What's cool in coag: clot signature curves

Anne Ford

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

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

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

With its recently released Sysmex CA-560 analyzer, Dade Behring, too, aims to provide D-dimer testing to low-volume laboratories. Medium-volume labs can look forward to the

summer release of BioMérieux's Coag-A-Mate MTX III, an updated version of the MTX II that will feature automated D-dimer capabilities.

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

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

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

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

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

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

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

Anne Ford is CAP TODAY senior editor.

Part 1 of 13	American Labor/Lab A.C.M. Inc.	American Labor/Lab A.C.M. Inc.
	Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705	Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705
	919-286-0726 or (tech support) 800-424-0443	919-286-0726 or (tech support) 800-424-0443
	www.americanlabor.org & www.labitec.de	www.americanlabor.org & www.labitec.de
	******.diffortouridation.org & ******.datico.do	www.amorioanasor.org a www.nasitoo.do
Instrument name/first year sold	CD2000/1986	CoaLab/1991
No. of units installed in U.S./outside U.S.	>500/>1,000	- /-
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany
Operational type	batch, discrete	discrete, batch
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	cuvette ring (automated)
Model type	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	5 x 12 x 8.5 in/9.2 lbs/1 sq ft	14 x 18 x 41 in/138.6 lbs/6 sq ft
FDA-cleared clotting-based tests	PT, PTT, fib., any citrated plasma clot-based assay	any clot based detection, PT, APTT, TT, PT-based fibrinogen, Clauss fibrinogen,
	, , ,	factor assays, protein C, protein S, LAC screen, LAC confirm, APCR-V
FDA-cleared chromogenic tests	none	none
FDA-cleared immunologic tests	none	none
Other FDA-cleared tests	none	none
User-defined tests in clinical use	none	none
Tests submitted for 510(k) clearance	none	none
Tests in development but not yet submitted	none	none
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing-optical detection	clot detection, optical (tungsten, turbidimetric)
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no
No. of different measured assays onboard simultaneously	no/no 2 (PT, APTT)	30
No. of different assays programmed and calibrated at one time	2 (F1, AF11) 1 (fib.)	30
No. of user-definable (open) channels	2	2
Of those defined, No. active simultaneously	2	varies with test-reagent combination
Factor assays require manual manipulation or dilutions	yes	no
No. of reag. containers onboard at one time/tests per container	5 or more/ reag. mftr. dependent	10/varies
Reagents refrigerated onboard	no	no no
Multiple reag. configurations supported	yes	yes
Reag., consumables loaded without interrupting testing	yes	no no
Same capabilities when 3rd-party reag. used	yes	yes
Max. time same lot number of reag. can be used	laboratory dependent	18 months
Walkaway capacity: No. of specimens/No. of tests Min. sample vol. aspirated precisely at one time	no manual pipetting	32/30 5 μL
Standard specimen vol. required to run PT or PTT/factor VIII activity	manuar prpetting 50 μL, min. 50 μL/50 μL, min. 50 μL	5 μL 50 μL, min. 50 μL/<50 μL, min. 50 μL
Disposables used/price of each	500 microcuvette w/ mixers in trays/11.6¢ ea., bulk 11¢ ea.; 500 macrocuvette w/	sample cups, measurement cuvette rings/prices vary
Dioposabiles assarprise of sasir	mixers in trays/12¢ ea., bulk 10.6¢ ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3,000	ouripio oupo, mouduromone ourous ringo, priodo rury
	tips bulk/3.9¢ ea.	
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Supports direct-from-track sampling	no	no
Primary tube sampling supported/pierces caps on primary tubes	no/no	ves (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no
Sample bar-code reading capability	no	yes
Reagent bar-code reading capability	10	no
Onboard test automatic inventory	no	yes
Measures No. of tests remaining	no	yes
Short sample detection	no	yes
Clot detection as preanalytical variable in plasma sample	no no	no no
Auto. detection of adequate reag. for aspir. & anal.	no	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard	no no/no	yes
Automatic rerun capability/auto reflex testing capability Lag time during which hypercoagulable samples will not be detected	no/no yes (3 sec)	yes/no yes (3 sec)
Read time extended for prolonged clotting times	yes, up to 999 sec	yes (selectable on menus)
User can set different-than-standard:	you, up to 555 555	you (occount on monuty)
Reag. volumes/sample volumes	yes/yes	yes/yes
No. and sources of reag.	yes	yes
Incub. times/reading times	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/no	no/yes
Auto shutdown/auto startup programmable	no/no	no/no
Stat time to completion of all analytes/throughput per hour for:		
• PT alone	120 sec/user defined	4 min/140 specimens
• PT, PTT	240 sec/user defined	8 min/140 specimens
• Fibrinogen	300 sec/user defined	4 min/140 specimens
Factor VIII activity assay Time delay from addring states assign of complete	300 sec/user defined	varies/varies
Time delay from ordering stat to aspir. of sample	none—all preanalytical	15 sec
Auto, transfer of QC results to LIS	no	NO ves (incl. OC: L - I plats)
Data management capability Interface supplied by instrument vendor	no no	yes (incl. QC: L-J plots) no
Interfaces in active user sites for:	call technical support for inquiry	n/a
Bidirectional interface capability	no	no
Results transferred to LIS as soon as test time complete	yes	no
LOINC codes transmitted with all results	no	no
How labs get LOINC codes for reagent kits	n/a	n/a
Electronic interface available (or will be) to automated	yes	no
(or robotic) specimen handling system		
Modem servicing	no	no
Time required for maintenance by lab personnel	daily: 30 sec (temp. check, cloth cleaning); weekly: 30 sec; monthly: 5 min (temp. calib. if needed)	daily: 10 min; weekly: 10 min; monthly: 5 min; biweekly: 5 min
Onboard maintenance records	no	yes
Training provided with purchase	videotape; on-site training extra	varies per site
Approx. No. of training hours needed per tech	2 h	varies
List price	\$4,200, special pricing available upon written request for quote	\$25,000
Ann suc contract cost (2/A h/7 d)/warranty with nurshoos	additional 2-vr initial contract \$000 (entional)/1 vr	various ontions available/1 vr
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	additional 2-yr initial contract \$900 (optional)/1 yr	various options available/1 yr
Unique advantages (provided by vendors)	smaller clinic; office, private, vet labs	• clot code electronic signatures available for each assay run, visualization,
	 low acquisition & service cost, low maintenance 	and printouts
	refurbished units available at reduced prices	extensive menu of clotting
	able to handle turbid/colored samples	 positive displacement pipetting for low maintenance and high precision

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Part 2 of 13	BioMérieux Inc.	BioMérieux Inc.	BioMérieux Inc.
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	919-620-2000	919-620-2000	919-620-2000
See accompanying article, page 56	www.biomerieux-usa.com	www.biomerieux-usa.com	www.biomerieux-usa.com
	WWW.blottlottoux dod.ootti	WWW.Diomonoux dod.com	WWW.biomonoux dod.oom
Instrument name/first year sold	Coag-A-Mate Max/1999	Coag-A-Mate MTX II/1999 (sold as MTX since 1997)	Coag-A-Mate XM/1989
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No. of units installed in U.S./outside U.S.	>185 worldwide	>500 worldwide	>2,000 worldwide
Country where analyzer designed/manufactured	Germany/Germany	Germany & U.S./Germany	U.S./U.S.
Operational type	random access	random access	discrete
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma Sample handling system	spun plasma	spun plasma	spun plasma manual pipetting into cuvette (4 wells at a time)
Model type	2 rotors (31 positions each) benchtop	rotor (32 positions) benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	15.3 x 40.2 x 28.3 in/134.5 lbs/8 sq ft, 11 w/ PC	19.7 x 30.7 x 21.3 in/100 lbs/5 sq ft, 8 w/ PC	4.6 x 14.7 x 20 in/20 lbs/2 sq ft
Dinionolono (ii x ii x b), itoligila moltamont lootpiint	1010 X 1012 X 2010 111/10 110 130/0 04 14 11 11/10	1011 X 0011 X 2110 111/100 130/0 04 14 0 11/10	110 X 1 111 X 20 111/20 130/2 04 10
FDA-cleared clotting-based tests	PT, APTT, TT, fib., PT & APTT factors	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays
FDA-cleared chromogenic tests	AT III, hep. antifactor Xa	AT III, hep. antifactor Xa, protein C	none
FDA-cleared immunologic tests	none	none (latex immunologic assay in development)	none (latex immunologic assay in development)
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	PT mix, APTT mix, lupus (dRVVT screen & confirm.),	alpha-2 antiplasmin, plasminogen, PT mix, APTT	none
	reptilase, proteins C & S (clotting), protein C	mix, LMWH (antifactor Xa)	
Tests submitted for 510(k) clearance	(chromo.), APCR, LMWH (antifactor Xa)	none	none
Tests in development but not yet submitted	none 	none quantitative D-dimer immunoassay	none
rests in development but not yet submitted	_	qualititative D-ullilei illilliulloassay	_
Methodologies supported	clotting, chromogenic assays; photo-optical	clotting, chromogenic assays; photo-optical	clotting assays; photo-optical
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	10	8	2
No. of different assays programmed and calibrated at one time	40	32	16
No. of user-definable (open) channels	18	up to 32	16
Of those defined, No. active simultaneously	10	8	2
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/tests per container	21 cooled, 16 for reagents, 5 for controls/15–160	16 cooled, 12 room temp. total 28/25–200	4/30–100
Reagents refrigerated onboard	yes (18°C)	yes (15°C)	no
Multiple reag. configurations supported Reag., consumables loaded without interrupting testing	yes consumables yes, reagents no	yes	yes
Same capabilities when 3rd-party reag. used	yes	no yes	yes yes
Max. time same lot number of reag. can be used	12–18 mos	12–18 mos	12–18 mos
Walkaway capacity: No. of specimens/No. of tests	62/232	32/32	4/4
Min. sample vol. aspirated precisely at one time	5 µL	2 μL	n/a
Standard specimen vol. required to run PT or PTT/factor VIII activity	60 μL/10 μL	50 μL/5 μL, min. 2 μL	100 μL/10 μL, min. 10 μL
Disposables used/price of each	cuvette racks, probe cleaner, predilution	cuvette rings, pipettor wash solution, cleaning	cuvettes, stir bars, optional: printer & paper/prices
	strips/prices available upon request	solution/prices available on request	available on request
Ownerstanding of from 1 1 1			
Supports direct-from-track sampling	no .vao/no	no waa/na	no no/no
Primary tube sampling supported/pierces caps on primary tubes	yes/no	yes/no	no/no
Sample bar-code reading capability Reagent bar-code reading capability	yes (2 internal bar-code scanners) no	yes no	no no
Onboard test automatic inventory	yes	yes	no
Measures No. of tests remaining	yes	yes	no
Short sample detection	no	no	no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	no
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	yes	yes	no
Automatic rerun capability/auto reflex testing capability	yes/yes	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 9 sec, APTT: 15 sec)	yes (PT: 3 sec, APTT: 5 sec)	yes (PT: 7 sec, APTT: 20 sec)
Read time extended for prolonged clotting times	yes	yes	yes
User can set different-than-standard:	yee has	uoo luoo	yee hee
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 no/ves	yes ves/ves	yes ves/ves
Incub. times/reading times Autocalibration or autocalib. alert/multipoint calibration supported	no/yes yes/yes	yes/yes yes/yes	yes/yes yes/yes
Auto shutdown/auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/throughput per hour for:			
• PT alone	<7 min/180 results	2 min/90 results	2 min/200 results (manual)
• PT, PTT	<7 min/120–140 results	5 min/60 results	5 min/50 PTT results (manual)
• Fibrinogen	<7 min/140–180 results	2 min/75 results	2-3 min/100 results (manual)
	<7 min/120–140 results	5 min/60 results	5 min/50 results (manual)
Factor VIII activity assay		30-60 sec	≤ 2 min
Time delay from ordering stat to aspir. of sample	<3 min		
Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS	yes	yes	no no
Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS Data management capability	yes yes (incl. QC: L-J plots)	yes yes (incl. QC: L-J plots)	no
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 (incl. QC: L-J plots) yes (additional cost)	yes yes (incl. QC: L-J plots) yes (additional cost)	no no
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:	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America	no no n/a
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	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes	yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes	no no n/a no
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:	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America	no no n/a
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	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes	yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes	no no n/a no no
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	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes	yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes	no n/a no no no
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	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a	yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a	no n/a no no no n/a
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	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a no	yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a	no n/a no no no n/a
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	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a no	yes yes (incl. QC: L-J plots) yes (additional cost) all commonly used LISs in North America yes yes no n/a no	no no n/a no
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	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: 30 min; monthly: <5 min	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 no n/a no no no n/a no no no daily: none; weekly: ~5 min; monthly: none
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	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: 30 min; monthly: <5 min	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	no no n/a no no no n/a no no daily: none; weekly: ~5 min; monthly: none no
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	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: 30 min; monthly: <5 min no 3 days at vendor offices	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	no no n/a no no no n/a no daily: none; weekly: ~5 min; monthly: none no 1/2 day on site
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	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: 30 min; monthly: <5 min no 3 days at vendor offices 1–2 h/30 min or less for basic operation	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	no n/a no no no n/a no no daily: none; weekly: ~5 min; monthly: none no 1/2 day on site 1–2 h
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	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: 30 min; monthly: <5 min no 3 days at vendor offices 1–2 h/30 min or less for basic operation	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	no no n/a no no no no no no no daily: none; weekly: ~5 min; monthly: none no 1/2 day on site 1–2 h \$5,198
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Reag., consumables loaded without interrupting testing				
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Supports direct-from-track sampling no no yes/yes no yes/yes no yes/yes no yes/yes no yes (3-5 mL)/no yes (3-5	Disposables used/price of each	cuvettes, bar-code labels, MDA probe cleaner/prices	cuvettes, printer paper/price varies with volume	reaction tubes, CA clean I, thermal paper/price varie
Primary tube sampling supported/pierces caps on primary tubes yes (internal bar-code scanner) no yes	·	available on request	,, ,, ,, ,	with volume
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Auto. detection of adequate reag. for aspir. & anal. Hemotysis/turbidity detection-quantitation Hemotysis/turbidity detection-quantitation yes no no no no no yes no no no yes no no no yes no no no no yes no no no no yes no no no yes no no no no yes per (PT: 5 sec, APTT: 15 sec) yes (electable on menus) yes (selectable on menus) User can set different-than-standard: * Reag, volumes/sample volumes * No. and sources of reag. * yes * yes * yes * yes * yes * lincub. times/reading times * no/yes * no/yes * yes/yes * no/yes * yes/yes * Auto shutdown/auto startup programmable * PT alone * PT alone * 12 min/180 results * 1 min/2 manual * PT, PTT * 12 min/180 results * 1 min/2 manual * T min/60 results * Flation yasay * T min/60 results * Flation yasay * T min/60 results * Flation yasay * T min/60 results * I min/n/a manual * T min/10 results * Flation yasay * T min/60 results * T min/10 results		•		-
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard 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: Ves (PT: default 3 sec, APTT: default 5 sec) Ves (Selectable on menus) Ves (Ves Ves Ves Ves Ves Ves Ves Ves Ves Ves				
Dilution of patient samples onboard Automatic rerun capability/auto reflex testing capability Automatic rerun capability/auto reflex testing capability Read time extended for prolonged clotting times 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 yes/yes **Ves/yes **Ves	. • .	•		
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 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 Stat time to completion of all analytes/throughput per hour for: PT alone PT alone PT alone PT alone 12 min/180 results PT II 22 min/180 results Fibrinogen Fibrinogen Fibrinogen Factor VIII activity assay 12 min/180 results 13 min/180 results 14 min/180 results 15 min/180 results 16 min/n/n amnual 17 min/60 results 18 min/14 results 19 min/160 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/60 results 18 min/14 results 19 min/180 results 10 min/n/n amnual 10 min/n/n amnual 11 min/n/n amnual 12 min/180 results 13 min/180 results 14 min/n/n amnual 15 min/n/n amnual 16 min/n/n amnual 17 min/60 results 18 min/14 results 19 min/180 results 10 min/n/n amnual 10 min/n/n amnual 11 min/n/n amnual 12 min/180 results 13 min/180 results 14 min/n/n amnual 15 min/n/n amnual 17 min/60 results 18 min/14 results 19 min/180 results 19 min/180 results 10 min/n/n amnual 10 min/n/n amnual 11 min/n/n amnual 12 min/180 results 13 min/180 results 14 min/n/n amnual 15 min/180 results 16 min/n/n amnual 17 min/60 results 18 min/14 results 19 min/180 results 10 min/n/n amnual 10 min/n/n amnual 11 min/n/n amnual 12 min/n/n amnual 13 min/n/n amnual 14 min/n/n amnual 15 min/n amnual 16 min/n amnual 17 min/n am			no	•
Read time extended for prolonged clotting times 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 Ves/yes PT alone PT, PTT 12 min/180 results PT, PTT 12 min/180 results PT, eptor VIII activity assay 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 PS, yes (selectable on menus) yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes yes/yes —/yes —/ye	Automatic rerun capability/auto reflex testing capability	no/no	no/yes	no/no
User can set different-than-standard: Reag. volumes/sample volumes No. and sources of reag. N	Lag time during which hypercoagulable samples will not be detected	yes (PT: default 3 sec, APTT: default 5 sec)	yes (PT: 5 sec, APTT: 15 sec)	yes (PT: <7 sec, PTT: <15 sec)
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No. and sources of reag. Incub. times/reading times Incub. times/reading times/r				
 Incub. times/reading times 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 12 min/180 results PT, PTT 12 min/180 results Inin/180 results Fibrinogen Fibrinogen Factor VIII activity assay Inin/180 results Inin/180 resu	•			
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 PT alone PT, PTT Epitrinogen Factor VIII activity assay 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 In min/180 results In/a In/a In/a In/a In/a In min/180 results In/a In min/n/a manual In min/180 results In min/n/a manual In min/n/a manual In min/n/a manual In min/n/a manual In min/180 results In min/n/a manual In min/180 results In min/n/a manual In min/n/a manual In min/180 results In min/n/a manual In min/n/a	Stat time to completion of all analytes/throughout per hour for			
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• Fibrinogen 12 min/180 results <1 min/na manual 7 min/60 results • Factor VIII activity assay 12 min/180 results n/a n/a/n n/a/n/a Time delay from ordering stat to aspir. of sample <1 min n/a 2 min Auto. transfer of QC results to LIS yes no yes Data management capability onboard (incl. QC: L-J plots, Westgard) no onboard (incl. QC: L-J plots) Interface supplied by instrument vendor yes (additional cost) n/a no no				
• Factor VIII activity assay 12 min/180 results n/a n/a n/a/n/a 2 min Auto. transfer of QC results to LIS Data management capability Interface supplied by instrument vendor 12 min/180 results n/a n/a n/a 2 min yes no yes no onboard (incl. QC: L-J plots, Westgard) n/a no no no no				
Time delay from ordering stat to aspir. of sample <1 min n/a 2 min Auto. transfer of QC results to LIS yes no yes Data management capability onboard (incl. QC: L-J plots, Westgard) no onboard (incl. QC: L-J plots) Interface supplied by instrument vendor yes (additional cost) n/a no				
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Data management capability onboard (incl. QC: L-J plots, Westgard) no onboard (incl. QC: L-J plots) Interface supplied by instrument vendor yes (additional cost) n/a no		yes	no	yes
				onboard (incl. QC: L-J plots)
Interfaces in active user sites for: all commonly used LISs in North America n/a Cerner. Sunquest, others	Data management capability			
$^{\prime}$	Data management capability Interface supplied by instrument vendor	all commonly used LISs in North America		, , ,
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	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			
	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	11/ 0	no	no
	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	ves	110	
(S. 1920an) operation nationing bytesin	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	yes		
Modem servicing yes no no	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	yes		
Time required for maintenance by lab personnel daily: ~35 min; weekly: 45 min; monthly: 10 min daily: 1 min daily: <5 min	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	•	no	no
Onboard maintenance records no no no	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	yes		
Training provided with purchase 3–5 days on site, 4 days at vendor offices video 2 days on site	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	yes daily: ~35 min; weekly: 45 min; monthly: 10 min	daily: 1 min	daily: <5 min
Approx. No. of training hours needed per tech 4–5 h 2 h	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	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no	daily: 1 min no video	daily: <5 min no 2 days on site
	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	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no	daily: 1 min no video	daily: <5 min no 2 days on site
List price \$92,295 \$8,037 \$44,100	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	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3–5 days on site, 4 days at vendor offices 4–5 h	daily: 1 min no video 2 h	daily: <5 min no 2 days on site 2 h
Ann. svc. contract cost (24 h/7 d)/warranty with purchase \$12,600/1 yr depot service (repair)/1 yr \$4,350 (business hours)/—	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	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3–5 days on site, 4 days at vendor offices 4–5 h \$92,295	daily: 1 min no video 2 h	daily: <5 min no 2 days on site 2 h \$44,100
Unique advantages (provided by yandars)	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	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3–5 days on site, 4 days at vendor offices 4–5 h	daily: 1 min no video 2 h	daily: <5 min no 2 days on site 2 h
	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 h/7 d)/warranty with purchase	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3–5 days on site, 4 days at vendor offices 4–5 h \$92,295 \$12,600/1 yr	daily: 1 min no video 2 h \$8,037 depot service (repair)/1 yr	daily: <5 min no 2 days on site 2 h \$44,100 \$4,350 (business hours)/—
	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	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3–5 days on site, 4 days at vendor offices 4–5 h \$92,295 \$12,600/1 yr • patented waveform analysis technology with flags for	daily: 1 min no video 2 h \$8,037 depot service (repair)/1 yr • 2-channel micro reagent volume clot-based technology	daily: <5 min no 2 days on site 2 h \$44,100 \$4,350 (business hours)/— • 5-parameter true random access
	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 h/7 d)/warranty with purchase	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3-5 days on site, 4 days at vendor offices 4-5 h \$92,295 \$12,600/1 yr • patented waveform analysis technology with flags for identifying abnormal waveforms (e.g. biphasic samples)	daily: 1 min no video 2 h \$8,037 depot service (repair)/1 yr • 2-channel micro reagent volume clot-based technology • opto-mechanical detection accurate on lipemic,	daily: <5 min no 2 days on site 2 h \$44,100 \$4,350 (business hours)/— • 5-parameter true random access clotting/chromogenic
• dyes in routine reagents for volume delivery check thermal printer • low-operating expense	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 h/7 d)/warranty with purchase	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3-5 days on site, 4 days at vendor offices 4-5 h \$92,295 \$12,600/1 yr • patented waveform analysis technology with flags for identifying abnormal waveforms (e.g. biphasic samples) • sensitive quantitative D-dimer assay for use in	daily: 1 min no video 2 h \$8,037 depot service (repair)/1 yr • 2-channel micro reagent volume clot-based technology • opto-mechanical detection accurate on lipemic, icteric samples	daily: <5 min no 2 days on site 2 h \$44,100 \$4,350 (business hours)/— • 5-parameter true random access clotting/chromogenic • small footprint, complete automation, specialty
• throughput remains the same regardless of test mix • perfect for low-vol. testing/backup to larger systems	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 h/7 d)/warranty with purchase	yes daily: ~35 min; weekly: 45 min; monthly: 10 min no 3-5 days on site, 4 days at vendor offices 4-5 h \$92,295 \$12,600/1 yr • 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	daily: 1 min no video 2 h \$8,037 depot service (repair)/1 yr • 2-channel micro reagent volume clot-based technology • opto-mechanical detection accurate on lipemic, icteric samples • automatic INR calculation, curve storage, built-in	daily: <5 min no 2 days on site 2 h \$44,100 \$4,350 (business hours)/— • 5-parameter true random access clotting/chromogenic • small footprint, complete automation, specialty assay capability

Part 4 of 13	Dade Behring Inc.	Dade Behring Inc.	Dade Behring Inc.
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	www.uauebeiiiiig.com	www.dadebelling.com	www.uauebelling.com
Instrument name/first year sold	Sysmex CA-1500/U.S.: 2000; worldwide: 1999	BCS/U.S.: 1998	Sysmex CA-7000/2002
No. of units installed in U.S./outside U.S.	—/—	—/—	—/—
Country where analyzer designed/manufactured Operational type	Japan/Japan continuous random access	Germany/Germany batch, continuous random access	Japan/Japan continuous random access
Reagent type	open reagent system (lyoph., reconst. manually),	open reagent system (reconst. manually), optimized	open reagent system
	optimized for Dade Behring instruments	for Dade Behring instruments	
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack x 5	rack	rack
Model type Dimensions (H x W x D)/weight/instrument footprint	benchtop 20 x 31.2 x 31.2 in/186 lbs/6.8 sq ft	benchtop 37 x 49 x 25 in/330 lbs/14 sq ft	benchtop 24.8 x 42 x 43.8 in/345.4 lbs/12.78 sq ft
- Simonorous (II X II X B), Holgita mottamont rootpinit	20 7 0 112 11 11 100 130/010 04 11	07 X 10 X 20 111/000 130/11 04 11	210 / 12 / 1010 11/01011 130/12/1004 1
FDA-cleared clotting-based tests	PT, APTT, fib., factor assays, reptilase time, thrombin	PT, APTT, fib., TT, factor assays, reptilase time, dRVVT	PT, APTT, fib., factor assays, protein C clotting, TT,
	time, protein C clotting	screen & confirm., factor V Leiden, protein C clotting	Lupus, dRVVT, batroxobin
FDA-cleared chromogenic tests	protein S activity, AT III, plasminogen, factor VIII chromo.,	AT III, alpha-2 antiplasmin, plasminogen, protein C	protein S activity, heparin AT III, factor VIII chromogenic,
FDA-cleared immunologic tests	alpha-2 antiplasmin, protein C chromo., heparin advanced D-dimer	chromo., heparin, protein S activity, factor VIII advanced D-dimer	plasminogen, alpha-2 antiplasmin, protein C chromogeni D-dimer
Other FDA-cleared tests	none	BC von Willebrand-ristocetin cofactor assay (agglut.	n/a
		of fixed Plts.)	
User-defined tests in clinical use	n/a	n/a	n/a
Tests submitted for 510(k) clearance	n/a	n/a	n/a
Tests in development but not yet submitted	dRVVT screen and confirm, factor V Leiden	n/a	factor V Leiden assay
Methodologies supported	clot detection, optical, turbidmetric; chromogenic;	clot detection: optical; xenon flasher lamp;	clot detection, optical, turbidimetric; chromogenic;
·	immunologic (latex agglutination)	chromogenic; immunologic (ristocetin cofactor)	immunologic (latex, transmitted light)
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	15 25	>20 tests/sample (theoretically 9,999)	20
No. of different assays programmed and calibrated at one time No. of user-definable (open) channels	25 25	99 8,999 (Nos. 1–1,000 are factory set & unalterable)	40 40
Of those defined, No. active simultaneously	15	>100	20
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/tests per container	39/up to 200	18–78/varies for micro volume assay format	58/varies up to 200
Reagents refrigerated onboard	yes (15°C)	yes (<15°C)	yes (15°C)
Multiple reag. configurations supported Reag., consumables loaded without interrupting testing	yes some consumables yes, reagents no	yes yes	yes yes
Same capabilities when 3rd-party reag, used	yes	yes	yes
Max. time same lot number of reag. can be used	12 mos	12 mos	12 mos
Walkaway capacity: No. of specimens/No. of tests	50/up to 1,000	110 samples/400 cuvettes	100/550 per hour PT and APTT, 300 per hour PT
Min. sample vol. aspirated precisely at one time	5 µL	5 μL	5 μL
Standard specimen vol. required to run PT or PTT/factor VIII activity Disposables used/price of each	50 µL/10 µL reaction tubes, sample plates, CA clean I & II, system	50 μL, min. 100 μL (incl. dead vols.)/50 μL, min. 100 μL cuvette rotors, washing solution, terralin disinfectant,	50 μL/10 μL reaction tubes, CA clean I & II, system buffer, haloger
Disposables used/price of each	buffer, halogen lamp, closed container sample	BC validation kit/price varies with volume	lamp, closed container sample replacement
	replacement needles/prices vary with volume		needles/prices vary with volume
Supports direct-from-track sampling	yes (Sysmex CST series)	no	yes (custom automation solutions available)
Primary tube sampling supported/pierces caps on primary tubes Sample bar-code reading capability	yes (3–5 mL)/yes yes	yes (all up to 100 mm long, ext. diam. 10–16 mm)/no yes	yes (3–5 mL)/yes yes
Reagent bar-code reading capability	yes	yes (avail. for user-defined tests)	yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining	yes	yes	yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample Auto. detection of adequate reag. for aspir. & anal.	no yes	no yes	no yes
Hemolysis/turbidity detection-quantitation	no/yes	yes/yes	no/yes
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/auto reflex testing capability	yes/yes	yes/yes	yes/yes
Lag time during which hypercoagulable samples will not be detected	yes (PT: 7 sec, PTT: 15 sec)	yes (PT & PTT: 7 sec)	yes (PT: 7 sec, PTT: 15 sec)
Read time extended for prolonged clotting times User can set different-than-standard:	yes (selectable on menus)	no	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/no	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	yes/yes	no/yes
Auto shutdown/auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes/throughput per hour for:			
PT alone	7 min/80 results	<5 min/~300 results (incl. abnormals)	7 min/280 results
• PT, PTT	8 min/120 results	<5 min/~270 results (incl. abnormals)	8 min/550 results
Fibrinogen Factor VIII activity assay	8 min/80 results	<5 min (if curve avail.)/~300 results	8 min/280 results
Factor VIII activity assay Time delay from ordering stat to aspir. of sample	8 min/n/a 2 min	<5 min (if curve avail.)/~280 results varies by test in progress, approx. <5 min	8 min/300 results 2 min
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots & Westgard)	limited	onboard (incl. QC: L-J plots & Westgard)
Interface supplied by instrument vendor	no .	no	no .
Interfaces in active user sites for:	Cerner, Sunquest, others	Cerner, Sunquest, Meditech, others	Cerner, others in development
Bidirectional interface capability Results transferred to LIS as soon as test time complete	yes (host query) yes	yes (host query) yes	yes (host query) 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	yes (Sysmex CST series)	possible future upgrade (not avail.)	yes (custom automation solutions avail.)
(or robotic) specimen handling system			
Modem servicing	no	yes	no
Time required for maintenance by lab personnel	daily: <5 min; weekly: <40 min; monthly: 1 min	daily: <5 min; weekly: <10 min; monthly: 15 min	per shift: <5 min; daily: <10 min; weekly: 1 min;
			quarterly: 5 min
Onboard maintenance records	NO	no	no
Training provided with purchase Approx. No. of training hours needed per tech	varies on site, 4 days at vendor offices 6 h	varies on site, 5 days at vendor offices 8 h on site	varies on site, 5 days at vendor offices 8 h on site
Approx. No. or maining nours needed per tech	VII.	O II UII SILG	O II OII SILG
List price	\$90,295 standard model; \$102,334 cap-piercing model	\$138,452	\$165,375 standard; \$181,913 with cap piercer
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	\$13,000 standard model; \$14,000 cap-piercing/1 yr	\$19,050/1 yr	\$18,500/1 yr
Unique advantages (provided by vendors)	simultaneous curve calibrating & patient testing	continuous loading of bar-coded reagent & samples	fastest throughput available for routine testing; PT,
omyao aavamagoo (provinca ny veniunio)	ability to load multiple bottles or multiple lots of	continuous roading of bar-coded reagent & samples multilot, multicurve reagent management	APTT results every 7 sec
	reagent	• PT/APTT/fib./AT III/D-dimer in <10 min	• continuous loading of reagents, consumables, &
		• simultaneous curve calibration & patient testing	patient samples without interruption
Tabulation dose not represent an andersoment by the Callege of Ameri			

Part 5 of 13	Diagnostica Stago Inc.	Diagnostica Stago Inc.	Diagnostica Stago Inc.
rait 9 Ui 13	Pascal Boulanger pascal.boulanger@stago-us.com	Pascal Boulanger pascal.boulanger@stago-us.com	Pascal Boulanger pascal.boulanger@stago-us.com
	5 Century Dr., Parsippany, NJ 07054 800-222-COAG	5 Century Dr., Parsippany, NJ 07054 800-222-COAG	5 Century Dr., Parsippany, NJ 07054 800-222-COAG
See accompanying article, page 56	www.stago-us.com	www.stago-us.com	www.stago-us.com
landari en en esta de la companya de	OTA Dillementaria Ocatema (4000	07A 0	0114/4000
Instrument name/first year sold	STA-R Hemostasis System/1998	STA Compact Hemostasis System/1996	Start 4/1998
No. of units installed in U.S./outside U.S.	193/1,128	993/4,217	683/7,498
Country where analyzer designed/manufactured 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 rack with continuous specimen access	spun plasma continuous specimen access-primary tube	spun plasma manual
Model type	floor standing	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	49.2 x 47.6 x 32.2 in/441 lbs/26.8 sq ft	25.2 x 38.8 x 25.8 in/351 lbs/25.6 sq ft	4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., reptilase, intr. & extr. factors,	PT, APTT, TT, fib., reptilase, intr. & extr. factors,	PT, APTT, TT, fib., reptilase, intr. & extr. factors,
FDA alcowed sharmonewis tests	proteins C & S, lupus anticoag. screen & confirm.	proteins C & S, lupus anticoag. screen & confirm.	proteins C & S, lupus anticoag. screen & confirm.
FDA-cleared chromogenic tests	unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin	unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin	
FDA-cleared immunologic tests	D-dimer, vWF, protein S antigen & AT III antigen	D-dimer, vWF antigen, protein S antigen & AT III	none
Other FDA-cleared tests	(microlatex agglut.) none	antigen (microlatex agglut.) none	none none
User-defined tests in clinical use	all clotting-based, chrom., & immunol. tests can have	all clotting-based, chrom., & immunol. tests can have	same as clotting-based tests above & dRVVT screen
	user-def. applications in addition to dRVVT screen & confirm assays & activated protein C resistance	user-def. applications in addition to dRVVT screen & confirm assay & activated protein C resistance	& confirm assays & activated protein C resistance
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clotting, chromogenic, & immunological assays	clotting, chromogenic, & immunological assays	clotting tests
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously No. of different assays programmed and calibrated at one time	up to 200 up to 200	up to 80 up to 80	1 20
No. of user-definable (open) channels	200	70	4
Of those defined, No. active simultaneously Factor assays require manual manipulation or dilutions	200	70	1 ves
No. of reag. containers onboard at one time/tests per container	no 70/up to 83	no 45/varies, up to 83	yes 4/varies, up to 100
Reagents refrigerated onboard	yes (15–19°C)	yes (15–19°C)	no
Multiple reag. configurations supported Reag., consumables loaded without interrupting testing	yes yes	yes yes	yes no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used Walkaway capacity: No. of specimens/No. of tests	18 mos 215/32 per specimen	18 mos 96/12 per sample	18 mos 4/1
Min. sample vol. aspirated precisely at one time	5 μL	5 µL	25 μL
Standard specimen vol. required to run PT or PTT/factor VIII activity	50 μL, min. 50 μL/50 μL, min. 50 μL	50 μL, min. 50 μL/50 μL, min. 50 μL	50 μL, min. 50 μL/50 μL, min. 50 μL
Disposables used/price of each	cuvettes, wash-cleaner solution/—	cuvettes, wash-cleaner solution/—	cuvettes, beads, ball/—
Supports direct-from-track sampling Primary tube sampling supported/pierces caps on primary tubes	yes yes/optional	no yes (5 & 2.5 mL tube sizes)/optional	no no/no (n/a)
Sample bar-code reading capability	yes	yes	no
Reagent bar-code reading capability Onboard test automatic inventory	yes (not for user-defined tests) yes	yes (not for user-defined tests)	no no
Measures No. of tests remaining	yes	yes yes	no
Short sample detection	yes	yes	no
Clot detection as preanalytical variable in plasma sample Auto, detection of adequate reaq, for aspir. & anal.	no yes	no 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/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.	yes	yes	yes
Incub. times/reading times Autocalibration or autocalib. alert/multipoint calibration supported	yes/yes yes/yes	yes/yes yes/yes	yes/yes no/yes
Auto shutdown/auto startup programmable	no/no (not needed)	no/no (not needed)	no no
Stat time to completion of all analytes/throughput per hour for:			
PT alone	<6 min/300 specimens	<6 min/150 specimens	<1 min/up to 120 specimens
• PT, PTT • Fibrinogen	7 min/150 specimens 7 min/180 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/180 specimens 7 min/180 specimens	7 min/70 specimens 7 min/70 specimens	varies/varies
Time delay from ordering stat to aspir. of sample	<15 sec	<15 sec	n/a
Auto. transfer of QC results to LIS Data management capability	yes onboard (incl. QC: L-J plots)	yes onboard (incl. QC: L-J plots)	no no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for: Bidirectional interface capability	contact marketing for updated list yes (host query)	contact marketing for updated list yes (host query)	n/a no
Results transferred to LIS as soon as test time complete	yes (nost query) yes	yes (nost query)	yes
LOINC codes transmitted with all results	no n/o	no	no
How labs get LOINC codes for reagent kits Electronic interface available (or will be) to automated	n/a yes (contact marketing for list of systems)	n/a no	n/a no
(or robotic) specimen handling system			
Modem servicing	Van	no	no
Time required for maintenance by lab personnel	yes		daily: <5 min; weekly: <5 min; monthly: <5 min
Outropy weight and a constant	daily: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <30 min; monthly: <30 min	
Onboard maintenance records Training provided with purchase	daily: none; weekly: <30 min; monthly: <30 min yes	yes	no 1 day on site
Onboard maintenance records Training provided with purchase Approx. No. of training hours needed per tech	daily: none; weekly: <30 min; monthly: <30 min		
Training provided with purchase Approx. No. of training hours needed per tech	daily: none; weekly: <30 min; monthly: <30 min yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center	yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center	1 day on site 1 h
Training provided with purchase	daily: none; weekly: <30 min; monthly: <30 min yes varies on site, 3 days at vendor offices	yes varies on site, 3 days at vendor offices	1 day on site
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	daily: none; weekly: <30 min; monthly: <30 min yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$149,995 prices available on request/1 yr	yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$75,000 prices available on request/1 yr	1 day on site 1 h \$9,600 prices available on request/1 yr
Training provided with purchase Approx. No. of training hours needed per tech List price	daily: none; weekly: <30 min; monthly: <30 min yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$149,995 prices available on request/1 yr • walkaway testing with robotics-capable interface to automated lines for high-volume testing, with	yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$75,000 prices available on request/1 yr • walkaway testing for routine & specialty hemostasis assays with 45 reag. positions, 96	1 day on site 1 h \$9,600 prices available on request/1 yr • excellent for low-volume testing or as backup to optical system
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	daily: none; weekly: <30 min; monthly: <30 min yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$149,995 prices available on request/1 yr • walkaway testing with robotics-capable interface to automated lines for high-volume testing, with touch-screen software & cap piercing option	yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$75,000 prices available on request/1 yr • walkaway testing for routine & specialty hemostasis assays with 45 reag. positions, 96 sample pos., up to 1,000 disposable cuvettes	1 day on site 1 h \$9,600 prices available on request/1 yr • excellent for low-volume testing or as backup to optical system • programmable and preprogrammed assays with
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	daily: none; weekly: <30 min; monthly: <30 min yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$149,995 prices available on request/1 yr • walkaway testing with robotics-capable interface to automated lines for high-volume testing, with	yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$75,000 prices available on request/1 yr • walkaway testing for routine & specialty hemostasis assays with 45 reag. positions, 96	1 day on site 1 h \$9,600 prices available on request/1 yr • excellent for low-volume testing or as backup to
Training provided with purchase Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	daily: none; weekly: <30 min; monthly: <30 min yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$149,995 prices available on request/1 yr • walkaway testing with robotics-capable interface to automated lines for high-volume testing, with touch-screen software & cap piercing option • continuous random access for up to 200 test	yes varies on site, 3 days at vendor offices 2 h basic, 24 h system training at training center \$75,000 prices available on request/1 yr • 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	1 day on site 1 h \$9,600 prices available on request/1 yr • excellent for low-volume testing or as backup to optical system • programmable and preprogrammed assays with curve storage, 4 independently timed incubation

Part 6 of 13	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us.com	Diagnostica Stago Inc. Pascal Boulanger pascal.boulanger@stago-us.com	Fisher Diagnostics Paul Gee paul.gee@fishersci.com
See accompanying article, page 56	5 Century Dr., Parsippany, NJ 07054 800-222-COAG	5 Century Dr., Parsippany, NJ 07054 800-222-COAG	8365 Valley Pike, Middletown, VA 22645 540-869-8224
Instrument name/first year sold	www.stago-us.com Start 8/1999	www.stago-us.com STA Compact CT/2001	www.fisherdiagnostics.com ThromboScreen 200/1994
<u> </u>		·	
No. of units installed in U.S./outside U.S. Country where analyzer designed/manufactured	>20/673 France/France	62/337 France/France	>25/>250 Germany/Germany
Operational type	batch	continuous random access	batch, discrete
Reagent type Operates on whole blood or spun plasma	open reagent system (lyoph., reconst. manually) spun plasma	open reagent system (lyoph., reconst. manually) spun plasma	open reagent system (reconst. manually) spun plasma
Sample handling system	manual	continuous specimen access—primary tube	manual
Model type Dimensions (H x W x D)/weight/instrument footprint	benchtop 4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft	benchtop 25.2 x 38.8 x 25.8 in/351 lbs/25.6 sq ft	benchtop 4 x 8 x 12 in/5 lbs/1 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, Clauss fibrinogen, derived fibrinogen, factor
	proteins C & S, lupus anticoag. screen & confirm	proteins C & S, lupus anticoag. screen & confirm	assays, thrombin time, venom time, APC resistance
FDA-cleared chromogenic tests FDA-cleared immunologic tests	none none	n/a n/a	none none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	same as clotting-based tests above & dRVVT screen & confirm. assays & activated protein C resistance	all clotting-based tests can have user-def. applications, dRVVT screen & confirm. assays & activated protein C resistance	n/a
Tests submitted for 510(k) clearance Tests in development but not yet submitted	none none	none none	none none
Methodologies supported	clotting tests	clot detection, mechanical	clot detection, optical
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	1	up to 80	2
No. of different assays programmed and calibrated at one time No. of user-definable (open) channels	20 4	up to 80 70	14 n/a
Of those defined, No. active simultaneously	1	70	1
Factor assays require manual manipulation or dilutions No. of reag. containers onboard at one time/tests per container	yes 4/varies, up to 100	no 45/varies, up to 83	yes 3/varies
Reagents refrigerated onboard	17 varies, up to 100 no	yes (15–19°C)	no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing Same capabilities when 3rd-party reag. used	no yes	yes yes	yes yes
Max. time same lot number of reag. can be used	18 mos	18 mos	18–24 mos
Walkaway capacity: No. of specimens/No. of tests	4/1 05 vi	96/12 per specimen	n/a/n/a
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, min. 50 μL	5 μL 50 μL, min. 50 μL/5 μL, min. 5 μL	25 μL 50 μL, min. 50 μL/—
Disposables used/price of each	cuvettes, beads, ball/—	cuvettes, wash-cleaner solution/—	cuvettes & pipette tips/prices vary
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	no/no (n/a)	yes (5 x 2.5 mL)/yes (optional)	no/no
Sample bar-code reading capability Reagent bar-code reading capability	no no	yes yes (not for user-defined tests)	no no
Onboard test automatic inventory	no	yes	no
Measures No. of tests remaining Short sample detection	no no	yes yes	no no
Clot detection as preanalytic variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no no tra	yes	no
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard	no/no no	no/no yes	no/no no
Automatic rerun capability/auto reflex testing capability	no/no	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times	no yes (selectable on menus)	no yes (selectable on menus)	no yes (selectable on menus)
User can set different-than-standard:	you (conoctable on monacy	you (octobrasio on monacy	Joo (dollocable on monae)
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 Auto shutdown/auto startup programmable	no/yes	yes/yes no/not needed	no/yes no/no
Stat time to completion of all analytes/throughput per hour for:	no	nv/nv.nccucu	110/110
• PT alone	<1 min/up to 120 specimens	<6 min/150 specimens	<1 min/120 specimens
• PT, PTT • Fibrinogen	n/a/n/a <1 min/up to 120 specimens	7 min/75 specimens 7 min/75 specimens	varies <1 min/120 specimens
Factor VIII activity assay	varies/varies	7 min/70 specimens	n/a
Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS	n/a	<15 sec	n/a
Auto. transfer of QC results to LIS Data management capability	no no	yes onboard (incl. QC: L-J plots)	no no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for: Bidirectional interface capability	n/a no	contact marketing for updated list yes (host query)	
Results transferred to LIS as soon as test time complete	yes	yes (nost query) yes	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 (or robotic) specimen handling system	n/a no	n/a no	n/a no
Modem servicing	no	NO wooddu 20 min monthlu 20 min	no
Time required for maintenance by lab personnel Onboard maintenance records	daily: <5 min; weekly: <5 min; monthly: <5 min no	weekly: <30 min; monthly: <30 min yes	daily: 5 min; weekly: 5 min; monthly: 5 min no
Training provided with purchase Approx. No. of training hrs needed per tech	1 day on site 1 h	varies on site, 3 days at vendor office 2 h basic, 24 h system training at training ctr.	1 day on site 1 h
List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	\$12,500 prices available on request/1 yr	\$50,000 prices available on request/1 yr	\$3,800 varies/1 yr
Unique advantages (provided by vendors)	excellent for low- & mid-volume testing or backup	walkaway testing for routine hemostasis assays	low volume or backup
omque auvantages (proviueu ny venuors)	excenent for low- & mid-volume testing or backup 32 incubation positions for samples, 8 measurement channels, 4 independent built-in timers for incubation; results in seconds and in various units (% ratio, INR, g/L, mg/dL, IU/mL), RS-232 interface lightweight and compact viscosity-based detection system	walkaway testing for routine nemostasis assays viscosity-based detection system able to standardize with other STA analyzers	small footprint—fits anywhere simple to operate

Part 7 of 13	Fisher Diagnostics Paul Gee paul.gee@fishersci.com	Fisher Diagnostics Paul Gee paul.gee@fishersci.com	Helena Laboratories Joe Golias helena@helena.com
See accompanying article, page 56	8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com	8365 Valley Pike, Middletown, VA 22645 540-869-8224 www.fisherdiagnostics.com	1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com
strument name/first year sold	ThromboScreen 400/1996	ThromboScreen 1000/2003	Cascade M/1991
o. of units installed in U.S./outside U.S.	/>150	_/_	>150/—
ountry where analyzer designed/manufactured perational type	Germany/Germany batch, discrete	Germany/Germany batch, random access	U.S./U.S. batch
leagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually)	open reagent system
perates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	carousel	manual
lodel type Dimensions (H x W x D)/weight/instrument footprint	benchtop 5 x 12 x 12 in/10 lbs/1 sq ft	benchtop 28 x 22 x 18 in/35 lbs/3 sq ft	benchtop 8 x 15 x 13 in/25 lbs/1.4 sq ft
	·	·	<u> </u>
DA-cleared clotting-based tests	PT, APTT, Clauss fibrinogen, derived fibrinogen, factor assays, thrombin time, venom time, APC resistance, proteins C&S	PT, APTT, fibrinogen	PT, APTT, fib., TCT, factor assays II, V, VII–XII
DA-cleared chromogenic tests	AT III, heparin	none	none
DA-cleared immunologic tests Ither FDA-cleared tests	none none	none none	none none
ser-defined tests in clinical use	n/a	n/a	PT, APTT, fib., TCT, factor assays II, V, VII–XII
ests submitted for 510(k) clearance	none	none	none
ests in development but not yet submitted	none	thrombin time	dRVVT
lethodologies supported per. must load sep. reag. pack for ea. specimen/test run	clot detection, optical, chromogenic no/no	optical turbodensitometry no/no	clot detection, optical, turbidimetric no/no
o. of different measured assays onboard simultaneously	2	3	1
o. of different assays programmed and calibrated at one time	18	3	1
o. of user-definable (open) channels	n/a	3	2
f those defined, No. active simultaneously actor assays require manual manipulation or dilutions	I VPS	3 n/a	I Ves
actor assays require manual manipulation or ciliutions o. of reag. containers onboard at one time/tests per container	yes 3/varies	n/a 6/varies	yes —/—
eagents refrigerated onboard	no	no	n/a
lultiple reag. configurations supported	yes	yes	n/a
eag., consumables loaded without interrupting testing ame capabilities when 3rd-party reag. used	yes	no voo	no voo
ame capabilities when 3rd-party reag, used lax, time same lot number of reag, can be used	yes 18–24 mos	yes 18–24 mos	yes 12 mos
/alkaway capacity: No. of specimens/No. of tests	n/a/n/a	18/3	no
lin. sample vol. aspirated precisely at one time	50 μL	10 μL	manual–50 μL
tandard specimen vol. required to run PT or PTT/Factor VIII activity	50 μL, min. 50 μL/—	50 μL, min. 50 μL/—	100 μL, min. 50 μL/100 μL (dil.), min. 50 μL (di
isposables used/price of each	cuvettes & pipette tips/prices vary	cuvette bars/prices vary	cuvettes/500@\$54; pipette tips/1,000@\$82
upports direct-from-track sampling	no 	no 	no
rimary tube sampling supported/pierces caps on primary tubes ample bar-code reading capability	no/no no	yes/no yes	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 voo	no no
lot detection as preanalytical variable in plasma sample	no no	yes no	no
uto. detection of adequate reag. for aspir. & anal.	no	yes	no
emolysis/turbidity detection-quantitation	no/no	no/no	no/no
ilution of patient samples onboard	no no/no	yes no/no	no no/no
utomatic rerun capability/auto reflex testing capability ag time during which hypercoagulable samples will not be detected	no/no no	yes (PT: 7 sec; PTT: 14 sec)	no/no yes (PT: 4 sec, PTT: 14 sec)
ead time extended for prolonged clotting times	yes	yes (selectable on menus)	yes (selectable on menus)
ser can set different-than-standard:			
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
utocalibration or autocalib. alert/multipoint calibration supported	no/yes	no/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/120 specimens	<5 min/100 specimens	3 min/120 specimens
PT, PTT	varies	<5 min/50 specimens	7 min/50 specimens
Fibrinogen	<1 min/120 specimens	<5 min/80 specimens	3 min/140 specimens
Factor VIII activity assay	n/a	n/a	7 min/50 specimens
ime delay from ordering stat to aspir. of sample uto. transfer of QC results to LIS	n/a no	<3 min	n/a no
uto. transter of QC results to LIS ata management capability	no no	yes no	no (incl. QC: L-J plots)
terface supplied by instrument vendor	no	no	no
sterfaces in active user sites for:	n/a	n/a	n/a
idirectional interface capability esults transferred to LIS as soon as test time complete	no no	NO Ves	no no
DINC codes transmitted with all results	no	yes no	no
ow labs get LOINC codes for reagent kits	n/a	n/a	-
lectronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	_
Nodem servicing	NO doily 5 min weekly 5 min monthly 5 min	NO daily 5 min weekly 15 min monthly 15 min	NO daily 10 min weekly 10 min monthly 20 min
ime required for maintenance by lab personnel Inboard maintenance records	daily: 5 min; weekly: 5 min; monthly: 5 min no	daily: 5 min; weekly: 15 min; monthly: 15 min no	daily: 10 min; weekly: 10 min; monthly: 20 min
raining provided with purchase upprox. No. of training hours needed per tech	1 day on site 1 h	4 h on site 4 h	1 day on site 2–4 h
ist price	\$6,100	\$18,000	\$6,219
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	varies/1 yr	varies/1 yr	\$714/1 yr
Jnique advantages (provided by vendors)	small footprint—fits anywhere chromogenic assay capability performs kinetic & endpoint determination	instrument low cost, fully automated analyzer for routine coagulation tests simple to operate	QC program onboard curve storage suitable for office lab or as backup analyzer

Part 8 of 13	Helena Laboratories Joe Golias helena@helena.com	Helena Laboratories Joe Golias helena@helena.com	Instrumentation Laboratory/Beckman Coulter In David Schaffner dfschaffner@beckman.com
See accompanying article, page 56	1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com	1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com	200 S. Kraemer Blvd., Brea, CA 92822 714-961-4556 www.beckmancoulter.com
nstrument name/first year sold	Cascade M-4/1992	Packs-4/1991	Electra 1400C/1995
lo. of units installed in U.S./outside U.S.	>100/—	150/180	_/_
Country where analyzer designed/manufactured Operational type	U.S./U.S. random access	U.S./U.S. random access	U.S./U.S. continuous random access
Reagent type	open reagent system	open reagent system	open reagent system (reconst. manually)
Operates on whole blood or spun plasma Sample handling system	spun plasma manual	spun plasma manual	spun plasma automatic pipetting from tray
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	8 x 15 x 13 in/25 lbs/1.4 sq ft	10 x 22 x 23 in/70 lbs/3.5 sq ft	19.7 x 41 x 27.2 in/198 lbs/7.74 sq ft
DA-cleared clotting-based tests	PT, APTT, fib., TCT, factor assays II, V, VII–XII	none	PT, APTT, fib. (Clauss), TT, factor assays, Pfib (lassay-based fib.), protein S
DA-cleared chromogenic tests	none	AT III, F-VIII:C, heparin, plasminogen, protein C	plasminogen, factor VIII, antithrombin, protein C heparin
DA-cleared immunologic tests	none	none	none
Other FDA-cleared tests User-defined tests in clinical use	none PT, APTT, fib., TCT, factor assays II, V, VII–XII	ristocetin cofactor and platelet aggreg. chrom: AT III, F-VIII:C, hep., plasmin., protein C, ristocetin cofactor, platelet aggregADP, EPI, COL, ristocetin, arach. acid	none none
Tests submitted for 510(k) clearance Tests in development but not yet submitted	none dRVVT	none	none none
	•		
Methodologies supported Oper. must load sep. reag. pack for ea. specimen/test run	clot detection, optical, turbidimetric no/no	chromogenic, ristocetin cofactor, platelet aggreg. no/no	clot detection, optical, tungsten; chromogenic no/no
lo. of different measured assays onboard simultaneously	4	4	11
lo. of different assays programmed and calibrated at one time lo. of user-definable (open) channels	4	4 12	11 4
o. or user-definable (open) channels f those defined, No. active simultaneously	2	12 4	4
actor assays require manual manipulation or dilutions	yes 0/n/o	yes	no Atrovico
lo. of reag. containers onboard at one time/tests per container leagents refrigerated onboard	O/n/a no	n/a/n/a no	4/varies yes (8°C ±4)
Iultiple reag. configurations supported	no	no	yes
eag., consumables loaded without interrupting testing ame capabilities when 3rd-party reag. used	no yes	no n/a	yes yes
lax. time same lot number of reag. can be used	12 mos	12 mos	12 mos recommended
/alkaway capacity: No. of specimens/No. of tests	no	no n/o	35/4 10 vl
lin. sample vol. aspirated precisely at one time tandard 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.)	n/a chromogenics: 75 µL, Plt. aggreg.: 225 µL PRP, Risto	10 μL 100 μL, min. 50 μL/100 μL (dil.), min. 50 μL (dil
		cofactor: 50 μL	
lisposables used/price of each	cuvettes/500@\$54; pipette tips/1,000@\$82	cuvettes/200@\$55.65; pipette tips/1,000@\$82; stir bars/30@\$62.25	cuvette, dual well, 560 pk/prices vary; heat exchanger, 10 pk/prices vary
upports direct-from-track sampling rimary tube sampling supported/pierces caps on primary tubes	no no	no no	no yes (13x75, 13x100, 10x85, 10x65, 12x91 mm
Pannala han aada yaadinn aanahiith			Sarstedt)/no
Sample bar-code reading capability Reagent bar-code reading capability	no no	no no	yes no
Inboard test automatic inventory	no	no	yes
Measures No. of tests remaining Short sample detection	no no	no no	yes yes
Clot detection as preanalytical variable in plasma sample	_		no
Auto. detection of adequate reag. for aspir. & anal.	no no /no	no no/no	yes
lemolysis/turbidity detection-quantitation Dilution of patient samples onboard	no/no no	no/no no	no/no yes
Automatic rerun capability/auto reflex testing capability	no/no	no/no	yes/yes
ag time during which hypercoagulable samples will not be detected lead time extended for prolonged clotting times	yes (PT: 4 sec, PTT: 14 sec) yes (selectable on menus)	n/a n/a	yes (PT: 7 sec, PTT: 14 sec) yes (selectable on menus)
lser can set different-than-standard:	you (outoutable on monae)	17,4	you (concottable on montal)
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 Auto shutdown/auto startup programmable	no/yes no/no	no/yes no/no	yes/yes no/no
tat time to completion of all analytes/throughput per hour for:	110/110	110/110	110/110
PT alone	3 min/140 specimens	_	approx. 3 min/200 specimens
PT, PTT Fibrinogen	7 min/80 specimens 3 min/160 specimens	_	approx. 7 min/136 specimens approx. 3 min/160 specimens
Factor VIII activity assay	7 min/80 specimens	20–24 specimens for any test	approx. 7 min/136 specimens
ime delay from ordering stat to aspir. of sample uto. transfer of QC results to LIS	n/a ves	n/a	none ves
ata management capability	yes no (incl. QC: L-J plots)	yes onboard (incl. QC: L-J plots, Westgard)	yes onboard (incl. QC: L-J plots, Westgard)
nterface supplied by instrument vendor	no	no	no
nterfaces in active user sites for:	_	_	Sunquest, Cerner, HBOC, Meditech, Dawning, Antrim, Soft Computer, others
idirectional interface capability	no	no	yes (host query)
esults transferred to LIS as soon as test time complete OINC codes transmitted with all results	yes no	yes no	yes no
ow labs get LOINC codes for reagent kits	_	_	in development
lectronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
lodem servicing ime required for maintenance by lab personnel	NO daily: 10 min: weekly: 10 min: monthly: 20 min	daily 15 min weekly 15 min menthly 1 h	NO daily 5 min weekly 15 min monthly 15 min
ime required for maintenance by lab personnel Onboard maintenance records	daily: 10 min; weekly: 10 min; monthly: 30 min no	daily: 15 min; weekly: 15 min; monthly: 1 h yes	daily: 5 min; weekly: 15 min; monthly: 15 min no
raining provided with purchase pprox. No. of training hours needed per tech	1 day on site 2 h	2 days on site 4–8 h	up to 3 days on site up to 24 h
ist price	\$8,403	\$16,650	\$41,194
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	\$966/1 yr	\$2,079/1 yr	various options available/1 yr
Inique advantages (provided by vendors)	4-channel manual analyzer QC program onboard singles or duplicates	 specialized coag instrument intended for platelet aggreg., ristocetin cofactor, & chromogenics 	integral bar-code readerstandardized test results

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Part 9 of 13	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckman Coulter Inc.	Instrumentation Laboratory/Beckman Coulter Inc
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See accompanying and ice, page 30	www.beckmancoulter.com	www.beckmancoulter.com	www.beckmancoulter.com
Instrument name/first year sold	Electra 1800C/1997	ACL 100/1988	ACL 1000/1991
No. of units installed in U.S./outside U.S.	— —	4,000+ (all models combined)/8,000+ (all models	4,000+ (all models combined)/8,000+ (all models
	,	combined)	combined)
Country where analyzer designed/manufactured	U.S./U.S. continuous random access	Italy/U.S. batch	Italy/U.S. batch
Operational type Reagent type	open reagent system (reconst. manually)	open reagent system, guarantee only IL products	open reagent system, guarantee only IL products
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system Model type	auto pipetting, rack benchtop	tray benchtop	tray benchtop
Dimensions (H x W x D)/weight/instrument footprint	25 x 48 x 30.4 in/283 lbs/10.13 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (Clauss), TT, factor assays, Pfib (PT	PT, APTT, fib. (PT-based), factor assays (extrinsic &	PT, APTT, fib. (PT-based), factor assays (extrinsic
	assay-based fib.), protein S	intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR, Clauss fib.	intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.
FDA-cleared chromogenic tests	plasminogen, factor VIII, antithrombin, protein C, heparin	none	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests User-defined tests in clinical use	none	none	none
Tests submitted for 510(k) clearance	none none	none none	none none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clot detection, optical, tungsten; chromogenic	clot detection, optical, nephelometric	clot detection, optical, nephelometric
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	12	3	3
No. of different assays programmed and calibrated at one time No. of user-definable (open) channels	12 4	1 0	1 0
Of those defined, No. active simultaneously	4	0	0
Factor assays require manual manipulation or dilutions	no S/varion	yes	yes
No. of reag. containers onboard at one time/tests per container Reagents refrigerated onboard	6/varies yes (8°C ±4)	3/varies by test yes (15°C)	3/varies by test yes (15°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded without interrupting testing Same capabilities when 3rd-party reag. used	yes	no vos	no vos
Max. time same lot number of reag. can be used	yes 12 mos recommended	yes 18 mos	yes 18 mos
Walkaway capacity: No. of specimens/No. of tests	100/4	18/36	18/36
Min. sample vol. aspirated precisely at one time Standard specimen vol. required to run PT or PTT/factor VIII activity	10 µL 100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)	10 μL 50 μL (PT), 53 μL (PTT)/40 μL	10 μL 50 μL (PT), 53 μL (PTT)/40 μL
Disposables used/price of each	cuvette, single well, 2,000 pk/price varies; heat exchanger, 10 pk/price varies	sample cups/price varies; rotors/price varies	rotors/price varies
	excitatiget, to propriee varies		
Supports direct-from-track sampling Primary tube sampling supported/pierces caps on primary tubes	no yes [13x75, 13x100 (closed & open tubes),	no no/no	no yes (13 x 75 mm)/no
	10x85,10x65, 12x91 Sarstedt (open)]/yes	10/110	
Sample bar-code reading capability Reagent bar-code reading capability	yes no	no	yes (optional) no
Onboard test automatic inventory	yes	no no	no
Measures No. of tests remaining	yes	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
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard	no/no yes	no/no yes	no/no yes
Automatic rerun capability/auto reflex testing capability	yes/yes	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: 7 sec, PTT: 14 sec)	yes (PT & PTT: 5.6 std, 6.7 ext)	yes (PT & PTT: 5.6 std, 6.7 ext)
Read time extended for prolonged clotting times User can set different-than-standard:	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
Reag. volumes/sample volumes	yes/yes	no/no	no/no
No. and sources of reag. Incub. times/reading times	yes vec/vec	no no/vos	no no/vos
Autocalibration or autocalib. alert/multipoint calibration supported	yes/yes yes/yes	no/yes 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:	0.1/22	EE : 1440	
• PT alone • PT, PTT	approx. 3 min/228 specimens approx. 7 min/120 specimens	5.5 min/110 specimens 8.5 min/80 specimens	5.5 min/110 specimens 8.5 min/80 specimens
• Fibrinogen	approx. 7 min/120 specimens	5.5 min/110 specimens	5.5 min/110 specimens
Factor VIII activity assay	approx. 7 min/120 specimens	9.5 min/80 specimens	9.5 min/80 specimens
Time delay from ordering stat to aspir. of sample Auto. transfer of QC results to LIS	none yes	15 sec no	15 sec no
Data management capability	onboard (incl. QC: L-J plots, Westgard)	no	no
Interface supplied by instrument vendor Interfaces in active user sites for:	no Sunquest, Cerner, HBOC, Meditech, Dawning,	no most major LIS vendors	no most major LIS vendors
	Antrim, Soft Computer, others	oc major 210 vonuoio	oct major 210 temuna
Bidirectional interface capability	yes (host query)	no ves	NO VAS
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	in development	in development	in development
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 10 min; weekly: 25 min; monthly: 30 min	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: 10 min; weekly: 15 min; monthly: 10 min
Onboard maintenance records	no up to 3 days on site	yes 2 days on site	yes 2 days on site
Training provided with purchase Approx. No. of training hrs needed per tech	up to 3 days on site 24 h max.	2 days on site 2 h	2 days on site 6 h
rippioni noi or manning me nooned per toon	A	\$16,000	\$21,500
List price	\$73,645 various options available/1 vr	various options available/1 vr	various options available/1 vr
List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	various options available/1 yr	various options available/1 yr	various options available/1 yr
List price		• part of the ACL family, uses same consumables/ reagents	part of ACL family, uses same consumables/reagents
List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	various options available/1 yr • cap piercing	• part of the ACL family, uses same consumables/	• part of ACL family, uses same

Part 10 of 13	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822	Instrumentation Laboratory/Beckman Coulter Inc. David Schaffner dfschaffner@beckman.com 200 S. Kraemer Blvd., Brea, CA 92822
See accompanying article, page 56	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 7000/1997	ACL 9000/2000	ACL Advance/2000
No. of units installed in U.S./outside U.S.	4,000+ (all models combined)/8,000+ (all models	300+/600+	500+/1,000+
Country where analyzer designed/manufactured	combined) Italy/U.S.	Italy/U.S.	U.S./U.S.
Operational type	random programming	random access	random access
Reagent type Operates on whole blood or spun plasma	open reagent system, guarantee only IL products spun plasma	open reagent system spun plasma	open reagent system, guarantee only IL products spun plasma
Sample handling system	tray	tray	racks, up to 12
Model type Dimensions (H x W x D)/weight/instrument footprint	benchtop 17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	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
	<u>`</u>	<u>`</u>	·
FDA-cleared clotting-based tests	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.	PT, APTT, PT-based fib., Clauss fib., TT, factor assays, proteins C & S, LAC screen, LAC confirm, APCR-V	PT, APTT, PT-based fib., Clauss fib., TT, factor assays, protein C, LAC screen, LAC confirm, APCR-V
FDA-cleared chromogenic tests	antithrombin, heparin Xa, plasminogen, antiplasmin, protein C	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin, factor VIII	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin
FDA-cleared immunologic tests	D-dimer (latex enhanced immunoassay), vWF	D-dimer (latex enhanced immunoassay), vWF (latex enhanced immunoassay), free protein S	D-dimer (latex enhanced immunoassay), vWF, free protein S
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use Tests submitted for 510(k) clearance	none none	none HS-CRP	none HS-CRP, protein S
Tests in development but not yet submitted	none	vWF activity	vWF activity
Methodologies supported	clot detection, optical, nephelometric; chromogenic;	clot detection, optical, nephelometric; chromogenic;	clot detection, optical; chromogenic; immunologic
Once must load can was mark for an analysis of the form	immunologic (optical, latex enhanced immunoassay)	immunologic	(optical, latex enhanced immunoassay)
Oper. must load sep. reag. pack for ea. specimen/test run No. of different measured assays onboard simultaneously	no/no 4	no/no 18	no/no varies with test-reagent combination, limited only
No. of different assays programmed and calibrated at one time	1	1	by No. of reag. positions 1
No. of user-definable (open) channels Of those defined, No. active simultaneously	10 (requires optional research package) 1	total test capacity: 300 (IL test channels 120+ open) varies with test-reagent combination	total test capacity: 100 (IL test channels + open) varies with test-reagent combination
Factor assays require manual manipulation or dilutions	no	no	no
No. of reag. containers onboard at one time/tests per container	3/varies by test	18/varies by test	42/varies by test, container size
Reagents refrigerated onboard Multiple reag. configurations supported	yes (15°C) yes	yes (15°C) yes	yes (15°C) yes
Reag., consumables loaded without interrupting testing	no	no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	18 mos 18/36	18 mos	18 mos 120/variable
Walkaway capacity: No. of specimens/No. of tests Min. sample vol. aspirated precisely at one time	10/30 10 µL	40/260 5 μL	10 µL
Standard specimen vol. required to run PT or PTT/factor VIII activity	50 μL (PT), 53 μL (PTT)/40 μL	50 μL/40 μL	50 μL /10 μL
Disposables used/price of each	rotors/price varies	rotors/price varies	cuvettes/price varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes (13 x 75 mm)/no	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes/no
Sample bar-code reading capability Reagent bar-code reading capability	yes	yes	yes
Onboard test automatic inventory	no no	no yes	no no
Measures No. of tests remaining	no	yes	no
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample Auto. detection of adequate reag. for aspir. & anal.	no yes	no yes	no yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	yes/yes
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/auto reflex testing capability	no/no	yes/yes	yes/no
Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times	yes (PT & PTT: 5.6 std, 6.7 ext) yes (selectable on menus)	yes (PT & PTT: 3 sec) yes (selectable on menus)	yes (PT: 7 sec., PTT: 10 sec) yes (selectable on menus)
User can set different-than-standard:	you (constitute on menus)	you (concernant on monato)	you (ostiootaaro on monae)
Reag. volumes/sample volumes No and sources of reag.	no/no	yes/yes	yes/yes
No. and sources of reag. Incub. times/reading times	no no/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	no/no
Stat time to completion of all analytes/throughput per hour for:			
• PT alone	5.5 min/175 specimens	4 min/175 specimens	2.5 min/240 specimens
• PT, PTT • Fibrinogen	8.5 min/110 specimens 5.5 min/175 specimens	8 min/110 specimens 4 min/175 specimens	8 min/180 specimens 2.5 min/240 specimens
Factor VIII activity assay	9.5 min/110 specimens	varies/110 specimens	2.5 min/180 specimens
Time delay from ordering stat to aspir. of sample	15 sec	15 sec	20 sec
Auto. transfer of QC results to LIS Data management capability	yes onboard (incl. QC: L-J plots)	yes onboard (incl. QC: L-J plots)	yes onboard (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	onboard (inci. QG: L-J piots) no	onboard (inci. qg: L-3 piots) no
Interfaces in active user sites for:	most major LIS vendors	_	most major LIS vendors
Bidirectional interface capability	yes (host query)	yes (broadcast download & host query)	yes (broadcast download)
Results transferred to LIS as soon as test time complete LOINC codes transmitted with all results	yes no	yes no	yes no
How labs get LOINC codes for reagent kits	in development	in development	in development
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel Onboard maintenance records	daily: 10 min; weekly: 15 min; monthly: 10 min	weekly: 10 min; monthly: 5 min; biweekly: 5 min	daily: 15 min; weekly: 15 min; monthly: 10 min
	yes 2 days on site	yes 5 days at vendor offices in Miami	yes 5 days at vendor offices in Miami
Training provided with purchase	•	varies	24 h
Training provided with purchase Approx. No. of training hrs needed per tech	12 h		
*·	\$45,000 various options available/1 yr	\$61,950 various options available/1 yr	\$79,500 various options available/1 yr
Approx. No. of training hrs needed per tech List price	\$45,000 various options available/1 yr • part of ACL family, uses same	various options available/1 yr • robotic transport arm	• extensive menu of clotting, chromogenic, &
Approx. No. of training hrs needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	\$45,000 various options available/1 yr • part of ACL family, uses same consumables/reagents	various options available/1 yr robotic transport arm extensive menu of clotting, chromogenic, &	various options available/1 yr extensive menu of clotting, chromogenic, & immunologic assays
Approx. No. of training hrs needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	\$45,000 various options available/1 yr • part of ACL family, uses same consumables/reagents • quantitative PT-based fib.	various options available/1 yr robotic transport arm extensive menu of clotting, chromogenic, & immunological assays in a small footprint	various options available/1 yr extensive menu of clotting, chromogenic, & immunologic assays high throughput
Approx. No. of training hrs needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	\$45,000 various options available/1 yr • part of ACL family, uses same consumables/reagents	various options available/1 yr robotic transport arm extensive menu of clotting, chromogenic, &	various options available/1 yr extensive menu of clotting, chromogenic, & immunologic assays

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See accompanying article, page 56	www.beckmancoulter.com	www.beckmancoulter.com	www.trinitybiotech.com
	www.bookmanooutor.oom	WWW.bookinghoutor.bom	www.anntybiotoon.com
Instrument name/first year sold	ACL 8000/2003	ACL 10000/2003	KC1∆/2001
,			
No. of units installed in U.S./outside U.S.	-/-	—/—	>100/>100
Country where analyzer designed/manufactured	Italy/U.S.	Italy/U.S.	Germany/Germany
Operational type	batch	batch	semiautomatic, single channel
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system Model type	tray benchtop	tray benchtop	manual
Dimensions (H x W x D)/weight/instrument footprint	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	benchtop 3.25 x 5.5 x 8.25 in/2.5 lbs/<1 sq ft
binicisions (if x w x b), weight instrument tootprint	25.0 X 50.2 X 20.0 III/ 150.0 ID5/0 54 It	20.0 X 30.2 X 20.0 III/ 100.0 IB3/0 34 It	0.20 X 0.3 X 0.20 III/2.0 Ib3/~1 34 It
FDA-cleared clotting-based tests	PT, APTT, TT, PT-based fib., Clauss fib., factor assays,	PT, APTT, TT, PT-based fib., Clauss fib., factor assays,	PT, APTT, fib., TT, instrinsic & extrinsic factors
	protein S & C, LAC screen, LAC confirm, APCR-V	protein S & C, LAC screen, LAC confirm, APCR-V	
FDA-cleared chromogenic tests	antithrombin, liquid antithrombin, factor VIII, heparin,	antithrombin, liquid antithrombin, factor VIII, heparin,	n/a
FDA alcohol immunication tooks	plasmin inhibitor, plasminogen, protein C	plasmin inhibitor, plasminogen, protein C	m/a
FDA-cleared immunologic tests	D-dimer (latex-enhanced immunoassay), vWF (latex- enhanced immunoassay), free protein S (latex	D-dimer (latex-enhanced immunoassay), vWF (latex- enhanced immunoassay), free protein S (latex	n/a
	turbidimetric ligand immunoassay)	turbidimetric ligand immunoassay)	
Other FDA-cleared tests	none	none	n/a
User-defined tests in clinical use	none	none	n/a
Tests submitted for 510(k) clearance	vWF activity, HS-CRP	vWF activity, HS-CRP	n/a
Tests in development but not yet submitted	silica clotting time, global protein C pathway, homocyst.	silica clotting time, global protein C pathway, homocyst.	n/a
Methodologies supported	clot detection, optical (tungsten, nephelometric);	clot detection, optical (tungsten, nephelometric);	clot detection, mechanical
One would had	chromogenic; immunologic	chromogenic; immunologic	
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	18	22	1 manual
No. of different assays programmed and calibrated at one time	1 300 (IL test channels 120+ open)	300 (II test channels 120± open)	manual n/a
No. of user-definable (open) channels Of those defined, No. active simultaneously	varies with test-reagent combination	300 (IL test channels 120+ open) varies with test-reagent combination	n/a n/a
Factor assays require manual manipulation or dilutions	no	no	yes
No. of reag. containers onboard at one time/tests per container	18/varies	22/varies	1/varies for each assay
Reagents refrigerated onboard	yes (15°C)	yes (15°C)	no
Multiple reag. configurations supported	yes	yes	no
Reag., consumables loaded without interrupting testing	no no	no	n/a, manual
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	18 mos	18 mos	12–18 mos
Walkaway capacity: No. of specimens/No. of tests	40/260	40/260	n/a, manual
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	n/a
Standard specimen vol. required to run PT or PTT/factor VIII activity	PT: 60 μL, min. 160; PTT: 63 μL, min. 163/18 μL, min. 118 μL	PT: 60 μL, min. 160; PTT: 63 μL, min. 163/18 μL, min. 118 μL	50 μL/10 μL
Disposables used/price of each	rotors/price varies	rotors/price varies	cuvettes & ball dispenser/inquire
	10107 p. 100 141100		
Supports direct-from-track sampling	no	no	n/a
Primary tube sampling supported/pierces caps on primary tubes	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	n/a
Sample bar-code reading capability	yes	yes	n/a
Reagent bar-code reading capability	no	no	n/a
Onboard test automatic inventory	yes	yes	n/a
Measures No. of tests remaining Short sample detection	yes	yes	n/a n/a
Clot detection as preanalytical variable in plasma sample	yes no	yes no	n/a
Auto. detection of adequate reag. for aspir. & anal.	no	no	n/a
Hemolysis/turbidity detection-quantitation	no/no	no/no	n/a
Dilution of patient samples onboard	yes	yes	n/a
Automatic rerun capability/auto reflex testing capability	yes/yes	yes/yes	n/a
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 3 sec)	yes (PT & PTT: 3 sec)	yes (PT & PTT: 4.5 sec)
		1	
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes
Read time extended for prolonged clotting times User can set different-than-standard:	,		
Read time extended for prolonged clotting times User can set different-than-standard: • Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
Read time extended for prolonged clotting times User can set different-than-standard: Reag. volumes/sample volumes No. and sources of reag.	yes/yes yes	yes/yes yes	yes/yes yes
Read time extended for prolonged clotting times User can set different-than-standard: Reag. volumes/sample volumes No. and sources of reag. Incub. times/reading times	yes/yes yes yes/yes	yes/yes yes yes/yes	yes/yes yes yes/yes
Read time extended for prolonged clotting times 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	yes/yes yes	yes/yes yes	yes/yes yes
Read time extended for prolonged clotting times 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 yes yes/yes no/yes	yes/yes yes yes/yes no/yes	yes/yes yes yes/yes no/yes
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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. Incub. times/reading times 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	yes/yes yes yes/yes no/yes no/no 4 min/175 specimens 8 min/110 specimens	yes/yes yes yes/yes no/yes no/no 4 min/175 specimens 8 min/110 specimens	yes/yes yes yes/yes no/yes no/no 75 sec/48 tests 350 sec/10 tests
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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. Incub. times/reading times 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 Approx. No. of training hours needed per tech List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	yes/yes yes yes/yes no/yes no/yes no/no 4 min/175 specimens 8 min/110 specimens 4 min/175 specimens varies/110 specimens 15 sec yes onboard (incl. QC: L-J plots) no n/a yes (broadcast download & host query) yes no — no no weekly: 10 min; monthly: 5 min; biweekly: 5 min yes on site varies/5 days at vendor offices varies \$52,000 various options available/1 yr	yes/yes yes yes/yes no/yes no/no 4 min/175 specimens 8 min/110 specimens 4 min/175 specimens varies/110 specimens 15 sec yes onboard (incl. QC: L-J plots) no n/a yes (broadcast download & host query) yes no — no no weekly: 10 min; monthly: 5 min; biweekly: 5 min yes on site varies/5 days at vendor offices varies \$59,995 various options available/1 yr	yes/yes yes yes/yes no/yes no/no 75 sec/48 tests 350 sec/10 tests 65 sec/55 tests 275 sec/13 tests n/a yes yes no n/a n/a none n/a as needed on site 2 h \$2,100 \$364 (M-F, 8-5)/1 yr • half volume PT & APTT testing for significant reagent savings
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Doub 10 of 10	Trinity Biotech	Trinity Biotech	Trinity Biotech
Part 12 of 13	Venita Shirley shirleyvc@trinityusa.com	Venita Shirley shirleyvc@trinityusa.com	Venita Shirley shirleyvc@trinityusa.com
	1930 Innerbelt Business Center Dr., St. Louis, MO 63114	1930 Innerbelt Business Center Dr., St. Louis, MO 63114	1930 Innerbelt Business Center Dr., St. Louis, MO 6311
See accompanying article, page 56	800-325-3424	800-325-3424	800-325-3424
	www.trinitybiotech.com	www.trinitybiotech.com	www.trinitybiotech.com
Instrument name/first year sold	KC4∆/2001	Amax 200/2001	Amax 400/1997
No. of units installed in U.S./outside U.S.	>100/>100	>200/>200	<50/<50
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	semiautomatic, 4 channels	random access	random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system Model type	manual benchtop	60-position continuous addition sample rack benchtop or floor standing	continuous feed sample chain floor standing
Dimensions (H x W x D)/weight/instrument footprint	4.7 x 13.9 x 17.7 in/14 lbs/1.7 sq ft	BT: 25 x 32.75 x 28.75 in/286 lbs/6.5 sq ft	52 x 56 x 27 in/803 lbs/10.5 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., TT, atroxin, intrinsic & extrinsic factors	APTT, atroxin, fib., PT, proteins C & S, TT, intrinsic &	PT, APTT, fib., TT, intrinsic & extrinsic factors,
		extrinsic factors, dRVVT	proteins C & S, dRVVT
FDA-cleared chromogenic tests FDA-cleared immunologic tests	n/a n/a	antithrombin, plasminogen, heparin-Xa, protein C D-dimer	heparin-Xa, antithrombin, plasminogen, protein C D-dimer
Other FDA-cleared tests	n/a	none	none
User-defined tests in clinical use	n/a	PT & APTT mixing studies, Plt. neutralization, Kaolin	PT & APTT mixing studies, Plt. neutralization, Kaoli
		clotting time, activated protein C resistance, protein S	clotting time, protein S (immunol.), vWF assay
		(immunol.), vWF assay (immunol.), thrombotest, heparin	(immunol.), thrombo test, heparin cofactor II, alpha
Tools submitted for F40(h) clearence	7/2	cofactor II, alpha-2 antiplasmin	antiplasmin
Tests submitted for 510(k) clearance Tests in development but not yet submitted	n/a n/a	none none	activated protein C resistance none
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Methodologies supported	clot detection, mechanical	clot detect., mechanical; clot detect., optical (tungsten, turbidimetric); chromogenic; immunologic (microparticles)	clot detect., mechanical; clot detect., optical (tungsten, turbidimetric); chromogenic; immunologic (micropartic
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	5	32	40
No. of different assays programmed and calibrated at one time	1/1	32	40
No. of user-definable (open) channels Of those defined, No. active simultaneously	n/a up to 4	32 12	40 40
or those defined, No. active simultaneously Factor assays require manual manipulation or dilutions	up to 4 yes	12 no	40 no
No. of reag. containers onboard at one time/tests per container	5/varies for test kit	24/varies with kit & operational mode	24/varies with assay & operational mode
Reagents refrigerated onboard	no	yes (15°C)	yes (15°C)
Multiple reag. configurations supported	no	yes	yes
Reag., consumables loaded without interrupting testing	n/a, manual	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used Walkaway capacity: No. of specimens/No. of tests	12–18 mos n/a, manual	12–18 mos 60/450	12–18 mos 1,250/450
Min. sample vol. aspirated precisely at one time	n/a	5 μL	3 µL
Standard specimen vol. required to run PT or PTT/factor VIII activity	50 μL/10 μL	25 μL/10 μL	25 μL/10 μL
Disposables used/price of each	cuvettes & ball dispenser/inquire	cuvettes/—, probe decontaminate/—	cuvettes/—, probe decontaminate/—, tubing/—
Supports direct-from-track sampling	n/a	no	no
Primary tube sampling supported/pierces caps on primary tubes	n/a	yes/no	yes/no
Sample bar-code reading capability	n/a	yes	yes
Reagent bar-code reading capability	n/a	no	no
Onboard test automatic inventory Measures No. of tests remaining	n/a	yes	yes
Short sample detection	n/a n/a	yes yes	yes yes
Clot detection as preanalytical variable in plasma sample	n/a	no	no
Auto. detection of adequate reag. for aspir. & anal.	n/a	yes	yes
Hemolysis/turbidity detection-quantitation	n/a	not necessary	not necessary
Dilution of patient samples onboard	n/a	yes	yes
Automatic rerun capability/auto reflex testing capability	n/a	yes/no	yes/yes (out of test)
Lag time during which hypercoagulable samples will not be detected Read time extended for prolonged clotting times		yes (4.5 sec)	yes (4.5 sec)
User can set different-than-standard:	yes	yes	yes
Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
No. and sources of reag.	yes	yes	yes
Incub. times/reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/auto startup programmable	no/no	yes/yes	yes/yes
Stat time to completion of all analytes/throughput per hour for:	75 ann (40 tanta	00 000/400 toota	00 000/205 tooks
• PT alone • PT, PTT	75 sec/48 tests 350 sec/10 tests	90 sec/190 tests 300 sec/120 tests	90 sec/325 tests 300 sec/480 tests
• Fibrinogen	65 sec/55 tests	70 sec/120 tests	70 sec/212 tests
• Factor VIII activity assay	275 sec/13 tests	300 sec/120 tests	300 sec/200 tests
Time delay from ordering stat to aspir. of sample	n/a	varies by test	varies by test
Auto. transfer of QC results to LIS	yes	yes	yes
-	yes	onboard (incl. QC: L-J plots, Westgard)	onboard (incl. QC: L-J plots, Westgard)
Data management capability		no all maior LIS vendors	no all major LIS vendors
Interface supplied by instrument vendor	<u>no</u>	all major cia vendors	an major are remuere
		yes (broadcast download & host query)	yes (broadcast download & host query)
Interface supplied by instrument vendor Interfaces in active user sites for:	_		yes (broadcast download & host query) yes
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	n/a	yes (broadcast download & host query) yes yes	
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	n/a yes —	yes (broadcast download & host query) yes yes	yes yes
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	n/a yes —	yes (broadcast download & host query) yes yes	yes
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	n/a yes — — n/a	yes (broadcast download & host query) yes yes — no	yes yes — yes
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	n/a yes —	yes (broadcast download & host query) yes yes	yes yes
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	n/a yes n/a n/a	yes (broadcast download & host query) yes yes no	yes yes yes yes
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	n/a yes n/a n/a n/a n/a n/a as needed on site	yes (broadcast download & host query) yes yes — no yes daily: <2 min; weekly: <35 min; monthly: <5 min no 5 days on site, 4 days at vendor office	yes yes yes yes yes daily: <10 min; weekly: <30 min; monthly: <5 min yes 5 days on site, 5 days at vendor office
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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 h/7 d)/warranty with purchase	n/a yes n/a n/a n/a none n/a as needed on site 2 h \$9,200 \$936 (M-F, 8-5)/1 yr	yes (broadcast download & host query) yes yes — no yes daily: <2 min; weekly: <35 min; monthly: <5 min no 5 days on site, 4 days at vendor office 16–24 h \$81,000 —/1 yr	yes yes yes yes daily: <10 min; weekly: <30 min; monthly: <5 min yes 5 days on site, 5 days at vendor office 48–72 h \$132,000 —/1 yr
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	n/a yes n/a n/a n/a none n/a as needed on site 2 h \$9,200 \$936 (M-F, 8-5)/1 yr • uses half volume for PT & APTT, reduced volume for	yes (broadcast download & host query) yes yes	yes yes yes yes daily: <10 min; weekly: <30 min; monthly: <5 min yes 5 days on site, 5 days at vendor office 48–72 h \$132,000 -/1 yr • true clot detection
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 h/7 d)/warranty with purchase	n/a yes n/a n/a n/a none n/a as needed on site 2 h \$9,200 \$936 (M-F, 8-5)/1 yr	yes (broadcast download & host query) yes yes	yes yes yes yes daily: <10 min; weekly: <30 min; monthly: <5 min yes 5 days on site, 5 days at vendor office 48–72 h \$132,000 —/1 yr
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Part 13 of 13	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, MO 63114	Trinity Biotech Venita Shirley shirleyvc@trinityusa.com 1930 Innerbelt Business Center Dr., St. Louis, MO 63114
See accompanying article, page 56	800-325-3424 www.trinitybiotech.com	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.	<50/<50	25/<25
Country where analyzer designed/manufactured Operational type	Germany & U.S./Germany random access	Germany/Germany discrete
Reagent type	open reagent system	uses MiniQuant D-dimer reagents
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system Model type	50 positions/5 racks benchtop	single cuvettes handheld-portable
Dimensions (H x W x D)/weight/instrument footprint	22 x 33 x 27 in/165 lbs/150 sq ft	4.3 x 7.9 x 8.9 in/2.75 lbs/1 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, & XII	none
FDA-cleared chromogenic tests	AT	none
FDA-cleared immunologic tests	D-dimer	D-dimer, quantitative microlatex
Other FDA-cleared tests User-defined tests in clinical use		none D-dimer
Tests submitted for 510(k) clearance	_	none
Tests in development but not yet submitted	_	none
Methodologies supported	clot detect., mechanical; clot detect., optical (turbidimetric); chromogenic; immunologic	immunologic (quantitative microlatex)
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no
No. of different measured assays onboard simultaneously	10 unlimited	1
No. of different assays programmed and calibrated at one time No. of user-definable (open) channels	unimited unlimited	<u>-</u>
Of those defined, No. active simultaneously	10	1
Factor assays require manual manipulation or dilutions	no	n/a
No. of reag. containers onboard at one time/tests per container	30/varies	—/50
Reagents refrigerated onboard Multiple reag. configurations supported	yes (12–16°C) yes	no no
Reag., consumables loaded without interrupting testing	yes	no
Same capabilities when 3rd-party reag. used	yes	no
Max. time same lot number of reag. can be used	varies by reagent	n/a
Walkaway capacity: No. of specimens/No. of tests Min. sample vol. aspirated precisely at one time	50/240 5 μL	n/a/n/a n/a
Standard specimen vol. required to run PT or PTT/factor VIII activity	50 μL/10 μL	n/a/n/a
Disposables used/price of each	reaction trays, ProWash/—	cuvettes/—
Supports direct-from-track sampling Primary tube sampling supported/pierces caps on primary tubes	no yes (standard, pediatric, micro)/no	no no/no
Sample bar-code reading capability	yes	no
Reagent bar-code reading capability	10	no
Onboard test automatic inventory Measures No. of tests remaining	yes yes	no no
Short sample detection	yes	no
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no no /no
Hemolysis/turbidity detection-quantitation Dilution of patient samples onboard	not necessary yes	no/no no
Automatic rerun capability/auto reflex testing capability	yes/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (3 sec)	n/a
Read time extended for prolonged clotting times	yes	n/a
User can set different-than-standard: • Reag. volumes/sample volumes	yes/yes	n/a
No. and sources of reag.	yes yes	n/a
Incub. times/reading times	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
	100,100	.J.W.IV.G
Stat time to completion of all analytes/throughput per hour for: • PT alone	<3 min/90 tests	-/-
• PT, PTT	-/-	-/-
Fibrinogen Factor VIII activity assay	—/— —/—	—/— —/—
Time delay from ordering stat to aspir. of sample	varies by test	
Auto. transfer of QC results to LIS	yes	no
Data management capability	onboard (incl. QC: L-J plots, Westgard)	no
Interface supplied by instrument vendor Interfaces in active user sites for:	no all major LIS vendors	- -
Bidirectional interface capability	yes (broadcast download & host query)	no
Results transferred to LIS as soon as test time complete	yes	no
LOINC codes transmitted with all results How labs get LOINC codes for reagent kits	yes —	no n/a
Electronic interface available (or will be) to automated	no	no
(or robotic) specimen handling system		
Modem servicing	no por chift: <2 min: weakly: <20 min: monthly: <5 min	no daily 5 min
Time required for maintenance by lab personnel Onboard maintenance records	per shift: <2 min; weekly: <30 min; monthly: <5 min yes	daily: 5 min no
Training provided with purchase	2 days on site	1 day on site
Approx. No. of training hours needed per tech	8 h	2 h
List price Ann. svc. contract cost (24 h/7 d)/warranty with purchase	\$49,000 —/1 yr	\$5,150 —/1 yr
Unique advantages (provided by vendors)	• true clot detection	• quantitative D-dimer
	IntuiTouch software expanded test menu (D-dimer)	• read time—5 minutes • easy to use
	- expanueu test inenu (D-uniter)	- Gasy IU use