SURVEY OF

Coagulation Analyzers

Part 1 of 11	American LAbor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de	American LAbor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de	American LAbor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad St., Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org & www.labitec.de
Instrument name/first year sold	CD2000/1986	CoaData 4001/FDA clearance pending	CoaLab 6000/available spring 2002
No. of units installed in U.S./outside U.S.	>500/>1,000	0/<500	0/<500
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	batch, discrete	discrete	discrete, batch
Reagent type	open reagent system (reconst. manually)	open reagent system (reconst. manually)	cuvette bar–open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	cuvette, semiautomated	automated
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	5 x 12 x 8.5 in/9.2 lbs/1 sq ft	11 x 14 x 5 in/9 lbs/—	28 x 18 x 22 in/44 lbs/—
FDA-cleared clotting-based tests	PT, PTT, fib., any citrated plasma clot-based assay	FDA clearance pending	FDA clearance pending
FDA-cleared chromogenic tests	none		
FDA-cleared immunologic tests	none		
Other FDA-cleared tests	none		
User-defined tests in clinical use	none		
Tests submitted for 510(k) clearance	none		
Tests in development but not yet submitted	none		PT, APTT, fib. (FDA pending)
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing–optical detection	optical-turbodensitometry	optical-turbodensitometry
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	1st batch only
No. of different measured assays onboard simultaneously	2 (PT, APTT)	1	up to 7
No. of different assays programmed and calibrated at one time	1 (fib.)	1	all
No. of user-definable (open) channels	2	4	6
Of those defined, no. active simultaneously	2	4	all
Factor assays require manual manipulation or dils	yes	yes	no
No. of reag. containers onboard at one time/tests per container	5 or more/ reag. mftr. dependent	4/1	6/1
Reagents refrigerated onboard	no	no	no
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded w/o interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	laboratory dependent	mftr. dependent	mftr. dependent
Walkaway capacity: no. of specimens/no. of tests	no	no	18/3
Min. sample vol. aspirated precisely at one time	manual pipetting	manual	50 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 50 µL/50 µL, min. 50 µL	50 µL, min. 50 µL/50 µL, min. 50 µL	50 µL, min. 50 µL/50 µL, min. 50 µL
Disposables used/price of each	500 micro cuvette w/ mixers in trays/11.6¢ ea., bulk 11¢ ea.; 500 macro cuvette w/ mixers in trays/12¢ ea., bulk 10.6¢ ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3,000 tips bulk 3.9¢ ea.	microcuvette (150–250) UL 7¢ ea.; 2,304 pipette tips trayed/5.1¢ ea., 3,000 tips bulk/3.9¢ ea.	cuvette rack w/ 6 cuvettes (125–250)/7¢ ea.
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	no/no	no/no	no/no
Sample bar-code reading capability	no	no	yes
Reagent bar-code reading capability	no	no	yes
Onboard test automatic inventory	no	no	yes
Measures no. of tests remaining	no	no	no
Short sample detection	no	no	yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	no	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	no	yes
Automatic rerun capability/auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (3 sec)	yes (3 sec)	yes (3 sec)
Read time extended for prolonged clotting times	yes, up to 999 sec	yes, up to 999 sec (selectable on menus)	yes, up to 999 sec (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/no	no/no	no/no
Auto shutdown/auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes and throughput per h. for:			
• PT alone	120 sec/user defined	120 sec/open, reag. mftr. defined	>120 PT, open, reag. mftr. defined
• PT, PTT	240 sec/user defined	240 sec/open, reag. mftr. defined	open, reag. mftr. defined
• Fibrinogen	300 sec/user defined	300 sec/open, reag. mftr. defined	open, reag. mftr. defined
• Factor VIII activity assay	300 sec/user defined	300 sec/open, reag. mftr. defined	open, reag. mftr. defined
Time delay from ordering stat to aspir. of sample	none—all preanalytical	none	<60 sec
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	no	yes
Interface supplied by instrument vendor	no	no	yes
Interfaces in active user sites for:	call technical support for inquiry	call technical support for inquiry	call technical support for inquiry
Bidirectional interface capability	no	no	no
Results transferred to LIS as soon as test time complete	yes	no	yes—end of run
LOINC codes transmitted with all results	no	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 30 sec (temp. check, cloth cleaning); weekly: 30 sec; monthly: 5 min (temp. calib. if needed)	daily: 5 min; weekly: 15 min; monthly: 15 min	daily: 5 min; weekly: 15 min; monthly: 15 min
Onboard maintenance records	no	no	no
Training provided with purchase	videotape; on-site training extra	yes	yes
Approx. no. of training hrs needed per tech	2 h	2 h	2 h
List price	$4,200, special pricing avail. upon written request for quotation	TBD	TBD
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	additional 2-yr initial contract $900 (optional)/1 yr	TBD	TBD
Unique advantages	• smaller clinic; office, private, vet labs • low acquisition & svc. cost, low maintenance • refurbished units avail. at reduced prices • able to handle turbid/colored samples	• economic, semiautomated coagulation analyzer for routine laboratories & backup for automated analyzers/confirmation testing	•the smallest automatic coagulation batch analyzer for emergency/stat/routine requirements

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

Survey editor: Raymond Aller, MD

SURVEY OF

Coagulation Analyzers

Part 2 of 11	bioMérieux Inc. Ginny Meihaus ginny.meihaus@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2000 www.biomerieux-usa.com	bioMérieux Inc. Ginny Meihaus ginny.meihaus@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2000 www.biomerieux-usa.com	bioMérieux Inc. Ginny Meihaus ginny.meihaus@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2000 www.biomerieux-usa.com
Instrument name/first year sold	Coag-A-Mate MAX/1999	Coag-A-Mate MTX II/1999 (sold as MTX since 1997)	Coag-A-Mate XM/1989
No. of units installed in U.S./outside U.S.	>100 worldwide	>500 worldwide	>2,000 worldwide
Country where analyzer designed/manufactured	Germany/Germany	Germany & U.S./Germany	U.S./U.S.
Operational type	random access	random access	discrete
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	2 rotors (31 positions each)	rotor (32 positions)	manual pipetting into cuvette (4 wells at a time)
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	15.3 x 40.2 x 28.3 in/134.5 lbs/8 sq ft, 11 w/ PC	19.7 x 30.7 x 21.3 in/100 lbs/5 sq ft, 8 w/ PC	4.6 x 14.7 x 20 in/20 lbs/2 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., PT & APTT factors	PT, APTT, TT, fib., PT & APTT factor assays	PT, APTT, TT, fib., PT & APTT factor assays
FDA-cleared chromogenic tests	ATIII, hep. anti-Xa	ATIII, hep. anti-Xa, protein C	none
FDA-cleared immunologic tests	none	none (latex immunologic assay under development)	none (latex immunologic assay under development)
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	PT mix, APTT mix, lupus (dRVVT screen & confirm.), reptilase, proteins C & S (clotting), protein C (chromo.), APCR, LMWH (anti-Xa), vWF & D-dimer	α-2-antiplasmin, plasminogen, PT mix, APTT mix, LMWH (anti-Xa)	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	—	vWF Ag latex immunoassay, D-dimer latex immunoassay	—
Methodologies supported	clotting, chromogenic assays; photo-optical measurement for all 3	clot detection, optical, tungsten; chromogenic	clot detection, optical, tungsten
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 (maximum)	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 (maximum)	8	2
Factor assays require manual manipulation or dils	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 RT. total 28/25–200	4/30–100
Reagents refrigerated onboard	yes (18°C)	yes (15°C)	no (37°C)
Multiple reag. configurations supported	yes (up to 9 predefined reag. blocks)	yes	yes
Reag., consumables loaded w/o interrupting testing	consumables yes, reagents no	no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12–18 mos	12–18 mos	12–18 mos
Walkaway capacity: no. of specimens/no. of tests	62/232	32/32	4/4
Min. sample vol. aspirated precisely at one time	5 µL	2 µL	n/a
Standard specimen vol. required to run PT or PTT/Factor VIII activity	60 µL/10 µL	50 µL/5 µL, min. 2 µL	100 µL/10 µL, min. 10 µL
Disposables used/price of each	cuvette racks, probe cleaner, Kaolin suspension, predilution strips, 20-mL reag. container/prices available upon request	cuvette rings, pipettor wash solution, cleaning solution, sample cups/prices available on request	cuvettes, stir bars, optional: printer & paper/prices available on request
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes/no	yes (75 mm tubes)/no	no/no
Sample bar-code reading capability	yes (2 internal bar-code scanners)	yes	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	yes	yes	no
Measures no. of tests remaining	no	yes	no
Short sample detection	yes (level sensing probe)	yes (level sensing probe)	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/yes	no/yes
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 (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes (vol. betw. 300 µL–500 µL)
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	no/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	yes/yes	yes/yes	yes/yes
Auto shutdown/auto startup programmable	no/no (not required)	no/no (not required)	no/no
Stat time to completion of all analytes and throughput per h for:			
• PT alone	<7 min/180 results	2 min/90 results	2 min/200 results (manual)
• PT, PTT	<7 min/120–140 results	5 min/60 results	5 min/50 PTT results (manual)
• Fibrinogen	<7 min/140–180 results	2 min/75 results	2–3 min/100 results (manual)
• Factor VIII activity assay	<7 min/120–140 results	5 min/60 results	5 min/50 results (manual)
Time delay from ordering stat to aspir. of sample	<5 min	30–60 sec	≤ 2 min
Auto. transfer of QC results to LIS	yes	yes	no
Data management capability	yes (incl. QC: L-J)	onboard (incl. QC: L-J)	no
Interface supplied by instrument vendor	yes (additional cost)	yes (additional cost)	no
Interfaces in active user sites for:	all commonly used LISs in north America	all commonly used LISs in North America	n/a
Bidirectional interface capability	yes (host query)	yes (host query)	no
Results transferred to LIS as soon as test time complete	yes	yes	no
LOINC codes transmitted with all results	no	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 5 min; weekly: 30 min; monthly <5 min	daily: ~5 min; weekly: ~1 min; monthly: ~5 min	daily: none; weekly: ~5 min; monthly: none
Onboard maintenance records	no	no	no
Training provided with purchase	3 d at vendor (train the trainer)	3 d at vendor offices (train the trainer)	1/2 d on-site
Approx. no. of training hrs needed per tech	1–2 h/30 min or less for basic operation	2–3 h	1–2 h
List price	$55,000	$49,995	$5,198
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$5,700/1 yr	$5,700/1 yr	depot service (repair)/1 yr
Unique advantages	• normalization of PT & APTT assays with other bioMérieux automated systems • workhorse analyzer for medium- to high-volume routine workload • easy operation & simple software means minimal training required	• normalization of PT & APTT results between bioMérieux automated systems • stat results within 2–5 min • flexibility; MTX can support new assays easily through user-programmable method files • internal bar-code reader for sample & test identification	• simple to operate: clot detection starts automatically on addition of start reagent • photo-optical detection system w/ floating baseline provides accurate, precise results • flexibility; test params. can be modified to accommodate various reagent systems

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Part 3 of 11	bioMérieux Inc. Ginny Meihaus ginny.meihaus@na.biomerieux.com 100 Rodolphe St., Durham, NC 27712 919-620-2000 www.biomerieux-usa.com	Dade Behring Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	Dade Behring Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com
Instrument name/first year sold	MDA II/1999	BFT II/U.S.: 1999	Sysmex CA-500/U.S.: 1998
No. of units installed in U.S./outside U.S.	>400 worldwide	90+/2,000+	850+/2,000+
Country where analyzer designed/manufactured	U.S./U.S.	Germany/Germany	Japan/Japan
Operational type	continuous random access	batch	batch, continuous random access
Reagent type	open reagent system	open reagent system (reconst. manually)	open reagent system (reconst. manually), optimized for Dade Behring instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	racks	manual	10-tube position sample rack
Model type	floor-standing	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	58 x 75 x 31 in/840 lbs/18 sq ft w/PC	3.9 x 7.9 x 11.8 in/8.4 lbs/1.5 sq ft	19 x 21 x 18.5 in/99 lbs/9 sq ft
FDA-cleared clotting-based tests	PT screening (moderate & low ISI), PT factors, quick%, APTT screening, APTT factors, PT mix, APTT mix, TT, fib.	PT, APTT, fib.	PT, APTT, fib., TT, factor assays, reptilase time, protein C
FDA-cleared chromogenic tests	hep. anti-Xa, ATIII, protein C, plasminogen, α-2-anti-plasmin, lupus (dRVVT screen and confirm.), APCR	none	AT III, protein C chromo, heparin
FDA-cleared immunologic tests	D-dimer (latex immunoassay)	none	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	clottable C & S, PNP, P & P (1 & 2), vWF, open assays-user definable for clotting, chrom. & microlatex assays	none	n/a
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	vWF Ag latex immunoassay	none	n/a
Methodologies supported	clot detection, optical, tungsten; chromogenic; immunologic (latex immunoassay)	clot detection, opto-mechanical	clot detection: optical light scatter, chromogenic
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	16	1	5
No. of different assays programmed and calibrated at one time	72	3	7
No. of user-definable (open) channels	20	n/a	7
Of those defined, no. active simultaneously	16	1	5
Factor assays require manual manipulation or dils	no	n/a	n/a
No. of reag. containers onboard at one time/tests per container	30/25-400	4/up to 2,000	10/varies, up to 200
Reagents refrigerated onboard	yes (8-15˚C)	no	yes (15˚C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded w/o interrupting testing	consumables yes, reag. no	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12–18 mos	12 mos	12 mos.
Walkaway capacity: no. of specimens/no. of tests	170/480	1/1	10/50
Min. sample vol. aspirated precisely at one time	5 µL	50 µL	10 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 50 µL/10 µL, min. 5 µL	50 µL	50 µL/n/a
Disposables used/price of each	cuvettes, bar-code labels, MDA probe cleaner/prices available on request	cuvettes, printer paper/price varies w/ vol.	reaction tubes, CA Clean I, thermal paper/price varies w/ vol.
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes (12x75, 13x75, 10x66, 11.5x66 mm)/yes	no	yes (3–5 mL)/no
Sample bar-code reading capability	yes (internal bar-code scanner)	no	yes
Reagent bar-code reading capability	yes	no	no
Onboard test automatic inventory	yes	no	yes
Measures no. of tests remaining	yes	no	yes
Short sample detection	yes (level sensing probe)	no	yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	no	yes
Hemolysis/turbidity detection-quantitation	yes/yes (detects bilirubin, corrects for lipemia)	no/no	no/yes
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/auto reflex testing capability	no (not necessary)/no	no/yes	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT: default 3 sec, APTT: default 5 sec)	yes (PT: 5 sec, APTT: 15 sec)	yes (PT: <7 sec, PTT: <15 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	no	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	no/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	yes/yes	yes/yes	—/yes
Auto shutdown/auto startup programmable	yes/yes	no/no	no/no
Stat time to completion of all analytes and throughput per h. for:			
• PT alone	12 min/180 results	1 min/n/a manual	7 min/50 specimens
• PT, PTT	12 min/180 results	n/a manual	8 min/33 specimens
• Fibrinogen	12 min/180 results	<1 min/n/a manual	7 min/50 specimens
• Factor VIII activity assay	12 min/180 results	n/a	n/a/n/a
Time delay from ordering stat to aspir. of sample	<1 min	n/a	2 min
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	onboard (incl. QC: L-J, Westgard)	no	onboard (incl. QC: L-J)
Interface supplied by instrument vendor	yes (additional cost)	n/a	no
Interfaces in active user sites for:	all commonly used LISs in North America	n/a	Cerner, Sunquest, others
Bidirectional interface capability	yes (broadcast download & host query)	no	yes (host query)
Results transferred to LIS as soon as test time complete	yes	no	yes
LOINC codes transmitted with all results	no	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	no	no
Modem servicing	yes	no	no
Time required for maintenance by lab personnel	daily: ~35 min; weekly: 45 min; monthly: 10 min	daily: 1 min	daily: <5 min
Onboard maintenance records	no	no	no
Training provided with purchase	3–5 d on-site, 4 d at vendor offices	video	2 d on-site
Approx. no. of training hrs needed per tech	4–5 h	2 h	2 h
List price	$92,295	$6,550	$32,833
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$10,700/1 yr	depot service (repair)/1 yr	$4,500/yr
Unique advantages	• patented waveform analysis technology with flags for identifying abnormal waveforms (e.g., biphasic samples) • sensitive quantitative D-dimer assay for use in diagnosis of VTE • dyes in routine reagents for volume delivery check • throughput remains the same regardless of test mix	• 2-channel micro reagent volume clot-based technology • opto-mechanical detection accurate on lipemic, icteric samples • automatic INR calculation, curve storage, built-in thermal printer • perfect for low-vol. testing/backup to larger systems	• 5-parameter true random access clotting/chromogenic • small footprint, complete automation • low operating expense

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Part 4 of 11	Dade Behring Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com	Dade Behring Jackie Hauser jackie_hauser@dadebehring.com 1717 Deerfield Rd., Deerfield, IL 60015 847-267-5383 www.dadebehring.com
Instrument name/first year sold	Sysmex CA-1500/U.S.: 2000/worldwide: 1999	BCS/U.S.: 1998
No. of units installed in U.S./outside U.S.	215+/400+	190+/800+
Country where analyzer designed/manufactured	Japan/Japan	Germany/Germany
Operational type	continuous random access	batch, continuous random access
Reagent type	open reagent system (lyoph., reconst. manually), optimized for Dade Behring instruments	open reagent system (reconst. manually), optimized for Dade Behring instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack x 5	rack
Model type	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	20 x 31.2 x 31.2 in/186 lbs/168 sq ft	37 x 49 x 25 in/330 lbs/14 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., factor assays, protein C, reptilase time	PT, APTT, fib., TT, factor assays, reptilase time, protein C, dRVVT screen & confirm., factor V Leiden
FDA-cleared chromogenic tests	AT III, plasminogen, factor VIII chromo, α2AP, protein C chromo, heparin	AT III, α2AP, plasminogen, protein C chromo, heparin
FDA-cleared immunologic tests	advanced D-dimer	advanced D-dimer
Other FDA-cleared tests	none	BC von Willebrand-ristocetin cofactor assay (agglut of fixed Plts.)
User-defined tests in clinical use	n/a	n/a
Tests submitted for 510(k) clearance	n/a	advanced D-dimer (latex agglut.—immunologic)
Tests in development but not yet submitted	thrombin time, dRVVT screen and confirm	n/a
Methodologies supported	clot detection, optical, turbidmetric; chromogenic; immunologic (latex agglutination in development)	clot detection: optical; xenon flasher lamp; chromogenic; immunologic (ristocetin cofactor)
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no
No. of different measured assays onboard simultaneously	15	>20 tests/sample (theoretically 9,999)
No. of different assays programmed and calibrated at one time	25	99
No. of user-definable (open) channels	25	8,999 (nos. 1–1,000 are factory set & unalterable)
Of those defined, no. active simultaneously	15	>100
Factor assays require manual manipulation or dils	no	no
No. of reag. containers onboard at one time/tests per container	39/up to 200	18–78/varies-micro volume assay format
Reagents refrigerated onboard	yes (15˚C)	yes (<15˚C)
Multiple reag. configurations supported	yes	yes
Reag., consumables loaded w/o interrupting testing	some consumables yes, reagents no	yes
Same capabilities when 3rd-party reag. used	yes	yes
Max. time same lot number of reag. can be used	12 mos	12 mos
Walkaway capacity: no. of specimens/no. of tests	50/up to 1,000	110 samples/400 cuvettes
Min. sample vol. aspirated precisely at one time	5 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/10 µL	50 µL, min. 100 µL (incl. dead vols.)/50 µL, min. 100 µL
Disposables used/price of each	reaction tubes, sample plates, CA Clean I & II, system buffer, halogen lamp, closed container sample replacement, needles/prices vary w/ vol.	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/price varies w/ vol.
Supports direct-from-track sampling	yes (Sysmex CST series)	no
Primary tube sampling supported/pierces caps on primary tubes	yes (3–5 mL)/yes	yes (all sizes up to 100 mm long, ext. diam. 10–16 mm)/no
Sample bar-code reading capability	yes	yes
Reagent bar-code reading capability	in development	yes (avail. for user-defined tests)
Onboard test automatic inventory	yes	yes
Measures no. of tests remaining	yes	yes
Short sample detection	yes	yes
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes
Hemolysis/turbidity detection-quantitation	no/yes	yes/yes
Dilution of patient samples onboard	yes	yes
Automatic rerun capability/auto reflex testing capability	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)
Read time extended for prolonged clotting times	yes (selectable on menus)	no
User can set different-than-standard:		
• Reag. volumes/sample volumes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes
• Incub. times/reading times	yes/yes	yes/no
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	yes/yes
Auto shutdown/auto startup programmable	no/no	no/no
Stat time to completion of all analytes and throughput per h. for:		
• PT alone	7 min/80 specimens	<5 min/~350 specimens (incl. abnormals)
• PT, PTT	8 min/120 specimens	<5 min/~160 specimens (incl. abnormals)
• Fibrinogen	8 min/80 specimens	<5 min (if curve avail.)/~350 specimens
• Factor VIII activity assay	8 min/n/a	<5 min (if curve avail.)/~280 specimens
Time delay from ordering stat to aspir. of sample	2 min	varies by test in progress, approx. <5 min
Auto. transfer of QC results to LIS	yes	yes
Data management capability	onboard (incl. QC: L-J & Westgard)	limited
Interface supplied by instrument vendor	no	no
Interfaces in active user sites for:	Cerner, Sunquest, others	Cerner, Sunquest, Meditech, others
Bidirectional interface capability	yes (host query)	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes (Sysmex CST series)	possible future upgrade (not avail.)
Modem servicing	no	yes
Time required for maintenance by lab personnel	daily: <5 min; weekly: <10 min; monthly: 1 min	daily: <5 min; weekly: <10 min; monthly: 15 min
Onboard maintenance records	no	no
Training provided with purchase	varies on-site, 4 d at vendor offices	varies on-site, 5 d at vendor offices
Approx. no. of training hrs needed per tech	6 h	8 h on-site
List price	$81,900 standard model; $92,820 cap-piercing model	$125,580
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$11,450 standard model; $12,300 cap-piercing/1 yr.	$16,800/yr
Unique advantages	• adapts easily to lab automation • simultaneous curve calibrating & patient testing • ability to load multiple bottles or multiple lots of reagent	• continuous loading of bar-coded reag. & samples • multi-lot, multi-curve reagent management • PT/APTT/fib./AT III/D-dimer in <10 min • simultaneous curve calibration & patient testing

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SURVEY OF

Coagulation Analyzers

Part 5 of 11

	Diagnostica Stago Inc. Pascal Boulanger pascal@stago-us.com Five Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Pascal Boulanger pascal@stago-us.com Five Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Pascal Boulanger pascal@stago-us.com Five Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	**STA-R Hemostasis System/1998**	**STA Hemostasis System/1993**	**STA Compact Hemostasis System/1996**
No. of units installed in U.S./outside U.S.	107/769	196/1,449	551/3,182
Country where analyzer designed/manufactured	France/France	France/France	France/France
Operational type	continuous random access	continuous random access	continuous random access
Reagent type	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	rack with continuous specimen access	continuous specimen access-primary tube	continuous specimen access-primary tube
Model type	floor-standing	floor-standing	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	44.7 x 36.6 x 25.8 in/551 lbs/23.5 sq ft	25.2 x 38.8 x 25.8 in/351 lbs/25.6 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.
FDA-cleared chromogenic tests	unfrac. hep., LMWH, protein C, ATIII, plasminogen & antiplasmin	unfrac. hep., LMWH, protein C, ATIII, plasminogen & antiplasmin	unfrac. hep., LMWH, protein C, ATIII, plasminogen & antiplasmin
FDA-cleared immunologic tests	D-dimer, vWF, protein S antigen & ATIII antigen (microlatex agglut)	D-dimer, vWF, protein S antigen & ATIII antigen (microlatex agglut)	D-dimer, vWF antigen, protein S antigen & ATIII antigen (microlatex agglut)
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVV screen. & confirm. assays & activated protein C resistance	all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVV screen. & confirm. assays & activated protein C resistance	all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVV screen. & confirm. assay & 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, and immunological assays	clotting, chromogenic, and immunological assays	clotting, chromogenic, and immunological assays
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	up to 200	up to 80	up to 80
No. of different assays programmed and calibrated at one time	up to 200	up to 80	up to 80
No. of user-definable (open) channels	200	70	70
Of those defined, no. active simultaneously	200	70	70
Factor assays require manual manipulation or dils	no	no	no
No. of reag. containers onboard at one time/tests per container	70/up to 83	45/varies, up to 83	45/varies, up to 83
Reagents refrigerated onboard	yes (15–19°C)	yes (15–19°C)	yes (15–19°C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded w/o interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	18 mos	18 mos	18 mos
Walkaway capacity: no. of specimens/no. of tests	215/32 per specimen	192/12 per specimen	96/12 per sample
Min. sample vol. aspirated precisely at one time	5 µL	5 µL	5 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL, min. 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, glycol., wash-cleaner solution/—
Supports direct-from-track sampling	yes	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes/optional	yes/no	yes (5 & 2.5 mL tube sizes)/optional
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes (not for user-def. tests)	yes (not for user-def. tests)	yes (not for user-def. tests)
Onboard test automatic inventory	yes	yes	yes
Measures no. of tests remaining	yes	yes	yes
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/auto reflex testing capability	yes/yes	yes/no	yes/no
Lag time during which hypercoagulable samples will not be detected	no	no	no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	yes/yes	yes/yes	yes/yes
Auto shutdown/auto startup programmable	no/no (not needed)	no/no (not needed)	no/no (not needed)
Stat time to completion of all analytes and throughput per h. for:			
• PT alone	<6 min/300 specimens	<6 min/300 specimens	<6 min/150 specimens
• PT, PTT	7 min/150 specimens	7 min/150 specimens	7 min/75 specimens
• Fibrinogen	7 min/180 specimens	7 min/180 specimens	7 min/75 specimens
• Factor VIII activity assay	7 min/180 specimens	7 min/180 specimens	7 min/70 specimens
Time delay from ordering stat to aspir. of sample	<15 sec	<15 sec	<15 sec
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J)	onboard (incl. QC: L-J)	onboard (incl. QC: L-J)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	contact marketing for updated list	contact marketing for updated list	contact marketing for updated list
Bidirectional interface capability	yes (host query)	yes (host query)	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes (contact marketing for list of systems)	no	no
Modem servicing	yes	no	no
Time required for maintenance by lab personnel	daily: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <30 min; monthly: <30 min	daily: none; weekly: <30 min; monthly: <30 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	varies on-site, 3 d at vendor offices	varies on-site, 3 d at vendor offices	varies on-site, 3 d at vendor offices
Approx. no. of training hrs needed per tech	2 h basic, 24 h system training at training center	2 h basic, 24 h system training at training center	2 h basic, 24 h system training at training center
List price	$149,995	$99,845	$75,000
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	prices available on request/1 yr	prices available on request/1 yr	prices available on request/1 yr.
Unique advantages	• walkaway testing w/ robotics-capable interface to automated lines for high-vol. testing, with touch-screen software & cap piercing option • cont. random access for up to 200 test selections w/ no carryover • able to standardize with other STA family of analyzers • unique viscosity-based detection system	• walkaway testing for routine & specialty hemostasis assays w/ 45 reag. positions, 192 sample pos., up to 1,000 dispos. cuvettes • cont. random access for up to 80 test selections with no carryover • able to standardize with other STA family of analyzers • unique viscosity-based detection system	• walkaway testing for routine & specialty hemostasis assays w/ 45 reag. positions, 96 sample pos., up to 1,000 dispos. cuvettes • cont. random access for up to 80 test selections with no carryover • able to standardize with other STA family of analyzers • unique viscosity-based detection system

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SURVEY OF

Coagulation Analyzers

Part 6 of 11	Diagnostica Stago Inc. Pascal Boulanger pascal@stago-us.com Five Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Pascal Boulanger pascal@stago-us.com Five Century Dr., Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	STart 4/1998	STart 8/1999
No. of units installed in U.S./outside U.S.	531/6,310	>20/451
Country where analyzer designed/manufactured	France/France	France/France
Operational type	batch	batch
Reagent type	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual
Model type	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft	4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.	PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.
FDA-cleared chromogenic tests	none	none
FDA-cleared immunologic tests	none	none
Other FDA-cleared tests	none	none
User-defined tests in clinical use	same as clotting-based tests above & dRVV screen. & confirm. assays & activated protein C resistance	same as clotting-based tests above & dRVV screen. & confirm. assays & activated protein C resistance
Tests submitted for 510(k) clearance	none	none
Tests in development but not yet submitted	none	none
Methodologies supported	clotting tests	clotting tests
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no
No. of different measured assays onboard simultaneously	1	1
No. of different assays programmed and calibrated at one time	20	20
No. of user-definable (open) channels	4	4
Of those defined, no. active simultaneously	1	1
Factor assays require manual manipulation or dils	yes	yes
No. of reag. containers onboard at one time/tests per container	4/varies, up to 100	4/varies, up to 100
Reagents refrigerated onboard	no	no
Multiple reag. configurations supported	yes	yes
Reag., consumables loaded w/o interrupting testing	no	no
Same capabilities when 3rd-party reag. used	yes	yes
Max. time same lot number of reag. can be used	18 mos	18 mos
Walkaway capacity: No. of specimens/no. of tests	4/1	4/1
Min. sample vol. aspirated precisely at one time	25 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
Disposables used/price of each	cuvettes, beads/ball/—	cuvettes, beads/ball/—
Supports direct-from-track sampling	no	no
Primary tube sampling supported/pierces caps on primary tubes	no/no (n/a)	no/no (n/a)
Sample bar-code reading capability	no	no
Reagent bar-code reading capability	no	no
Onboard test automatic inventory	no	no
Measures no. of tests remaining	no	no
Short sample detection	no	no
Clot detection as preanalytic variable in plasma sample	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	no
Hemolysis/turbidity detection-quantitation	no/no	no/no
Dilution of patient samples onboard	no	no
Automatic rerun capability/auto reflex testing capability	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	no	no
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:		
• Reag. volumes/sample volumes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes
• Incub. times/reading times	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	no/yes
Auto shutdown/auto startup programmable	no	no
Stat time to completion of all analytes and throughput per h. for:		
• PT alone	<1 min/up to 120 specimens	<1 min/up to 120 specimens
• PT, PTT	n/a/n/a	n/a/n/a
• Fibrinogen	<1 min/up to 120 specimens	<1 min/up to 120 specimens
• Factor VIII activity assay	varies/varies	varies/varies
Time delay from ordering stat to aspir. of sample	n/a	n/a
Auto. transfer of QC results to LIS	no	no
Data management capability	no	no
Interface supplied by instrument vendor	no	no
Interfaces in active user sites for:	n/a	n/a
Bidirectional interface capability	no	no
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no
Modem servicing	no	no
Time required for maintenance by lab personnel	daily: <5 min; weekly: <5 min; monthly: <5 min	Daily: <5 min; weekly: <5 min; monthly: <5 min
Onboard maintenance records	no	no
Training provided with purchase	1 d on-site	1 d on-site
Approx. no. of training hrs needed per tech	1 h	1 h
List price	$9,600	$12,500
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	prices available on request/1 yr.	prices available on request/1 yr.
Unique advantages	• excellent for low-volume testing or as backup to optical system • programmable and preprogrammed assays with curve storage, 4 independently timed incubation stations, electronically linked multiple pipettor, 40-character display and internal thermal printer • lightweight and compact • unique viscosity-based detection system	• excellent for low–mid volume testing or backup • 32 incubation positions for samples, 8 measurement channels, 4 independent built-in timers for incubation; results in seconds and in various units (% ratio, INR, g/L, mg/dL, IU/mL). RS232 interface • lightweight and compact • unique viscosity-based detection system

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Diagnostica Stago 4c—.25T 0101--35

Circle No. 25 on reader service card

SURVEY OF

Coagulation Analyzers

Part 7 of 11	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com
Instrument name/first year sold	Thor/1997	Cascade M/1991	Cascade M-4/1992
No. of units installed in U.S./outside U.S.	>15/0	>150/—	>100/—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	random access	batch	random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	6 racks, 10 positions each	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	23 x 44 x 28 in/252 lbs/8.5 sq ft	8 x 15 x 13 in/25 lbs/1.4 sq ft	8 x 15 x 13 in/25 lbs/1.4 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., thromb. clotting time, factor assays II, V, VII–XII with 8 user-definable tests	PT, APTT, fib., TCT, factor assays II, V, VII–XII	PT, APTT, fib., TCT, factor assays II, V, VII–XII
FDA-cleared chromogenic tests	none	none	none
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	PT, APTT, fib., TCT, factors II, V, VII–XII	PT, APTT, fib., TCT, factor assays II, V, VII–XII	PT, APTT, fib., TCT, factor assays II, V, VII–XII
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	dRVVT	dRVVT	dRVVT
Methodologies supported	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	12	1	4
No. of different assays programmed and calibrated at one time	1	1	4
No. of user-definable (open) channels	8	2	4
Of those defined, no. active simultaneously	12	1	2
Factor assays require manual manipulation or dils	no	yes	yes
No. of reag. containers onboard at one time/tests per container	11/200	—/—	0/n/a
Reagents refrigerated onboard	yes (5°C)	n/a	no
Multiple reag. configurations supported	yes	n/a	no
Reag., consumables loaded w/o interrupting testing	yes	no	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12 mos	12 mos	12 mos
Walkaway capacity: No. of specimens/no. of tests	60/12 per sample	no	no
Min. sample vol. aspirated precisely at one time	50 µL	manual–50 µL	manual-50 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	200 µL, min.100 µL/200 µL, min.100 µL	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)
Disposables used/price of each	reagent reservoirs & tubing (5 sets) 5 pumps/$187.75 per set; cuvettes (4 tests/500)/$173=11.5¢ per test; biohazard trays/5@$16.25	cuvettes/500@$54; pipette tips/1,000@$82	cuvettes/500@$54; pipette tips/1,000@$82
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	yes (tube sizes 5 mL and lower)/yes	no	no
Sample bar-code reading capability	yes	no	no
Reagent bar-code reading capability	yes (not for user-defined tests)	no	no
Onboard test automatic inventory	yes	no	no
Measures no. of tests remaining	yes	no	no
Short sample detection	yes	no	no
Clot detection as preanalytical variable in plasma sample	—	—	—
Auto. detection of adequate reag. for aspir. & anal.	yes	no	no
Hemolysis/turbidity detection-quantitation	yes/yes	no/no	no/no
Dilution of patient samples onboard	yes	no	no
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: 4 sec, PTT: 14 sec)	yes (PT: 4 sec, PTT: 14 sec)	yes (PT: 4 sec, PTT: 14 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes and throughput per h. for:			
• PT alone	8 min/ 240 specimens	3 min/120 specimens	3 min/140 specimens
• PT, PTT	10 min/144 specimens	7 min/50 specimens	7 min/80 specimens
• Fibrinogen	5 min/360 specimens	3 min/140 specimens	3 min/160 specimens
• Factor VIII activity assay	10 min/144 specimens	7 min/50 specimens	7 min/80 specimens
Time delay from ordering stat to aspir. of sample	30 sec–1 min	n/a	n/a
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	onboard (incl. QC: L-J, Westgard)	no (incl. QC: L-J)	no (incl. QC: L-J)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Meditech, Cerner	n/a	—
Bidirectional interface capability	yes (broadcast download & host query)	no	no
Results transferred to LIS as soon as test time complete	yes	no	yes
LOINC codes transmitted with all results	no	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	—	no
Modem servicing	TBD	no	no
Time required for maintenance by lab personnel	daily: 15 min; weekly: 30 min; monthly: 1 h	Daily: 10 min; weekly: 10 min; monthly: 20 min	Daily: 10 min; weekly: 10 min; monthly: 30 min
Onboard maintenance records	yes	no	no
Training provided with purchase	3–5 d at vendor offices	1 d on-site	1 d on-site
Approx. no. of training hrs needed per tech	8 h	2–4 h	2 h
List price	$67,600	$6,219	$8,403
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$7,900/1 yr.	$714/1 yr.	$966/1 yr.
Unique advantages	• primary tube sampling with cap piercing • integral bar-code reader to ensure positive patient ID • truly a walkaway coag analyzer	• QC program onboard • curve storage • suitable for office lab or as backup analyzer	• 4-channel manual analyzer • QC program onboard • singles or duplicates

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SURVEY OF

Coagulation Analyzers

Part 8 of 11	Helena Laboratories Joe Golias helena@helena.com 1530 Lindbergh Dr., Beaumont, TX 77704 800-231-5663 www.helena.com	Instrumentation Laboratory/Beckman Coulter Inc. Katie Garvin kjgarvin@beckman.com 200 S. Kraemer Blvd., Brea, CA 92621 714-993-8749 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Katie Garvin kjgarvin@beckman.com 200 S. Kraemer Blvd., Brea, CA 92621 714-993-8749 www.beckmancoulter.com
Instrument name/first year sold	Packs-4/1991	Electra 1400C/1995	Electra 1800C/1997
No. of units installed in U.S./outside U.S.	150/180	—/—	—/—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	random access	continuous random access	continuous random access
Reagent type	open reagent system	open reagent system (reconst. manually)	open reagent system (reconst. manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	automatic pipetting from tray	auto pipetting, rack
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	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	25 x 48 x 30.4 in/283 lbs/10.13 sq ft
FDA-cleared clotting-based tests	none	PT, APTT, fib. (Clauss), TT, factor assays, Pfib (PT assay-based fib.), protein S	PT, APTT, fib. (Clauss), TT, factor assays, Pfib (PT assay-based fib.), protein S
FDA-cleared chromogenic tests	AT III, F-VIII:C, hep., plasminogen, protein C	plasminogen, factor VIII, antithrombin, protein C, heparin	plasminogen, factor VIII, antithrombin, protein C, heparin
FDA-cleared immunologic tests	none	none	none
Other FDA-cleared tests	ristocetin cofactor and platelet aggreg.	none	none
User-defined tests in clinical use	chrom: ATIII, F-VIII:C, hep., plasmin., protein C, ristocetin cofactor, platelet aggreg.–ADP, EPI, COL, ristocetin, arach. acid	none	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	Liquid RecombiPlastin	Liquid RecombiPlastin
Methodologies supported	chromogenic, ristocetin cofactor, platelet aggreg.	clot detection, optical, tungsten; chromogenic	clot detection, optical, tungsten; chromogenic
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	4	11	12
No. of different assays programmed and calibrated at one time	4	11	12
No. of user-definable (open) channels	12	4	4
Of those defined, no. active simultaneously	4	4	4
Factor assays require manual manipulation or dils	yes	no	no
No. of reag. containers onboard at one time/tests per container	n/a/n/a	4/varies	6/varies
Reagents refrigerated onboard	no	yes (8˚C ±4)	yes (8˚C ±4)
Multiple reag. configurations supported	no	yes	yes
Reag., consumables loaded w/o interrupting testing	no	yes	yes
Same capabilities when 3rd-party reag. used	n/a	yes	yes
Max. time same lot number of reag. can be used	12 mos	12 mos recommended	12 mos recommended
Walkaway capacity: No. of specimens/no. of tests	no	35/4	100/4
Min. sample vol. aspirated precisely at one time	n/a	10 µL	10 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	chromogenics: 75 µL, Plt. aggreg: 225 µL PRP, Risto cofactor: 50 µL	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)	100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)
Disposables used/price of each	cuvettes/200@$55.65; pipette tips/1,000@$82; stir bars/30@$62.25	cuvette, dual well, 560 pk/price varies; heat exchanger, 10 pk/price varies	cuvette, single well, 2,000 pk/price varies; heat exchanger, 10 pk/price varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	no	yes (13x75, 13x100, 10x85, 10x65, 12x91 mm Sarstedt)/no	yes [13x75, 13x100 (closed & open tubes), 10x85,10x65, 12x91 Sarstedt (open)]/yes
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	yes
Measures no. of tests remaining	no	yes	yes
Short sample detection	no	yes	yes
Clot detection as preanalytical variable in plasma sample	—	no	no
Auto. detection of adequate reag. for aspir. & anal.	no	yes	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/auto reflex testing capability	no/no	yes/yes	yes/yes
Lag time during which hypercoagulable samples will not be detected	n/a	yes (PT: 7 sec, PTT: 14 sec)	yes (PT: 7 sec, PTT: 14 sec)
Read time extended for prolonged clotting times	n/a	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	yes/yes	yes/yes
Auto shutdown/auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes and throughput per h. for:			
• PT alone		approx. 3 min/200 specimens	approx. 3 min/228 specimens
• PT, PTT		approx. 7 min/136 specimens	approx. 7 min/120 specimens
• Fibrinogen		approx. 3 min/160 specimens	approx. 7 min/146 specimens
• Factor VIII activity assay	20–24 specimens for any test	approx. 7 min/136 specimens	approx. 7 min/120 specimens
Time delay from ordering stat to aspir. of sample	n/a	none	none
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J, Westgard)	onboard (incl. QC: L-J, Westgard)	onboard (incl. QC: L-J, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	Sunquest, Cerner, HBOC, Meditech, Dawning, Antrim, Soft Computer, others	Sunquest, Cerner, HBOC, Meditech, Dawning, Antrim, Soft Computer, others
Bidirectional interface capability	no	yes (host query)	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	TBD	no	no
Time required for maintenance by lab personnel	daily: 15 min; weekly: 15 min; monthly: 1 h	daily: 5 min; weekly: 15 min; monthly: 15 min	daily: 10 min; weekly: 25 min; monthly: 30 min
Onboard maintenance records	yes	no	no
Training provided with purchase	2 d on-site	up to 3 d on-site	up to 3 d on-site
Approx. no. of training hrs needed per tech	4–8 h	up to 24 h	24 h max.
List price	$16,650	$41,194	$73,645
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$2,079/1 yr.	variety of options avail./1 yr.	variety of options avail./1 yr.
Unique advantages	• specialized coag instrument intended for platelet aggreg., ristocetin cofactor, & chromogenics	• integral bar-code reader • standardized test results	• cap piercing • standardized test results • automatic sample predilution, including parallelism function

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SURVEY OF

Coagulation Analyzers

Part 9 of 11	Instrumentation Laboratory/Beckman Coulter Inc. Katie Garvin kjgarvin@beckman.com 200 S. Kraemer Blvd., Brea, CA 92621 714-993-8749 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Katie Garvin kjgarvin@beckman.com 200 S. Kraemer Blvd., Brea, CA 92621 714-993-8749 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Katie Garvin kjgarvin@beckman.com 200 S. Kraemer Blvd., Brea, CA 92621 714-993-8749 www.beckmancoulter.com
Instrument name/first year sold	ACL 100/1988	ACL 1000/1991	ACL 7000/1997
No. of units installed in U.S./outside U.S.	4,000+ (all models combined)/8,000+ (all models combined)	4,000+ (all models combined)/8,000+ (all models combined)	4,000+ (all models combined)/8,000+ (all models combined)
Country where analyzer designed/manufactured	Italy/U.S.	Italy/U.S.	Italy/U.S.
Operational type	batch	batch	random programming
Reagent type	open reagent system, guarantee only IL products	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	tray	tray	tray
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft	17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR, Clauss fib.	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.	PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.
FDA-cleared chromogenic tests	none	none	antithrombin, hep. Xa, plasminogen, antiplasmin, protein C
FDA-cleared immunologic tests	none	none	D-dimer (latex enhanced immunoassay), vWF
Other FDA-cleared tests	none	none	none
User-defined tests in clinical use	none	none	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted	none	none	none
Methodologies supported	clot detection, optical, nephelometric	clot detection, optical, nephelometric	clot detection, optical, nephelometric; chromogenic; immunologic (optical, latex enhanced immunoassay)
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	3	3	4
No. of different assays programmed and calibrated at one time	1	1	1
No. of user-definable (open) channels	0	0	10 (requires optional research package)
Of those defined, no. active simultaneously	0	0	1
Factor assays require manual manipulation or dils	yes	yes	no
No. of reag. containers onboard at one time/tests per container	3/varies by test	3/varies by test	3/varies by test
Reagents refrigerated onboard	yes (15˚C)	yes (15˚C)	yes (15˚C)
Multiple reag. configurations supported	yes	yes	yes
Reag., consumables loaded w/o interrupting testing	no	no	no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	18 mos	18 mos	18 mos
Walkaway capacity: No. of specimens/no. of tests	18/36	18/36	18/36
Min. sample vol. aspirated precisely at one time	10 µL	10 µL	10 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL (PT), 53 µL (PTT)/40 µL	50 µL (PT), 53 µL (PTT)/40 µL	50 µL (PT), 53 µL (PTT)/40 µL
Disposables used/price of each	sample cups/price varies; rotors/price varies	rotors/price varies	rotors/price varies
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/pierces caps on primary tubes	no/no	yes (13 x 75 mm)/no	yes (13 x 75 mm)/no
Sample bar-code reading capability	no	yes (optional)	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	no	no
Measures no. of tests remaining	no	no	no
Short sample detection	yes	yes	yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	yes
Hemolysis/turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 5.6 std, 6.7 ext)	yes (PT & PTT: 5.6 std, 6.7 ext)	yes (PT & PTT: 5.6 std, 6.7 ext)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	no/no	no/no	no/no
• No. and sources of reag.	no	no	no
• Incub. times/reading times	no/yes	no/yes	no/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes and throughput per h. for:			
• PT alone	5.5 min/110 specimens	5.5 min/110 specimens	5.5 min/175 specimens
• PT, PTT	8.5 min/80 specimens	8.5 min/80 specimens	8.5 min/110 specimens
• Fibrinogen	5.5 min/110 specimens	5.5 min/110 specimens	5.5 min/175 specimens
• Factor VIII activity assay	9.5 min/80 specimens	9.5 min/80 specimens	9.5 min/110 specimens
Time delay from ordering stat to aspir. of sample	15 sec	15 sec	15 sec
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	no	onboard (incl. QC: L-J)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major LIS vendors	most major LIS vendors	most major LIS vendors
Bidirectional interface capability	no	no	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: 10 min; weekly: 15 min; monthly: 10 min	daily: 10 min; weekly: 15 min; monthly: 10 min
Onboard maintenance records	yes	yes	yes
Training provided with purchase	2 d on-site	2 d on-site	2 d on-site
Approx. no. of training hrs needed per tech	2 h	6 h	12 h
List price	$16,000	$21,500	$45,000
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	variety of options avail./1 yr.	variety of options avail./1 yr.	variety of options avail./1 yr.
Unique advantages	• part of the ACL family, uses same consumables/reagents • quantitative PT-based fib. • positive displacement pipetting for low maintenance & high precision	• part of ACL family, uses same consumables/reagents • quantitative PT-based fib. • positive displacement pipetting for low maintenance & high precision	• part of ACL family, uses same consumables/reagents • quantitative PT-based fib. • positive displacement pipetting for low maintenance & high precision

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SURVEY OF

Coagulation Analyzers

Part 10 of 11

	Instrumentation Laboratory/Beckman Coulter Inc. Katie Garvin kjgarvin@beckman.com 200 S. Kraemer Blvd., Brea, CA 92621 714-993-8749 www.beckmancoulter.com	Instrumentation Laboratory/Beckman Coulter Inc. Katie Garvin kjgarvin@beckman.com 200 S. Kraemer Blvd., Brea, CA 92621 714-993-8749 www.beckmancoulter.com	Sigma Diagnostics Lada Sochynsky lsochynsky@sial.com 545 South Ewing Ave., St. Louis, MO 63103 800-325-3424 www.sigma-aldrich.com
Instrument name/first year sold	**ACL 9000/2000**	**ACL Advance/2000**	**KC1Δ Coagulation Analyzer/2001**
No. of units installed in U.S./outside U.S.	85+/300+	350+/700+	<500/<500
Country where analyzer designed/manufactured	Italy/U.S.	U.S./U.S.	Germany/Germany
Operational type	random access	random access	semiautomatic, single channel
Reagent type	open reagent system	open reagent system, guarantee only IL products	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray	racks, up to 12	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H x W x D)/weight/instrument footprint	23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft	32.2 x 41 x 24.8 in/185 lbs/15 sq ft	3.25 x 5.5 x 8.25 in/2.5 lbs/<1 sq ft
FDA-cleared clotting-based tests	PT, APTT, PT-based fib., Clauss fib., TT, factor assays, protein C, protein S, LAC screen, LAC confirm, APCR-V	PT, APTT, PT-based fib., Clauss fib., TT, factor assays, protein C, LAC screen, LAC confirm, APCR-V	PT, APTT, fib, TT, instrinsic & extrinsic factors
FDA-cleared chromogenic tests	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin	antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin	n/a
FDA-cleared immunologic tests	D-dimer (latex enhanced immunoassay), vWF (latex enhanced immunoassay), free protein S	D-dimer (latex enhanced immunoassay), vWF, free protein S	n/a
Other FDA-cleared tests	none	none	n/a
User-defined tests in clinical use	none	none	n/a
Tests submitted for 510(k) clearance	none	none	n/a
Tests in development but not yet submitted	vWF activity, HS-CRP, Liquid RecombiPlastin	protein S functional, vWF activity, HS-CRP, Liquid RecombiPlastin	n/a
Methodologies supported	clot detection, optical, nephelometric; chromogenic; immunologic	clot detection, optical; chromogenic; immunologic (optical, latex enhanced immunoassay)	clot detection, mechanical
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	18	varies with test-reag. combination, limited only by no. of reag. positions	1
No. of different assays programmed and calibrated at one time	1	1	manual
No. of user-definable (open) channels	total test capacity: 300 (IL test channels 120+ open)	total test capacity: 100 (IL test channels + open)	n/a
Of those defined, no. active simultaneously	varies with test-reagent combination	varies with test-reag. combination	n/a
Factor assays require manual manipulation or dils	no	no	yes
No. of reag. containers onboard at one time/tests per container	18/varies by test	42/varies by test, container size	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 w/o interrupting testing	no	yes	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	120/variable	n/a, manual
Min. sample vol. aspirated precisely at one time	5 µL	10 µL	n/a
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/40 µL	50 µL /10 µL	50 µL/50 µL
Disposables used/price of each	rotors/price varies	cuvettes/price varies	cuvettes & ball dispenser/inquire
Supports direct-from-track sampling	no	no	n/a
Primary tube sampling supported/pierces caps on primary tubes	yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no	yes/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	no	n/a
Measures no. of tests remaining	yes	no	n/a
Short sample detection	yes	yes	n/a
Clot detection as preanalytical variable in plasma sample	no	no	n/a
Auto. detection of adequate reag. for aspir. & anal.	yes	yes	n/a
Hemolysis/turbidity detection-quantitation	no/no	yes/yes	n/a
Dilution of patient samples onboard	yes	yes	n/a
Automatic rerun capability/auto reflex testing capability	yes/yes	yes/no	n/a
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 3 sec)	yes (PT: 7 sec., PTT: 10 sec)	yes (PT & PTT: 4.5 sec)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	yes
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/auto startup programmable	no/no	no/no	no/no
Stat time to completion of all analytes and throughput per h. for:			
• PT alone	4 min/175 specimens	2.5 min/240 specimens	75 sec/48
• PT, PTT	8 min/110 specimens	8 min/180 specimens	350 sec/10
• Fibrinogen	4 min/175 specimens	2.5 min/240 specimens	65 sec/55
• Factor VIII activity assay	varies/110 specimens	2.5 min/180 specimens	275 sec/13
Time delay from ordering stat to aspir. of sample	15 sec	20 sec	n/a
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J)	onboard (incl. QC: L-J)	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	most major LIS vendors	—
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download)	n/a
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	n/a
Modem servicing	no	no	n/a
Time required for maintenance by lab personnel	daily: 0; weekly: 10 min; monthly: 5 min; biweekly: 5 min	Daily: 15 min; weekly: 15 min; monthly: 10 min	none
Onboard maintenance records	yes	yes	n/a
Training provided with purchase	5 d at vendor offices in Miami	5 d at vendor offices in Miami	as needed on-site
Approx. no. of training hrs needed per tech	varies	24 h	2 h
List price	$61,950	$79,500	$2,100
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	various options avail./1 yr.	various options avail./1 yr	$350 (M–F, 8–5)/1 yr
Unique advantages	• robotic transport arm • extensive menu of clotting, chromogenic, & immunological assays in a small footprint • positive displacement pipetting for low maintenance & high precision	• extensive menu of clotting, chromogenic, & immunologic assays • high throughput • positive displacement pipetting for low maintenance & high precision	• half volume PT & APTT testing for significant reag. savings • patented ball technology for extremely reproducible & reliable results • optional printer to ensure quality of test results

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SURVEY OF

Coagulation Analyzers

Part 11 of 11

	Sigma Diagnostics Lada Sochynsky lsochynsky@sial.com 545 South Ewing Ave., St. Louis, MO 63103 800-325-3424 www.sigma-aldrich.com	Sigma Diagnostics Lada Sochynsky lsochynsky@sial.com 545 South Ewing Ave., St. Louis, MO 63103 800-325-3424 www.sigma-aldrich.com	Sigma Diagnostics Nancy Rector nrector@sial.com 545 South Ewing Ave., St. Louis, MO 63103 800-325-3424 www.sigma-aldrich.com
Instrument name/first year sold	KC4Δ Coagulation Analyzer/2001	AMAX 200 Coagulation Analyzer/2001	AMAX 400 Coagulation Analyzer/1997
No. of units installed in U.S./outside U.S.	<500/<500	<500/<500	<500/<500
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	semiautomatic, 4 channels	random access	random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	60-position continuous addition sample rack	continuous feed sample chain
Model type	benchtop	benchtop or floor-standing	floor-standing
Dimensions (H x W x D)/weight/instrument footprint	4.7 x 13.9 x 17.7 in/14 lbs/1.7 sq ft	BT: 25 x 32.75 x 28.75 in/286 lbs/6.5 sq ft FS: 53.25 x 32.75 x 28.75 in/451 lbs/6.5 sq ft	52 x 56 x 27 in/803 lbs/10.5 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib, TT, atroxin, intrinsic & extrinsic factors	APTT, atroxin, fib., PT, protein C, TT, protein S, intrinsic & extrinsic factors, dRVVT	PT, APTT, fib, TT, intrinsic & extrinsic factors, protein C & S, dRVVT
FDA-cleared chromogenic tests	n/a	antithrombin, plasminogen, hep-Xa, protein C	hep-Xa, antithrombin, plasminogen, protein C
FDA-cleared immunologic tests	n/a	D-dimer	D-dimer
Other FDA-cleared tests	n/a	none	none
User-defined tests in clinical use	n/a	PT & APTT mixing studies, Plt. neutralization, Kaolin clotting time, activated protein C resistance, protein S (immunol.), vWF assay (immunol.), thrombotest, hep. cofactor II, alpha-2-antiplasmin	PT & APTT mixing studies, Plt. neutralization, Kaolin clotting time, protein S (immunol.), vWF assay (immunol.), thrombo test, hep. cofactor II, alpha-2-antiplasmin
Tests submitted for 510(k) clearance	n/a	none	activated protein C resistance
Tests in development but not yet submitted	n/a	activated protein C resistance	none
Methodologies supported	clot detection, mechanical	clot detect., mechanical; clot detect., optical, tungsten, turbidimetric; chromogenic; immunologic (microparticles)	clot detect., mechanical; clot detect., optical, tungsten, turbidimetric; chromogenic; immunologic (microparticles)
Oper. must load sep. reag. pack for ea. specimen/test run	no/no	no/no	no/no
No. of different measured assays onboard simultaneously	5	32	40
No. of different assays programmed and calibrated at one time	1/1	32	40
No. of user-definable (open) channels	n/a	32	40
Of those defined, no. active simultaneously	up to 4	12	40
Factor assays require manual manipulation or dils	yes	no	no
No. of reag. containers onboard at one time/tests per container	5/varies for test kit	24/varies with kit & operational mode	24/varies with assay & operational mode
Reagents refrigerated onboard	no	yes (15˚C)	yes (15˚C)
Multiple reag. configurations supported	no	yes	yes
Reag., consumables loaded w/o interrupting testing	n/a, manual	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Max. time same lot number of reag. can be used	12–18 mos	12–18 mos	12–18 mos
Walkaway capacity: No. of specimens/no. of tests	n/a, manual	60/450	1,250/450
Min. sample vol. aspirated precisely at one time	n/a	5 µL	3 µL
Standard specimen vol. required to run PT or PTT/Factor VIII activity	50 µL/50 µL	50 µL/50 µL	50 µL/50 µL
Disposables used/price of each	cuvettes & ball dispenser/inquire	cuvettes/—, probe decontaminate/—	cuvettes/—, probe decontaminate/—, tubing/—
Supports direct-from-track sampling	n/a	no	no
Primary tube sampling supported/pierces caps on primary tubes	n/a	yes/no	yes/no
Sample bar-code reading capability	n/a	yes	yes
Reagent bar-code reading capability	n/a	no	no
Onboard test automatic inventory	n/a	yes	yes
Measures no. of tests remaining	n/a	yes	yes
Short sample detection	n/a	yes	yes
Clot detection as preanalytical variable in plasma sample	n/a	n/a	n/a
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
Lag time during which hypercoagulable samples will not be detected	yes (PT & PTT: 4.5 sec)	yes (4.5 sec)	yes (4.5 sec)
Read time extended for prolonged clotting times	yes	yes (selectable on menus)	yes (selectable on menus)
User can set different-than-standard:			
• Reag. volumes/sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reag.	yes	yes	yes
• Incub. times/reading times	yes/yes	yes/yes	yes/yes
Autocalibration or autocalib. alert/multipoint calibration supported	no/yes	no/yes	no/yes
Auto shutdown/auto startup programmable	no/no	yes/yes	yes/yes
Stat time to completion of all analytes and throughput per h. for:			
• PT alone	75 sec/48	90 sec/190 tests	90 sec/325 tests
• PT, PTT	350 sec/10	300 sec/120 tests	300 sec/480 tests
• Fibrinogen	65 sec/55	70 sec/115 tests	70 sec/212 tests
• Factor VIII activity assay	275 sec/13	300 sec/120 tests	300 sec/200 tests
Time delay from ordering stat to aspir. of sample	n/a	varies by test	varies by test
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes	onboard (incl. QC: L-J, Westgard)	onboard (incl. QC: L-J, Westgard)
Interface supplied by instrument vendor	no	yes (included in instrument price)	yes (included in instrument price)
Interfaces in active user sites for:	—	all major LIS companies	in development
Bidirectional interface capability	n/a	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	n/a	no	yes
Modem servicing	n/a	yes	yes
Time required for maintenance by lab personnel	none	daily: <2 min; weekly: <35 min; monthly: <1 h	daily: <10 min; weekly: <30 min; monthly: <1 h
Onboard maintenance records	n/a	no	yes
Training provided with purchase	as needed on-site	5 d on-site, 4 d at vendor office	5 d on-site, 5 d at vendor office
Approx. no. of training hrs needed per tech	2 h	16–24 h	48–72 h
List price	$9,200	$81,000	$132,000
Ann. svc. contract cost (24 h/7 d)/warranty with purchase	$900 (M–F, 8–5)/1 yr	$8,000/1 yr	$14,000/1 yr
Unique advantages	• single micro-cuvettes for all tests; uses half volume for PT & APTT, reduced volume for all other tests • incub. area at 37˚C; 12 samples, 5 reag., 2 pipettes • 4 simultaneously usable test positions using patented ball method for extremely reproducible & reliable results • optional printer to ensure quality of test results	• optical & mechanical testing for greatest reliability; can perform simultaneous chrom. & clotting tests • quarter volume PT & APTT (half-vol. other tests) • easy-to-use software monitors quality at all times	• selective multichannel hemostasis testing offering true random access • patented ball method technology • parallel clotting & chromogenic testing

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