chromo., hepari
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use Tests submitted for 510(k) clearance	none	n/a none	n/a n/a
Tests in development but not yet submitted	none	n/a	_
Methodologies supported	turbodensitometric	clot detect., optical, turbidmetric; chromogen.; immunolog.	clot detection, optical, turbidmetric; chrom
Oper, must load sen, read, 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 No. of user-definable (open) channels	3 n/a	7 7	25 25
Of those defined, No. active simultaneously	1	5	15
Factor assays require manual manipulation or dilutions No. 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
Reagents refrigerated onboard Multiple reage configurations supported	no	yes (15°C)	yes (15°C)
Reag., consumables loaded without interrupting testing	yes	consumables yes, reagents no	yes some consumables yes, reagents no
Same capabilities when 3rd-party reag. used Max. time same lot No. of reag. can be used	yes 12 months	yes 12 months	yes 12 months
Walkaway capacity: No. of specimens/No. of tests	1/1	10/50	50/up to 1,000
Min. sample vol. aspirated precisely at one time Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 μL 50 μL	10 μL 50 μL/n/a	5 μL 50 μL/10 μL
Disposables used/Price of each	cuvettes, printer paper/price varies with volume	reaction tubes, CA clean I, thermal paper/price varies with volume	reaction tubes, sample plates, CA clean I & buffer, halogen lamp, closed container sam replacement poodles/arises ware with volu
Cumunte direct from treat compliant			ven (Cummer OCT namina)
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
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining Short sample detection	no no	yes ves	yes ves
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal. Hemolysis/Turbidity detection-quantitation	no no/no	yes no/ves	yes no/ves
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability Lag time during which hypercoagulable samples will not be detected	no/yes ves (PT: 5 sec. APTT: 15 sec)	no/no ves (PT: <7 sec. PTT: <15 sec)	yes/yes ves (PT: 7 sec. PTT: 15 sec)
Read time extended for prolonged clotting times	no	yes (selectable on menus)	yes (selectable on menus)
Vser can set different-than-standard: Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
No. and sources of reag. Inouh times/Reading times	yes vec/vec	yes waa waa	yes voo/voo
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes	-/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:	1 min/n/n merriel	7 min/64 vc subs	7 min/100
• PT alone • PT, PTT	n min/n/a manuai n/a manuai	/ mm/o4 results 8 min/43 results	7 min/120 results 8 min/80 results
Fibrinogen Eastar VIII activity accay	<1 min/n/a manual	7 min/54 results	8 min/120 results 8 min/n/c
Time delay from ordering stat to aspir. of sample	n/a	2 min	2 min
Auto. transfer of QC results to LIS	no	yes onhoard (incl. Oc. L. Lalota)	yes anhaard (incl. Act. I. I. I. I. alata & Waatward)
Interface supplied by instrument vendor	n/a	no No	onovaru (inci. qu: L-J piots & Westgard) No
Interfaces in active user sites for: Ridirectional interface canability	n/a no	Cerner, Misys (formerly Sunquest), others	Cerner, Misys (formerly Sunquest), others
Results transferred to LIS as soon as test time complete	no	yes (nost quely) Yes	yes (nost query) Yes
LOINC codes transmitted with all results	no 	no	no n/a
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	yes (Sysmex CST series)
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 1 min	daily: <5 min	daily: <5 min; weekly: <40 min; monthly: 1
Unboard maintenance records Training provided with purchase	no video	no 2 days on site	no varies on site. 4 davs at vendor offices plus
Annrox. No. of training hours needed per tech	2 h	2 h	directed online class
	\$7.910	\$43 390	\$88,830 standard model: \$100,700 con riser
Ann. svc. contract cost (24/7)/Warranty with purchase	depot service (repair)/1 yr	\$4,500 (business hours)/—	\$9,750 standard model; \$10,950 cap-pierci
Unique advantages (provided by vendors)	 2-channel micro reagent volume clot-based technology opto-mechanical detection accurate on lipemic, icteric samples automatic INR calculation, curve storage, built-in 	 5-parameter true random access clotting/chromogenic small footprint, complete automation, specialty assay capability 	 simultaneous curve calibrating & patient ability to load multiple bottles or multiple reagent

Coaquilation Analyzers

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RUM	Coagulation	Analyzers	
Part 4 of 13 See accompanying article, page 20	Dade Behring Inc. Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015	Dade Behring Inc. Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us 5 Century Dr., Parsippany, NJ 07054
Instrument name/first year cold	847-267-5383 www.dadebehring.com	847-267-5383 www.dadebehring.com	800-222-COAG www.stago-us.com
No. of units installed in U.S. /Outside U.S.		Systillex CA-7000/2002	
Country where analyzer designed/Manufactured Operational type Reagent type	Germany/Germany batch, continuous random access open reagent system (reconst. manually), optimized for Dade Behring instruments	Japan/Japan continuous random access open reagent system	France/France continuous random access open reagent system (lyoph., reconst. manua
Operates on whole blood or spun plasma Sample handling system Model type	spun plasma rack benchtop	spun plasma rack benchtop	spun plasma 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 47.6 x 32.2 in/441 lbs/26.8 sq ft
FDA-cleared clotting-based tests FDA-cleared chromogenic tests	PT, APTT, fib., TT, factor assays, reptilase time, dRVVT screen & confirm., factor V Leiden, protein C clotting AT III, alpha-2 antiplasmin, plasminogen, protein C chromo., heparin, protein S activity, factor VIII	factor V Leiden assay, PT, APTT, fib., factor assays, protein C clotting, TT, lupus, dRVVT, batroxobin protein S activity, heparin AT III, factor VIII chromogenic, plasminogen, alpha-2 antiplasmin, protein C chromogenic	PT, APTT, TT, fib., reptilase, intr. & extr. facto C & S, lupus anticoag. screen & confirm. unfrac. hep., LMWH, protein C, AT III, plasmino antiplasmin
FDA-cleared immunologic tests Other FDA-cleared tests	advanced D-dimer BC von Willebrand-risto. cofactor assay (agglut. of fixed Plts.)	D-dimer n/a ·	D-dimer, vWF, protein S ant. & AT III ant. (micro none
User-defined tests in clinical use Tests submitted for 510(k) clearance	n/a	n/a n/a	all clotting-based, chrom., & immunol. tests car def. applications in addition to dRVVT screen & assays & activated protein C resistance none
Tests in development but not yet submitted	n/a	_	none
Methodologies supported Oper. must load sep. reag. pack for ea. specimen/Test run No. of different measured assays onboard simultaneously	clot detect.: optical; xenon flasher lamp; chromogen.; immunol. no/no 28 tests/samples	clot detection, optical, turbidimetric; chromogenic; immunol. no/no 20	clotting, chromogenic, & immunologic assays no/no up to 200
No. of different assays programmed and calibrated at one time No. of user-definable (open) channels	99 8,999 (Nos. 1–1,000 are factory set & unalterable)	40 40	up to 200 200
Of those defined, No. active simultaneously	>100	20	200
No. of reag. containers onboard at one time/Tests per container	86/—	58/varies up to 200	70/up to 83
Reagents refrigerated onboard Multiple reag. configurations supported	yes (<15°C) yes	yes (15 C) yes	yes (15–19°C) yes
Reag., consumables loaded without interrupting testing Same capabilities when 3rd-party reag. used	yes ves	yes ves	yes ves
Max. time same lot No. of reag. can be used	12 months	12 months 100/550 per heur DT and ADTT 200 per heur DT	18 months 215 /22 new operations
Min. sample vol. aspirated precisely at one time	5 μL	5 μL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity Disposables used/Price of each	50 µL, min. 100 µL (incl. dead vols.)/50 µL, min. 100 µL cuvette rotors, washing solution, terralin disinfectant, BC validation kit/price varies with volume	50 µL/10 µL reaction tubes, CA clean I & II, system buffer, halogen lamp, closed container sample replacement needles/prices vary with volume	50 µL, min. 50 µL/50 µL, min. 50 µL cuvettes, wash-cleaner solution/—
Supports direct-from-track sampling Primary tube sampling supported/Pierces caps on primary tubes	no ves (all up to 100 mm long, ext, diam, 10–16 mm)/no	yes (custom automation solutions available) ves (3–5 mL)/ves	yes ves/optional
Sample bar-code reading capability	yes	yes	yes vac /not for usor_dafinad tasts)
Onboard test automatic inventory	yes (avail. for user-defined tests)	yes	yes
Measures No. of tests remaining Short sample detection	yes ves	yes ves	yes ves
Clot detection as preanalytical variable in plasma sample	no	no	no
Hemolysis/Turbidity detection-quantitation	yes yes/yes	no/yes	no/no
Dilution of patient samples onboard Automatic rerun capability/Auto reflex testing capability	yes ves/ves	yes ves/ves	yes ves/ves
Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times User can set different-than-standard:	yes (PT & PTT: 7 sec) no	yes (PT: 7 sec, PTT: 15 sec) yes (selectable on menus)	no yes (selectable on menus)
Reag. volumes/Sample volumes No. and sources of reag.	yes/yes ves	yes/yes ves	yes/yes ves
Incub. times/Reading times	yes/no	yes/yes	yes/yes
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable	yes/yes no/no	no/yes no/no	yes/yes no/no (not needed)
Stat time to completion of all analytes/Throughput per hour for: • PT alone	-5 min/- 315 results (incl. abnormala)	7 min/280 results	<6 min/300 energiments
• PT, PTT	<5 min/~285 results (incl. abnormals)	8 min/480 results	7 min/150 specimens
Factor VIII activity assay	<5 mm (n curve avan.)/~315 results <5 min (if curve avail.)/~280 results	o mm/200 results 8 min/300 results	7 min/180 specimens 7 min/180 specimens
Time delay from ordering stat to aspir. of sample Auto. transfer of OC results to LIS	varies by test in progress, approx. <5 min ves	2 min ves	<15 sec ves
Data management capability	limited	onboard (incl. QC: L-J plots & Westgard)	onboard (incl. QC: L-J plots)
Interfaces supplied by instrument vendor Interfaces in active user sites for: Bidirectional interface capability Results transferred to LIS a scorp as test time complete	no Cerner, Misys (formerly Sunquest), Meditech, others yes (host query) yes	Cerner, others in development yes (host query) ves	no contact marketing for updated list yes (host query)
LOINC codes transmitted with all results	NO 10	no	no no
How labs get LOINC codes for reagent kits Electronic interface available (or will be) to automated (or robotic) specimen handling system	n/a possible future upgrade (not available)	n/a custom automated connectivity with Stream Lab in development	n/a yes (contact marketing for list of systems)
Modem servicing Time required for maintenance by lab personnel Onboard maintenance records	yes daily: <5 min; weekly: <10 min; monthly: 15 min no	no per shift: <5 min; daily: <10 min; weekly: 1 min; quarterly: 5 min no	yes daily: none; weekly: <30 min; monthly: <30 m ves
Training provided with purchase	varies on site, 5 days at vendor offices for 2 operators (regular and advanced)	varies on site, 5 days at vendor offices for 2 operators	varies on site, 3 days at vendor offices
Approx. No. of training hours needed per tech	8 h on site	8 h on site	2 h basic, 24 h system training at training cer
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$136,200 \$16,450/1 yr	\$179,000 \$16,450/1 yr	\$149,995 prices available on request/1 yr
Unique advantages (provided by vendors)	 cont. loading of bar-coded reagent & samples multilot, multicurve reagent management PT/APTT/fib./AT III/D-dimer in <10 min simultaneous curve collibration & national texture 	fastest throughput available for routine testing; PT, APTT results every 7 sec continuous loading of reagents, consumables, & patient complex without intervention	walkaway testing with robotics-capable in automated lines for high-volume testing, with touch-screen software & cap piercing option



Coagulation Analyzers

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	Soagulation An	alyzers	4
Part 5 of 13	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-C0AG	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us.com 5 Century Dr., Parsippany, NJ 07054 800-222-COAG
see accompanying arucie, page 20	www.stago-us.com	www.stago-us.com	www.stago-us.com
nstrument name/first year sold	STA Compact Hemostasis System/1996	Start 4/1998	STA Compact CT/2001
No. of units installed in U.S./Outside U.S. Country where analyzer designed/Manufactured Operational type Reagent type Operates on whole blood or spun plasma Sample handling system	—/— France/France continuous random access open reagent system (lyoph., reconst. manually) spun plasma continuous specimen access-primary tube banebten	—/— France/France batch open reagent system (lyoph., reconst. manually) spun plasma manual banchtan	—/— France/France continuous random access open reagent system (lyoph., reconst. manually) spun plasma continuous specimen access—primary tube banchton
Dimensions (H x W x D)/Weight/Instrument footprint	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	25.2 x 38.8 x 25.8 in/351 lbs/25.6 sq ft
DA-cleared clotting-based tests DA-cleared chromogenic tests DA-cleared immunologic tests Other FDA-cleared tests Iser-defined tests in clinical use	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm. unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin D-dimer, vWF antigen, protein S antigen & AT III antigen (microlatex agglut.) none all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVVT screen & confirm assay & activated protein C resistance	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm. none none same as clotting-based tests above & dRVVT screen & confirm assays & activated protein C resistance	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm n/a n/a none all clotting-based tests can have user-def. applications, dRWT screen & confirm. assays & activated protein C resistance
Tests submitted for 510(k) clearance Tests in development but not vet submitted	none	none	none
Nethodologies supported Dper. must load sep. reag, pack for ea. specimen/Test run	clotting, chromogenic, & immunologic assays	clotting tests no/no	clot detection, mechanical no/no
NO. OT different measured assays onboard simultaneously No. of different assays programmed and calibrated at one time	up to 80 up to 80	20	up to 80 up to 80 To
10. of user-definable (open) channels)f those defined, No. active simultaneously	70 70	4 1	70 70
actor assays require manual manipulation or dilutions o. of reag. containers onboard at one time/Tests per container	no 45/varies, up to 83	yes 4/varies, up to 100	no 45/varies, up to 83
eagents refrigerated onboard Iultiple reag. configurations supported	yes (15–19°C) ves	no Ves	yes (15–19°C) ves
eag., consumables loaded without interrupting testing ame canabilities when 3rd-narty reag. used	yes ves	no ves	yes ves
ax. time same lot No. of reag. can be used	18 months	18 months	18 months
alkaway capacity: No. of specimens/No. of tests in. sample vol. aspirated precisely at one time	96/12 per sample 5 µL	4/1 25 μL	96/12 per specimen 5 µL
andard specimen vol. required to run PT or PTT/Factor VIII activity sposables used/Price of each	50 µL, min. 50 µL/50 µL, min. 50 µL cuvettes, wash-cleaner solution/—	50 μL, min. 50 μL/50 μL, min. 50 μL cuvettes, beads, ball/—	50 μL, min. 50 μL/5 μL, min. 5 μL cuvettes, wash-cleaner solution/—
upports direct-from-track sampling	no	no	no
rimary tube sampling supported/Pierces caps on primary tubes ample bar-code reading capability	yes (5 & 2.5 mL tube sizes)/optional yes	no/no (n/a) no	yes (5 x 2.5 mL)/yes (optional) yes
agent bar-code reading capability	yes (not for user-defined tests)	no no	yes (not for user-defined tests)
assures No. of tests remaining	yes	no	yes yes
ort sample detection ot detection as preanalytic variable in plasma sample	yes no	no no	yes no
ito. detection of adequate reag. for aspir. & anal.	yes no/no	no no/no	yes no/no
anorysis/ rurbiany detection-quantitation lution of patient samples onboard	iiu/no yes	no/no No	no/no yes
no time during which hypercogniable samples will not be detected	yes/no no	no/no	yes/no no
ead time extended for prolonged clotting times ead states as the definition of the standard:	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
Incub. times/Reading times	yes/yes	yes/yes	yes/yes
utocalibration or autocalib. alert/Multipoint calibration supported uto shutdown/Auto startup programmable	yes/yes no/no (not needed)	no/yes no	yes/yes no/not needed
at time to completion of all analytes/Throughput per hour for:			
PT alone PT, PTT	<6 min/150 specimens 7 min/75 specimens	<1 min/up to 120 specimens n/a/n/a	<6 min/150 specimens 7 min/75 specimens
Fibrinogen Factor VIII activity assay	7 min/75 specimens 7 min/70 specimens	<1 min/up to 120 specimens varies/varies	7 min/75 specimens 7 min/70 specimens
me delay from ordering stat to aspir. of sample	<15 sec	n/a	<15 sec
ito. transfer of QC results to LIS ata management capability	yes onboard (incl. QC: L-J plots)	no no	yes onboard (incl. QC: L-J plots)
terface supplied by instrument vendor	no no	no	no
ienaces in active user sites for: directional interface capability	contact marketing for updated list yes (host query)	iva No	contact marketing for updated list yes (host query)
esults transferred to LIS as soon as test time complete	yes no	yes no	yes no
w labs get LOINC codes for reagent kits	n/a	n/a	n/a
ectronic interface available (or will be) to automated (or robotic) specimen handling system	no	по	по
odem servicing	NO daily nono weakly 20 min months. 00 min	NO doibe of minumative of minumative of min	NO wookly 20 min menthly 20 min
nboard maintenance records	uany: none; weekiy: <30 min; monthly: <30 min yes	uany: <ə min; weekiy: <ə min; montniy: <5 min no	weekiy: <30 min; montniy: <30 min yes
raining provided with purchase pprox. No. of training hrs needed per tech	varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center	1 day on site 1 h	varies on site, 3 days at vendor office 2 h basic, 24 h system training at training ctr.
ist price .nn. svc. contract cost (24/7)/Warranty with purchase	\$75,000 prices available on request/1 yr	\$9,600 prices available on request/1 yr	\$50,000 prices available on request/1 yr
Jnique advantages (provided by vendors)	 walkaway testing for routine & specialty hemostasis assays with 45 reag. positions, 96 sample pos., up to 1,000 disposable cuvettes continuous random access for up to 80 test selections with no carryover able to standardize with other STA analyzers viscosity-based detection system 	 excellent for low-volume testing or as backup to optical system programmable and preprogrammed assays with curve storage, 4 independently timed incubation stations, electronically linked multiple pipettor, 40-character display and internal thermal printer lightweight and compact 	 walkaway testing for routine hemostasis assays viscosity-based detection system able to standardize with other STA analyzers

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	Goagunaition A	INAIIYZEI'S	
Part 6 of 13	Fisher Diagnostics	Fisher Diagnostics	Fisher Diagnostics
	Paul Gee paul.gee@fishersci.com	Paul Gee paul.gee@fishersci.com	Paul Gee paul.gee@fishersci.com
	8365 Valley Pike, Middletown, VA 22645 540-869-8224	8365 Valley Pike, Middletown, VA 22645 540-860-8224	8365 Valley Pike, Middletown, VA 22645 540-869-8224
See accompanying article, page 20	www.fisherdiagnostics.com	www.fisherdiagnostics.com	www.fisherdiagnostics.com
Instrument name/first year sold	ThromboScreen 200/1994	ThromboScreen 400/1996	ThromboScreen 1000/2003
No. of units installed in U.S./Outside U.S.	>50/>300	15/>150	>40/10
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
operational type Reagent type	valch, uiscrete open reagent system (reconst manually)	valch, discrete open reagent system (reconst-manually)	valon, random access 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 Dimonsions (H x W x D) (Weight/Instrument factoriet	benchtop 4 x 8 x 12 in/5 lbo/1 og ft	benchtop 5 x 12 x 12 in/10 lbs/1 og #	benchtop 28 x 22 x 19 in/25 lbs/2 on #
איז	4 X O X 12 III/J IU5/1 SY IL	5 x 12 x 12 m/ 10 m/s/ 1 sq tt	20 x 22 x 10 111/30 105/3 SQ TC
FDA-cleared clotting-based tests	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance, proteins C&S	PT, APTT, fibrinogen
FDA-cleared chromogenic tests	none	AT III, heparin	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	n/a	n/a	n/a
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	thrombin time
Methodologies supported	clot detection, optical	clot detection, optical, chromogenic	optical turbodensitometry
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	2	2	3
No. of user-definable (open) channels	n/a	n/a	3
Of those defined, No. active simultaneously	1	1	3
Factor assays require manual manipulation or dilutions	yes	yes	n/a
No. of reag. containers onboard at one time/Tests per container	3/varies	3/varies	6/varies
Reagents retrigerated onboard Multiple read, configurations supported	no ves	NU Ves	NO Ves
Reag., consumables loaded without interrupting testing	ves	ves	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used	18–24 months	18–24 months	18–24 months
Walkaway capacity: No. of specimens/No. of tests	n/a/n/a	n/a/n/a	18/3
Min. sample vol. aspirated precisely at one time Standard specimon vol. required to run PT or PTT/Factor VIII activity	25 μL 50 μL min 50 μl /	50 µL 50 ul. min 50 ul./	10 µL 50 ul. min 50 ul./
Disposables used/Price of each	cuvettes & pipette tips/prices vary	cuvettes & pipette tips/prices vary	cuvette bars/prices vary
Supports direct-from-track sampling Primary tube sampling supported/Pierces cans on primary tubes	no no/no	no no/no	no ves/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. or rests remaining	10	nu no	10
Clot detection as preanalytical variable in plasma sample	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	110/110 no	110/NO no	110/110 Ves (PT: 7 sec: PTT: 1/ sec)
Read time extended for prolonged clotting times	ves (selectable on menus)	Ves	ves (selectable on menus)
User can set different-than-standard:	, ()		,,
Reag. volumes/Sample volumes	yes/yes	yes/yes	yes/yes
No. and sources of reag.	yes	yes	yes
Incub. times/Reading times Autopolitration or outpoolit, plant/Multimeint collibution to a second a se	yes/yes	yes/yes	yes/yes
Autocanitration or autocanit, are criminipoint canoration supported Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:			
• PT alone	<1 min/120 specimens	<1 min/120 specimens	<5 min/100 specimens
• PT, PTT	varies	varies	<5 min/50 specimens
• Fibrinogen	<1 min/120 specimens	<1 min/120 specimens	<5 min/80 specimens
Eactor VIII activity accay	n/a	n/a	n/a
Time delay from ordering stat to conir of commis	n/a	n/o	-2 min

I lime delay from ordering stat to aspir. Of sample	n/a	n/a	<3 min
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	no	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	-	n/a	n/a
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	no	no	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	n/a	n/a	n/a
Electronic interface available (or will be) to automated	no	no	no
(or robotic) specimen handling system			
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 5 min: weekly: 5 min: monthly: 5 min	daily: 5 min: weekly: 5 min: monthly: 5 min	daily: 5 min: weekly: 15 min: monthly: 15 min
Anhoard maintenance records	no	no	
Training provided with nurchase	1 day on site	1 day on site	A h on site
Training provided with purchase	1 day on site	1 day on site	4 h on site 4 h
Training provided with purchase Approx. No. of training hours needed per tech	1 day on site 1 h	1 day on site 1 h	4 h on site 4 h
Training provided with purchase Approx. No. of training hours needed per tech List price	1 day on site 1 h \$3.800	1 day on site 1 h \$6,100	4 h on site 4 h \$18.000
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase	1 day on site 1 h \$3,800 varies/1 yr	1 day on site 1 h \$6,100 varies/1 yr	4 h on site 4 h \$18,000 varies/1 yr
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase	1 day on site 1 h \$3,800 varies/1 yr	1 day on site 1 h \$6,100 varies/1 yr	4 h on site 4 h \$18,000 varies/1 yr
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase Unique advantages (provided by vendors)	1 day on site 1 h \$3,800 varies/1 yr • low volume or backup • small footnrint_fits anywhere	1 day on site 1 h \$6,100 varies/1 yr • small footprint—fits anywhere • chromogenic assay canability	4 h on site 4 h \$18,000 varies/1 yr • fibrinogen curve provided for reagents used on instrument
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase Unique advantages (provided by vendors)	1 day on site 1 h \$3,800 varies/1 yr • low volume or backup • small footprint—fits anywhere • simple to operate	1 day on site 1 h \$6,100 varies/1 yr • small footprint—fits anywhere • chromogenic assay capability • performs kinetic & endpoint determination	4 h on site 4 h \$18,000 varies/1 yr • fibrinogen curve provided for reagents used on instrument • low cost fully automated analyzer for routine
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase Unique advantages (provided by vendors)	1 day on site 1 h \$3,800 varies/1 yr • low volume or backup • small footprint—fits anywhere • simple to operate	1 day on site 1 h \$6,100 varies/1 yr • small footprint—fits anywhere • chromogenic assay capability • performs kinetic & endpoint determination	4 h on site 4 h \$18,000 varies/1 yr • fibrinogen curve provided for reagents used on instrument • low cost, fully automated analyzer for routine caaquilation tests
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase Unique advantages (provided by vendors)	1 day on site 1 h \$3,800 varies/1 yr • low volume or backup • small footprint—fits anywhere • simple to operate	1 day on site 1 h \$6,100 varies/1 yr • small footprint—fits anywhere • chromogenic assay capability • performs kinetic & endpoint determination	4 h on site 4 h \$18,000 varies/1 yr • fibrinogen curve provided for reagents used on instrument • low cost, fully automated analyzer for routine coagulation tests • simple to operate
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase Unique advantages (provided by vendors)	1 day on site 1 h \$3,800 varies/1 yr • low volume or backup • small footprint—fits anywhere • simple to operate	1 day on site 1 h \$6,100 varies/1 yr • small footprint—fits anywhere • chromogenic assay capability • performs kinetic & endpoint determination	4 h on site 4 h \$18,000 varies/1 yr • fibrinogen curve provided for reagents used on instrument • low cost, fully automated analyzer for routine coagulation tests • simple to operate
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase Unique advantages (provided by vendors)	1 day on site 1 h \$3,800 varies/1 yr • low volume or backup • small footprint—fits anywhere • simple to operate	1 day on site 1 h \$6,100 varies/1 yr • small footprint—fits anywhere • chromogenic assay capability • performs kinetic & endpoint determination	4 h on site 4 h \$18,000 varies/1 yr • fibrinogen curve provided for reagents used on instrument • low cost, fully automated analyzer for routine coagulation tests • simple to operate
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24/7)/Warranty with purchase Unique advantages (provided by vendors)	1 day on site 1 h \$3,800 varies/1 yr • low volume or backup • small footprint—fits anywhere • simple to operate	1 day on site 1 h \$6,100 varies/1 yr • small footprint—fits anywhere • chromogenic assay capability • performs kinetic & endpoint determination	4 h on site 4 h \$18,000 varies/1 yr • fibrinogen curve provided for reagents used on instrument • low cost, fully automated analyzer for routine coagulation tests • simple to operate

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Coagulation Analyzers

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Part 7 of 13	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704
See accompanying article, page 20	800-231-3003 www.helena.com	800-231-3003 www.helena.com	800-231-3003 www.helena.com
Instrument name/first year sold	Cascade M/1991	Cascade M-4/1992	Packs-4/1991
No. of units installed in U.S./Outside U.S. Country where analyzer designed/Manufactured	>150/— U.S./U.S.	>100/— U.S./U.S.	150/180 U.S./U.S.
Operational type Reagant type	batch	random access	random access
Derates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual	manual
lodel type Dimensions (H x W x D)/Weight/Instrument footprint	benchtop 8 x 15 x 13 in/25 lbs/1.4 sq ft	benchtop 8 x 15 x 13 in/25 lbs/1.4 sq ft	benchtop 10 x 22 x 23 in/70 lbs/3.5 sq ft
DA-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	AT III, F-VIII:C, heparin, plasminogen, protein C
Other FDA-cleared tests	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	chrom: AT III, F-VIII:C, hep., plasmin., protein C, ristocetin cofactor, platelet aggreg.–ADP, EPI, COL, 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	chromogenic, ristocetin cofactor, platelet aggreg.
Dper. must load sep. read. pack for ea. specimen/Test run	no/no	no/no	no/no
Io. of different measured assays onboard simultaneously	1	4	4
lo. of different assays programmed and calibrated at one time	1	4	4
f those defined, No. active simultaneously	1	2	4
actor assays require manual manipulation or dilutions	yes	yes	yes
o. of reag. containers onboard at one time/Tests per container eagents refrigerated onboard	—/— n/a	U/n/a no	n/a/n/a no
ultiple reag. configurations supported	n/a	no	no
eag., consumables loaded without interrupting testing	no vec	no	no n/a
lax. time same lot No. of reag. can be used	12 months	12 months	12 months
Valkaway capacity: No. of specimens/No. of tests	no monuel 50 ul	NO monuel 50 ul	no
Standard specimen vol. required to run PT or PTT/Factor VIII activity	100 μL, min. 50 μL/100 μL (dil.), min. 50 μL (dil.)	100 μL, min. 50 μL/100 μL (dil.), min. 50 μL (dil.)	chromogenics: 75 µL, Plt. aggreg.: 225 µL PRP, Risto
Disposables used/Price of each	cuvettes/500@\$54; pipette tips/1,000@\$82	cuvettes/500@\$54; pipette tips/1,000@\$82	cofactor: 50 µL cuvettes/200@\$55.65; pipette tips/1,000@\$82; stir bars/30@\$62.25
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no	no	no
eagent bar-code reading capability	no	no	no
nboard test automatic inventory	no	no	no
leasures No. of tests remaining hort sample detection	no no	no	no
lot detection as preanalytical variable in plasma sample	<u> </u>	<u> </u>	
uto. detection of adequate reag. for aspir. & anal.	no no/no	no no/no	no no/no
ilution of patient samples onboard	no	no/no	no
utomatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
ag ume auring which hypercoagulable samples will not be detected ead time extended for prolonged clotting times	yes (r1: 4 sec, r11: 14 sec) yes (selectable on menus)	yes (r1: 4 sec, r11: 14 sec) yes (selectable on menus)	n/a
ser can set different-than-standard:			
reag. volumes/sample volumes No. and sources of reag.	yes/yes ves	yes/yes ves	yes/yes ves
Incub. times/Reading times	yes/yes	yes/yes	yes/yes
utocalibration or autocalib. alert/Multipoint calibration supported uto shutdown/Auto startup programmable	no/yes no/no	no/yes no/no	no/yes no/no
tat time to completion of all analytics/Threuchaut new hour for			
PT alone	3 min/120 specimens	3 min/140 specimens	_
PT, PTT Fibringgon	7 min/50 specimens	7 min/80 specimens	_
Factor VIII activity assay	7 min/50 specimens	7 min/80 specimens	
me delay from ordering stat to aspir. of sample	n/a	n/a	n/a
uto. transfer of QC results to LIS ata management capability	no no (incl. QC: L-J plots)	yes no (incl. QC: L-J plots)	yes onboard (incl. OC: L-J plots. Westpard)
terface supplied by instrument vendor	no	no	no
terfaces in active user sites for: directional interface canability	n/a no	<u>—</u>	 po
esults transferred to LIS as soon as test time complete	no	yes	yes
DINC codes transmitted with all results	no	no	no
ectronic interface available (or will be) to automated	_	no	no
(or robotic) specimen handling system			
lodem servicing	NO daily: 10 min: weekly: 10 min: monthly: 20 min	NO daily: 10 min: weekly: 10 min: monthly: 20 min	
nboard maintenance records	no	no	yes
raining provided with purchase pprox. 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 \$714/1 yr	\$8,403 \$966/1 vr	\$16,650 \$2.079/1 vr
Unique advantages (provided by vendors)	• OC program onboard	• 4-channel manual analyzer	• specialized coao instrument intended for nlatelet
יייקבי אשראוואפטט (אוסדוגטע אין דטוועטוט)	curve storage suitable for office lab or as backup analyzer	• QC program onboard • singles or duplicates	aggreg., ristocetin cofactor, & chromogenics

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RUNI	Coagulation A	nalyzers	
Part 8 of 13	Instrumentation Laboratory/Beckman Coulter Inc. Steven Edwards sjedwards@beckman.com	Instrumentation Laboratory/Beckman Coulter Inc. Steven Edwards sjedwards@beckman.com	Instrumentation Laboratory/Beckman Steven Edwards sjedwards@beckman
See accompanying article, page 20	200 S. Kraemer Bivd., Brea, GA 92822 714-961-4556 www.beckmancoulter.com	200 S. Kraemer Bivd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	200 S. Kraemer Bivd., Brea, CA 92822 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	4,000+ (all models combined)/8,000+ (all models	4,000+ (all models combined)/8,000+
Country where analyzer designed/Manufactured	combined) Italy/U.S.	combined) Italy/U.S.	combined) Italy/U.S.
Operational type Reagent type	batch open reagent system, guarantee only II, products	batch onen reagent system, guarantee only II, products	random programming
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample nandling system Model type	tray benchtop	tray benchtop	tray benchtop
Dimensions (H x W x D)/Weight/Instrument footprint	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR, Clauss fib.	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.	PT, APTT, fib. (PT-based), factor assay intrinsic), proteins C & S (clottable), T anticoag., APCR-V, Clauss fib. antithrombin benarin Ya plasminone
			protein C
	none	lione	D-aimer (latex enhanced immunoassa
Uther FDA-cleared tests User-defined tests in clinical use	none	none none	none
Tests submitted for 510(k) clearance Tests in development but not vet submitted	none	none —	none —
Mathadalagias supported	olat dataction ontical nonholomatric	olat dataction antical nonholomatric	olat datastian antical nonholomatric
		ciot detection, optical, nepiteionieuto	immunologic (optical, latex enhanced
Oper. must load sep. reag. pack for ea. specimen/lest run No. of different measured assays onboard simultaneously	no/no 3	no/no 3	no/no 4
No. of different assays programmed and calibrated at one time No. of user-definable (open) channels	1 0	1 0	1 10 (requires optional research packad
Of those defined, No. active simultaneously	0	0	1
No. of reag. containers onboard at one time/Tests per container	yes 3/varies by test	yes 3/varies by test	no 3/varies by test
Reagents refrigerated onboard Multiple read, configurations supported	yes (15℃) ves	yes (15°C) ves	yes (15°C) ves
Reag., consumables loaded without interrupting testing	no	no	no
Same capabilities when 3rd-party reag. used Max. time same lot No. of reag. can be used	yes 18 months	yes 18 months	yes 18 months
Walkaway capacity: No. of specimens/No. of tests Min. sample vol. aspirated precisely at one time	18/36 10 uL	18/36 10 uL	18/36 10 uL
Standard specimen vol. required to run PT or PTT/Factor VIII activity Disposables used/Price of each	50 μL (PT), 53 μL (PTT)/40 μL sample cups/price varies; rotors/price varies	50 μL (PT), 53 μL (PTT)/40 μL rotors/price varies	50 µL (PT), 53 µL (PTT)/40 µL rotors/price varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes Sample bar-code reading capability	no/no no	yes (13 x 75 mm)/no ves (optional)	yes (13 x 75 mm)/no ves
Reagent bar-code reading capability	no	no	no
Measures No. of tests remaining	no	no	no
Short sample detection Clot detection as preanalytical variable in plasma sample	yes no	yes no	yes no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
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	no/no ves (PT & PTT: 5.6 std. 6.7 ext)	no/no ves (PT & PTT: 5.6 std. 6.7 ext)	no/no ves (PT & PTT: 5.6 std. 6.7 ext)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
• 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/no	no/yes no/no	no/yes no/no
 Tailone PT alone 	5.5 min/110 specimens	5.5 min/110 specimens	5.5 min/175 specimens
• PT, PTT • Fibrinoaen	8.5 min/80 specimens 5.5 min/110 specimens	8.5 min/80 specimens 5.5 min/110 specimens	8.5 min/110 specimens 5.5 min/175 specimens
Factor VIII activity assay Time delay from exclusion at the service of exclusion	9.5 min/80 specimens	9.5 min/80 specimens	9.5 min/110 specimens
Auto. transfer of QC results to LIS	10 Sec NO	10 Sec No	id sec yes
Data management capability Interface supplied by instrument vendor	no no	no no	onboard (incl. QC: L-J plots) no
Interfaces in active user sites for:	most major LIS vendors	most major LIS vendors	most major LIS vendors
Results transferred to LIS as soon as test time complete	yes	yes	yes (nost query) yes
LOINC codes transmitted with all results How labs get LOINC codes for reagent kits	no in development	no in development	no in development
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; monthl
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 	part of ACL family, uses same consumables/reagents quantitative PT-based fib. nositive displacement pinetting for low	part of ACL family, uses same consumables/reagents quantitative PT-based fib. positive displacement pipetting for

Coagulation Analyzers

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7	Coagulation /	Analyzers	
Part 9 of 13	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckma
See accompanying article, page 20	Steven Edwards sjedwards@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Steven Edwards sjedwards@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com	Steven Edwards sjedwards@beckmar 200 S. Kraemer Blvd., Brea, CA 9282 714-961-4556 www.beckmancoulte
Instrument name/first year sold	ACL 9000/2000	ACL Advance/2000	ACL 8000/2003
No. of units installed in U.S./Outside U.S.	300+/600+ U.S./U.S	500+/1,000+ U.S./U.S	—/— !!\$/!!\$
Operational type	random access	random access	batch
Reagent type Operates on whole blood or spun plasma	open reagent system snun niasma	open reagent system, guarantee only IL products soun plasma	open reagent system (reconst. manu spun plasma
Sample handling system	tray	racks, up to 12	tray
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 32.2 x 41 x 24.8 in/185 lbs/15 sq ft	benchtop 23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq f
FDA-cleared clotting-based tests	PT, APTT, PT-based fib., Clauss fib., TT, factor assays,	PT, APTT, PT-based fib., Clauss fib., TT, factor	PT, APTT, TT, PT-based fib., Clauss fit
	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
FDA-cleared chromogenic tests	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin, factor VIII	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin	antithrombin, liquid antithrombin, fa heparin, plasmin inhibitor, plasmino
FDA-cleared immunologic tests	D-dimer (latex enhanced immunoassay), vWF (latex enhanced immunoassay), free protein S	D-dimer (latex enhanced immunoassay), vWF, free protein S	D-dimer (latex-enhanced immunoas (latex- enhanced immunoassay), fre (latex turbidimetric ligand immunoa
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use Tests submitted for 510(k) clearance	none none	none none	none —
Tests in development but not yet submitted	-	-	silica clotting time, global protein C pa homocyst.
Methodologies supported	clot detection, optical, nephelometric; chromogenic;	clot detection, optical; chromogenic; immunologic	clot detection, optical (tungsten, nep
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	18	varies with test-reagent combination, limited only by No. of reag. positions	18
No. of different assays programmed and calibrated at one time No. of user-definable (open) channels	1 total test canacity: 300 (II-test channels 120+ open)	1 total test capacity: 100 (II_test channels + open)	1 300 (II. test channels 120+ onen)
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. of reag. containers onboard at one time/Tests per container	no 18/varies by test	no 42/varies by test, container size	no 18/varies
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	yes (15°C)
Reag., consumables loaded without interrupting testing	yes no	yes ves	yes no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot No. of reag. can be used Walkaway canacity: No. of specimens/No. of tests	18 months 40/260	18 months 120/variable	18 months 40/260
Min. sample vol. aspirated precisely at one time	5 μL	10 μL	40/200 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, min. 160; PTT: 63 μL, min.
Disposables used/Price of each	rotors/price varies	cuvettes/price varies	rotors/price varies
Supports direct-from-track sampling Primary tube sampling supported/Pierces caps on primary tubes	no ves (13 x 64, 75, 100 mm; 11,5 x 64, 92 mm)/no	no ves/no	no ves (13 x 64, 75, 100 mm; 11,5 x 64,
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability Onboard test automatic inventory	NO Ves	no	no ves
Measures No. of tests remaining	yes	no	yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	NO Ves	NO Ves	N0
Hemolysis/Turbidity detection-quantitation	no/no	yes/yes	no/no
Dilution of patient samples onboard	yes ,	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes ves (PT & PTT: 3 sec)	yes/no ves (PT: 7 sec., PTT: 10 sec)	yes/yes ves (PT & PTT: 3 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard: • Read, volumes/Sample volumes	ves/ves	ves/ves	vec/vec
No. and sources of reag.	yes	yes	yes
Incub. times/Reading times Autocalibration or autocalib. alort/Multipoint calibration supported	yes/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:		a	
PT alone PT, PTT	4 min/175 specimens 8 min/110 specimens	2.5 min/240 specimens 8 min/180 specimens	4 min/1/5 specimens 8 min/110 specimens
• Fibrinogen	4 min/175 specimens	2.5 min/240 specimens	4 min/175 specimens
 Factor VIII activity assay Time delay from ordering stat to aspir of sample 	varies/110 specimens	2.5 min/180 specimens	varies/110 specimens
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots)
Interfaces in active user sites for:		most major LIS vendors	n/a
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)	yes (broadcast download & host que
Results transferred to LIS as soon as test time complete	yes no	yes no	yes no
How labs get LOINC codes for reagent kits	in development	in development	_
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	NO	NO daile 15 min waakke 15 min maatke 10 min	no
Onboard maintenance records	yes	daliy: 15 min; weekly: 15 min; montniy: 10 min yes	yes
Training provided with purchase Approx. No. of training hrs needed per tech	5 days at vendor offices in Miami varies	5 days at vendor offices in Miami 24 h	on site varies/5 days at vendor office varies
List price	\$61,950	\$79,500	\$52,000
Ann. svc. contract cost (24/7)/Warranty with purchase	various options available/1 yr	various options available/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	 robotic transport arm extensive menu of clotting, chromogenic, & immunologic assays in a small footprint positive displacement pipetting for low 	 extensive menu of clotting, chromogenic, & immunologic assays high throughput positive displacement pipetting for low 	 PT-based fibrinogen, quantitative extensive menu of clotting, chromo immunologic assays in a small footp positive displacement pipetting for

Coagulation Analyzers

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Y	Coagulation Analyzer	S
Part 10 of 13	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckman Coulter Inc.
	200 S. Kraemer Blvd., Brea, CA 92822	200 S. Kraemer Blvd., Brea, CA 92822
See accompanying article, page 20	714-961-4556 www.beckmancoulter.com	714-961-4556 www.beckmancoulter.com
Instrument name/first vear sold	ACL 10000/2003	ACL TOP/2004
No. of units installed in 11 S /Autside 11 S.		20/40
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.
Operational type Reagent type	batch open reagent system (reconst. manually)	continuous random access open reagent sys., bar-coded reag. (reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system Model type	tray benchtop	rack 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	28.7 x 59.4 x 29.9 in/330.7 lbs/21 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, PT-based fib., Clauss fib., factor assays, protein S & C, LAC screen,	PT, APTT, Clauss fib., factor assays
EDA-cleared chromogenic tests	LAC confirm, APCR-V antithrombin, liquid antithrombin, factor VIII, heparin, plasmin inhibitor,	AT protein C
	plasminogen, protein C	
FDA-cleared immunologic tests	D-dimer (latex-enhanced immunoassay), vWF (latex- ennanceo immunoassay), free protein S (latex turbidimetric ligand immunoassay)	D-dimer, vWF antigen, free protein S
Other FDA-cleared tests	none	none
User-defined tests in clinical use Tests submitted for 510(k) clearance	none 	none liquid AT. protein C (clotting), APCR-V, heparin, vWF activity, LAC
	we have a stated matter & anthrow how outside	
Tests in development but not yet submitted	silica clotting time, global protein C pathway, homocyst.	silica clotting time, D-dimer H S
Methodologies supported	clot detection. optical (tungsten, nephelometric); chromogenic; immunologic	clot detection, optical (turbidimetric); chromogenic; immunolo
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no	no/no
No. of different measured assays on board sinultaneously No. of different assays programmed and calibrated at one time	1	500
No. of user-definable (open) channels	300 (IL test channels 120+ open)	250
Of those defined, no. active simultaneously	varies with test-reagent complination	varies with test-reagent combination, initial only by number o positions (up to 60 avail.)
Factor assays require manual manipulation or dilutions	NO 92 histor	no (automatic)
No. Of reag. containers onboard at one time/ rests per container Reagents refrigerated onboard	zzvanes yes (15°C)	44/varies yes (15°C)
Multiple reag. configurations supported	yes no	yes vas
Same capabilities when 3rd-party reag. used	yes	no
Max. time same lot No. of reag. can be used Walkaway canacity: No. of specimens/No. of tests	18 months 40/260	18 months 120 (12 racks)/varies
Min. sample vol. aspirated precisely at one time	40/200 5 μL	4 μL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	PT: 60 μL, min. 160; PTT: 63 μL, min. 163/18 μL, min. 118 uL	PT: 100 μL; PTT: 50 μL; factor VIII: 25 μL
Disnosables used/Price of each	rotors/price varies	varies
Supporte direct-from-track sampling	70	vas (in development)
Primary tube sampling supported/Pierces caps on primary tubes	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes (in development) yes/yes
Sample bar-code reading capability Reagent har-code reading capability	yes no	yes ves
Onboard test automatic inventory	yes	yes
Measures No. of tests remaining Short sample detection	yes ves	yes ves
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal. Hemolysis/Turhidity detection-quantitation	10 no/no	yes no/no
Dilution of patient samples onboard	yes ,	yes
Automatic rerun capability/Auto reflex testing capability Lag time during which hypercoagulable samples will not be detected	yes/yes ves (PT & PTT: 3 sec)	yes/yes no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (option available for user-defined tests only)
User can set different-than-standard: • Reag. volumes/Sample volumes	ves/ves	ves/ves
No. and sources of reag.	yes	yes
 Incub. times/Reading times Autocalibration or autocalib. alert/Multipoint calibration supported 	yes/yes no/yes	yes/yes yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for:		
• PT alone • PT PTT	4 min/175 specimens 8 min/110 specimens	<3 min/360 samples /165 samples
• Fibrinogen	4 min/175 specimens	—/ 103 salipies —/—
• Factor VIII activity assay Time delay from ordering stat to asnir, of sample	varies/110 specimens	-/ denands on test routing
Auto. transfer of QC results to LIS	yes	yes
Data management capability Interface supplied by instrument vendor	onboard (incl. QC: L-J plots)	onboard (incl. QC, L-J plots) ves
Interfaces in active user sites for:	n/a	Misys, Cerner, ILIMS
Bidirectional interface capability Results transferred to LIS as soon as test time complete	yes (broadcast download & host query) ves	yes (broadcast download & host query)
LOINC codes transmitted with all results	no	no
How labs get LOINC codes for reagent kits Flectronic interface available (or will be) to automated	 P0	
(or robotic) specimen handling system		
Modem servicing	no	no
Time required for maintenance by lab personnel	weekly: 10 min; monthly: 5 min; biweekly: 5 min	daily: <10 min; weekly: 10 min —
Training provided with purchase	on site varies/5 days at vendor offices	5 days at vendor offices
Approx. No. of training hours needed per tech	varies	-
		\$122 160 (hass unit)
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$59,995 various ontions available/1 vr	\$132,100 (base unit) various ontions available/1 vr
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$59,995 various options available/1 yr	various options available/1 yr

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Part 11 of 13 See accompanying article, page 20	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, N 800-325-3424 www.trinitybiotech.com
Instrument name/first year sold	KC1∆/2001	KC4∆/2001
No. of units installed in U.S./Outside U.S.	>100/>100	>100/>100
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany
Reagent type	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual
Model type Dimensions (H x W x D)/Weight/Instrument footprint	benchtop 3.25 x 5.5 x 8.25 in/2.5 lbs/<1 sq ft	benchtop 4.7 x 13.9 x 17.7 in/14 lbs/1.7 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib.	PT, APTT, fib., TT, atroxin, intrinsic & extrinsic
FDA-cleared chromogenic tests	n/a	n/a
FDA-cleared immunologic tests	n/a	n/a
Other FDA-cleared tests User-defined tests in clinical use	n/a n/a	n/a n/a
Tests submitted for 510(k) clearance	n/a	n/a
Tests in development but not yet submitted	n/a	n/a
Methodologies supported	clot detection, mechanical	clot detection, mechanical
Oper. must load sep. reag. pack for ea. specimen/Test run	no/no 1	no/no 5
No. of different assays programmed and calibrated at one time	manual	1/1
No. of user-definable (open) channels	n/a	n/a
Of those defined, No. active simultaneously	n/a	up to 4
ractor assays require manual manipulation or dilutions No. of reag, containers onboard at one time/Tests per container	yes 1/varies for each assav	yes 5/varies for test kit
Reagents refrigerated onboard	no	no
Multiple reag. configurations supported	no	no
Reag., consumables loaded without interrupting testing Same canabilities when 3rd-narty read, used	n/a, manual ves	n/a, manual ves
Max. time same lot No. of reag. can be used	12–18 months	12–18 months
Walkaway capacity: No. of specimens/No. of tests	n/a, manual	n/a, manual
Min. sample vol. aspirated precisely at one time	n/a F0 vit /m/o	n/a 50 vil /10 vil
Disposables used/Price of each	cuvettes & ball dispenser/inquire	cuvettes & ball dispenser/inquire
Supports direct-from-track sampling	n/a	n/a
Primary tube sampling supported/Pierces caps on primary tubes	n/a	n/a
Sample bar-code reading capability	n/a R/o	n/a
Reagent bar-code reading capability Onboard test automatic inventory	n/a n/a	n/a n/a
Measures No. of tests remaining	n/a	n/a
Short sample detection	n/a	n/a
Clot detection as preanalytical variable in plasma sample Auto, detection of adequate reag, for aspir, & anal	n/a n/a	n/a n/a
Hemolysis/Turbidity detection-guantitation	n/a	n/a
Dilution of patient samples onboard	n/a	n/a
Automatic rerun capability/Auto reflex testing capability	n/a	n/a
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 4.5 sec)	yes (PT & PTT: 4.5 sec)
User can set different-than-standard:	yea	yca
Reag. volumes/Sample volumes	yes/yes	yes/yes
No. and sources of reag.	yes	yes
Autocalibration or autocalib. alert/Multipoint calibration supported	yes/yes no/yes	yes/yes no/yes
Auto shutdown/Auto startup programmable	no/no	no/no
Stat time to completion of all analytes/Throughput per hour for: • PT alone	75 sec/48 tests	75 sec/48 tests
• PT, PTT	350 sec/10 tests	350 sec/10 tests
Fibrinogen Foster VIII getivity assess	65 sec/55 tests	65 sec/55 tests
 racion will account assay Time delay from ordering stat to aspir, of sample 	210 Sec/10 Lests	2/0 Sec/13 Tests n/a
Auto. transfer of QC results to LIS	yes	yes
Data management capability	yes	yes
Interface supplied by instrument vendor	no 	no
menaces in acuve user sites for: Bidirectional interface canability	n/a	 n/a
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	-	-
How labs get LOINC codes for reagent kits		
(or robotic) specimen handling system	iva	11/ a
Modem servicing	n/a	n/a
nine requireu ior maintenance by lab personnel Onboard maintenance records	none n/a	none n/a
Training provided with purchase	as needed on site	as needed on site
Approx. No. of training hours needed per tech	2 h	2 h
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$2,100 \$364 (M-F, 8-5)/1 yr	\$9,200 \$936 (M-F, 8-5)/1 yr
Unique advantages (provided by vendors)	patented ball technology for extremely reproducible & reliable results	4 test positions can be used simultaneous natented ball method for extremely received
	 provides significant cost savings when used with Trinity's reagents & controls 	 parentee bail method for extremely reproc reliable results provides significant cost savings when us Trinity's reagents & controls

January 2005

The Pathologists' Meeting" 05 September 11-14, 2005

- Connection Café and Exhibits
- Abstract Posters and Presentations
- Entertainment by Neil Goldgerg's Cirque unique, colorful - fun for the family!
- Industry Demonstrations and Workshops





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42 / CAP TODAY

irleyvc@trinityusa.com iness Center Dr., St. Louis, MO 63114 .com y tem nuous addition sample rack standing 8.75 in/286 lbs/6.5 sq ft x 28.75 in/286 lbs/6.5 sq ft , PT, proteins C & S, TT, intrinsic & dRVVT sminogen, heparin-Xa, protein C studies, Ptt. neutralization, Kaolin ated protein C resistance, protein S ssay (immunol.), thrombotest, heparin e antiplasmin nical; clot detect., optical (tungsten, mogenic; immunologic	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, M0 63114 800-325-3424 www.trinitybiotech.com Amax 400/1997 <50/<50 Germany/Germany random access open reagent system spun plasma continuous feed sample chain floor standing 52 x 56 x 27 in/803 lbs/10.5 sq ft PT, APTT, fib., TT, intrinsic & extrinsic factors, proteins C & S, dRVVT heparin-Xa, antithrombin, plasminogen, protein C D-dimer none PT & APTT mixing studies, Plt. neutralization, Kaolin clotting time, protein S (immunol.), vWF assay (immunol.), thrombo test, heparin cofactor II, alpha- antiplasmin activated protein C resistance none clot detect., mechanical; clot detect., optical (tungsten, turbidimetric); chromogenic; immunologic (microparticles) no/no 40 40 40 40 40 40 40 40 40
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e decontaminate/—	cuvettes/—, probe decontaminate/—, tubing/—
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	yes
	yes/yes (out of test)
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	200/200
	y85/y85
	905 Ves/ves
	no/ves
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	<3 min/325 tests
	 < mm/ 220 tests 300 sec/480 tasts
	70 sec/212 tests
	300 sec/200 tests
	varies by test
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	onboard (incl. QC: L-J plots, Westgard)
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January 2005

Coagulation Analyzers

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Part 13 of 13	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr.	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr.		
See accompanying article, page 20	St. Louis, M0 63114 800-325-3424 www.trinitybiotech.com	St. Louis, MO 63114 800-325-3424 www.trinitybiotech.com		
Instrument name/first year sold	Amax Destiny/2003	MiniQuant D-dimer System/2002		
No. of units installed in U.S./Outside U.S. Country where analyzer designed/Manufactured Operational type	>50/<50 Germany & U.S./Germany random access	25/<25 Germany/Germany discrete		
Reagent type Onerates on whole blood or shun plasma	open reagent system	uses MiniQuant D-dimer reagents		
Sample handling system	50 positions/5 racks	spun plasma single cuvettes bandhold portable		
Dimensions (H x W x D)/Weight/Instrument footprint	22 x 33 x 27 in/165 lbs/150 sq ft	4.3 x 7.9 x 8.9 in/2.75 lbs/1 sq ft		
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, & XII	none		
FDA-cleared chromogenic tests	AT, heparin Xa	none		
FDA-cleared immunologic tests Other FDA-cleared tests	D-dimer 	D-dimer, quantitative microlatex		
User-defined tests in clinical use	_	D-dimer		
Tests submittee for 510(k) clearance Tests in development but not yet submitted	_	none		
Methodologies supported	clot detect., mechanical; clot detect., optical	immunologic (quantitative microlatex)		
Oper. must load sep. reag. pack for ea. specimen/Test run	(turbiaimetric); chromogenic; immunologic no/no	no/no		
No. of different measured assays onboard simultaneously No. of different assays programmed and calibrated at one time	10 unlimited	1 1		
No. of user-definable (open) channels Of those defined, No. active simultaneously	unlimited 10	1		
Factor assays require manual manipulation or dilutions	no 30/varies	n/a —/50		
Reagents refrigerated onboard	yes (12–16°C)	no		
Reag., consumables loaded without interrupting testing	yes yes	no no		
Same capabilities when 3rd-party reag. used Max. time same lot No. of reag. can be used	yes varies by reagent	no n/a		
Walkaway capacity: No. of specimens/No. of tests Min, sample vol. aspirated precisely at one time	50/240 5 ul	n/a/n/a n/a		
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 μL/10 μL roaction trave. DroWook (n/a/n/a		
	reaction trays, Prowash/—	cuvelles/—		
Primary tube sampling supported/Pierces caps on primary tubes	yes (standard, pediatric, micro)/no	no/no		
Sample bar-code reading capability Reagent bar-code reading capability	yes in process	no no		
Onboard test automatic inventory Measures No. of tests remaining	yes yes	no no		
Short sample detection Clot detection as preanalytical variable in plasma sample	yes no	no		
Auto. detection of adequate reag. for aspir. & anal.	yes	no no		
Dilution of patient samples onboard	not necessary yes	no/no no		
Automatic rerun capability/Auto reflex testing capability Lag time during which hypercoagulable samples will not be detected	yes/yes O sec	no/no n/a		
Read time extended for prolonged clotting times	yes	n/a		
Reag. volumes/Sample volumes	yes/yes	n/a		
No. and sources of reag. Incub. times/Reading times	yes yes/yes	n/a		
Autocalibration or autocalib. alert/Multipoint calibration supported Auto shutdown/Auto startup programmable	no/yes yes/yes	n/a/yes n/a/n/a		
Stat time to completion of all analytes/Throughput per hour for:				
• PT alone • PT. PTT	<3 min/100 tests —/80	—/— —/—		
• Fibrinogen	—/100 m/2			
• Factor vill activity assay Time delay from ordering stat to aspir. of sample	n/a varies by test	/ 		
Auto. transfer of QC results to LIS Data management capability	yes onboard (incl. QC: L-J plots, Westgard)	no no		
Interface supplied by instrument vendor Interfaces in active user sites for:	no all major LIS vendors	_		
Bidirectional interface capability Besults transferred to LIS as soon as test time complete	yes (broadcast download & host query)	no no		
LOINC codes transmitted with all results		no		
Electronic interface available (or will be) to automated	no	n/a NO		
(or robotic) specimen handling system				
Modem servicing Time required for maintenance by lab personnel	no per shift: <5 min; weekly: <30 min; monthly: <5 min	no daily: 5 min		
Onboard maintenance records Training provided with nurchase	yes 2–4 davs on site	no 1 dav on site		
Approx. No. of training hours needed per tech	8h	2 h		
List price Ann. svc. contract cost (24/7)/Warranty with purchase	\$49,000 —/1 yr	\$5,150 —/1 yr		
Unique advantages (provided by vendors)	true clot detection active contraction	quantitative D-dimer read time_ E minutes		
	easy to use intuitouch somware expanded test menu to include D-dimer and	 reau unite—o minutes easy to use 		
	neparin Xa			



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