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	Bio/Data Corporation **Margaret Knowles-Tuchman** margaret.knowles-tuchman@biodatacorp.com **Horsham, PA 19044, 155 Gibraltar Road** www.biodatacorp.com
Instrument name/first year sold	**CD2000/1986**	**CoaData 2004/4004/2010**	**Platelet Aggregation Profiler, Model-PAP 8E/2005**
Number of units installed in U.S./Outside U.S.	>500/>1,000	—/>500	>180/>300
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	U.S./U.S.
Operational type	batch, discrete	discrete	batch, random access
Reagent type	open reagent system (reconstituted manually)	open reagent system	open reagent system, assay kits, reagents, controls, diluents, buffer, specialty products, others
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	cuvette, semiautomated	semiautomated manual pipette-auto start	programmable electronic pipette, optional bar-code scanner
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	5 × 12 × 8.5 in/9.2 lbs/1 sq ft	10.7 × 13.7 × 4.9 in/8.6 lbs/2 sq ft	22.5 × 14.0 × 21.7 in/45 lbs/2.2 sq ft
FDA-cleared clotting-based tests	PT, PTT, fib., any citrated plasma clot-based assay	PT, APTT	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	—	—	ristocetin cofactor assay, ristocetin and heparin-induced platelet aggregation, platelet aggreg. (ADP, EPI, arachidonic acid, trap< collagen), spontaneous aggregation, sticky platelets, dose response/EC/IC50, others
User-defined tests in clinical use	—	—	templates for user-defined tests included in software, specialty agonists, antiplatelet compounds, others
Tests submitted for 510(k) clearance	—	PT, APTT, fibrinogen	—
Tests in development but not yet submitted	—	—	proprietary
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing–optical detection	clot detection, optical; turbodensitometric	UV LED, platelet agglutination, platelet aggreg., turbidometric and rate reaction assays, digital circuitry and software
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	2 (PT, APTT)	1	up to 10
Number of different assays programmed and calib. at one time	1 (fibrinogen)	3	>256
Number of user-definable (open) channels	2	—	8
Of those defined, number active simultaneously	2	1	8
Factor assays require manual manipulation or dilutions	yes	yes	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	5 or more/reagent manufacturer defined/no	4/reagent manufacturer defined/no	2 stirred, adapters for various sized vials/varies/no
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Maximum time same lot number of reagents can be used	laboratory dependent	reagent manufacturer defined	up to 18 months
Walkaway capacity: Number of specimens/Number of tests	—/—	18 incubational positions/2	8/8
Minimum sample volume aspirated precisely at one time	manual pipetting	50 µL (150 µL total volume)	25 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL, minimum 50 µL/50 µL, minimum 50 µL	50 µL/—	—/—
Disposables used/Price of each	500 microcuv. w/mixers in trays/11.6¢ ea., bulk 11¢; 500 macrocuv. w/mixers in trays/12¢ ea., bulk 10.6¢; 2,304 pipette tips-trayed/5.1¢ ea., 3k tips bulk/3.9¢ ea.	micro single cuvette, printer paper/—	siliconized test tubes: 100 @ $25.75, plastic-coated stir bars: 50 @ $13.75, pipette tips: 960 @ $33.00; MagneTube: 50 @ $39.50
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	no
Measures No. of tests remaining/Short sample detection	no/no	no/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	no	no	no
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no
Dilution of patient samples onboard	no	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable sample not detected	yes (3 seconds)	no	no
Read time extended for prolonged clotting times	yes, up to 999 seconds	yes, selectable on operator menus	no
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/no	no/yes	V2.1 hardware/software update adds optical calibration
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	120 seconds/user defined	limited by user pipetting capabilities	—/—
• PT, PTT	240 seconds/user defined	limited by user pipetting capabilities	—/—
• Fibrinogen	300 seconds/user defined	limited by user pipetting capabilities	—/—
• Factor VIII activity assay	300 seconds/user defined	limited by user pipetting capabilities	—/—
Time delay from ordering stat to aspir. of sample	—, all preanalytical	—	—
Auto. transfer of QC results to LIS	no	no	yes
Data management capability	no	no	yes (onboard, includes QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	call technical support for inquiry	not yet	—
Bidirectional interface capability	no	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
How labs get LOINC codes for reagent kits	—	no	e-mail query
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 seconds; weekly: 30 seconds; monthly: 5 minutes	per shift: <1 minute (cleaning housing); daily: <1 minute (cleaning housing); weekly: <5 minutes (cleaning housing and incubating block)	weekly: 15 minutes; monthly: 30 minutes
Onboard maintenance records	no	no	yes
Training provided with purchase	videotape; on-site training extra	1 day, on request	1.5 days on site
Approximate number of training hours needed per tech	2	4	4–6
List price	$900, special pricing upon written request for quote	—	$15,990
Annual service contract cost (24/7)/Warranty with purchase	add. 1-yr init. contract $500 (opt.)/1 yr, $300 renewal	12 months	$1,990 for 1 year, $2,990 for 2 years/2 years
Unique advantages (provided by vendors)	smaller clinic; office, private, vet labs; low acquisition and service cost, low maintenance; refurbished units available at reduced prices; able to handle turbid/colored samples	inexpensive two-channel (2004) and four-channel (4004) protime instruments with few moving parts; for small lab/doctor's office; updated version of CoaData/Accustasis; low maintenance and repair costs	two-year warranty; no-charge software upgrades during warranty period; optional PDQ platelet function centrifuge standardizes sample preparation, reduces preparation time to five minutes

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Survey Editor: Raymond Aller, MD

Coagulation analyzers

Part 2 of 11	Cepheid Larry Hambleton larry.hambleton@cepheid.com 904 Caribbean Drive, Sunnyvale, CA 94089 888-838-3222 www.cepheid.com	Chrono-Log Corp. Kathy Jacobs jacobs@chronolog.com Havertown, PA 19083 610-853-1130 www.chronolog.com	Diagnostica Stago, Inc. Paul Riley, PhD paul.riley@stago-us.com 5 Century Drive, Parsippany, NJ 07054 973-671-1200 ext. 4238 www.stago-us.com
Instrument name/first year sold	GeneXpert/2005	Whole Blood-Optical Lumi-Aggregation System, Model 700-2/700-4/2006	Calibrated Automated Thrombogram/2006
Number of units installed in U.S./Outside U.S.	>1,700 globally	160/205	—
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	The Netherlands/Finland
Operational type	batch, random access, continuous random access	batch, random access	batch, discrete
Reagent type	self-contained single-use catridges/packages/slides (lyophilized reconstituted manually)	open reagent system, assay kits, reference plasmas, controls (lyophilized reconstituted manually)	self-contained single-use and multi-use cartridges-packages-slides, open reagent system (lyophilized, reconstituted manually)
Operates on whole blood or spun plasma	whole blood	whole blood, spun plasma	spun plasma
Sample handling system	self-contained cartridge	manual	96 well plate pipetted manually, inserted into instrument where the last reagent is automatically dispensed
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	GX IV: 14 × 11.75 × 12.25 in/26 lbs/.999 sq ft GX XVI: 30 × 21 × 15 in/125 lbs/.999 sq ft	8.5 × 14.0 × 18.0 in/40 lbs/ M700-2: 1.75 sq ft; M700-4: 3.5 sq ft	34 × 42 × 42 cm/30 lbs/2 sq ft
FDA-cleared clotting-based tests	—	—	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	molecular PCR testing for Factor II/V	platelet dense granule secretion, whole blood impedance aggregation, LTA aggregation, ristocetin cofactor assay	—
User-defined tests in clinical use	Xpert HemosIL Factor II/V (distributed exclusively by Instrumentation Labs)	platelet dense granule secretion, whole blood impedance aggreg., LTA aggreg. w/all stand. reagents, ristocetin cofactor assay	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	fluorescence-based detection of thrombin generation and microparticle determination
Methodologies supported	molecular PCR testing	turbidimetric, platelet dense granule secretion, whole blood impedance aggreg., LTA aggreg., ristocetin cofactor assay	quartz-halogen, fluorescence based detection of thrombin generation
Operator must load sep. reagent pack per specimen/Test run	yes, 1 assay per pack/—	no/—	no/no
Number of different measured assays onboard simultaneously	GX IV: 4; GX XVI: 16	2–4	5
Number of different assays programmed and calib. at one time	1 to 16	4–8	5
Number of user-definable (open) channels	—	2–4	16
Of those defined, number active simultaneously	GX IV: 4; GX XVI: 16	2–4	16
Factor assays require manual manipulation or dilutions	no	yes	—
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	GX IV: 4; GX XVI: 16/1/no, temp: 15° to 30°C	no/—/no	—/16/no
Multiple reagent configurations supported	yes	yes	
Reagents, consumables loaded without interrupting testing	yes	yes	
Same capabilities when 3rd-party reag. used	no	no	
Maximum time same lot number of reagents can be used	—	12–30 months	
Walkaway capacity: Number of specimens/Number of tests	GX-IV: 4; GX-XVI: 16/GX-IV: 4; GX-SVI: 16	2–4/4–8	16/16
Minimum sample volume aspirated precisely at one time	—	—	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	—/50 µL	225 µL PRP-lumi aggregation 450 µL; 450 µL whole blood-lumi aggregation 450 µL/25 µL ristocetin cofactor 50 µL	—
Disposables used/Price of each	Xpert Cartridge	cuvettes/144 @ $34, stir bars/144 @ $30, impedance probes/25 @ $130, pipette tips/1,000 @ $73, $55 and $60	—
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	yes	no	no
Reagent bar-code reading capability	yes	no	no
Onboard test automatic inventory	no	no	no
Measures No. of tests remaining/Short sample detection	no/no	no/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	no	no	no
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/no (not necessary for internal calibration technology)
Dilution of patient samples onboard	no	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	no/no
Lag time during which hypercoagulable sample not detected	—	—/—	no
Read time extended for prolonged clotting times	—	yes	no
User can set different-than-standard:			
• Reagent volumes/Sample volumes	no/no	yes/yes	yes/yes
• No. and sources of reagent	no	yes	yes
• Incub. times/Reading times	no/no	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/—	yes	yes/no
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete 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	yes	no	no
Data management capability	yes (onboard, includes QC)	yes (onboard)	onboard
Interface supplied by instrument vendor	no	yes	no
Interfaces in active user sites for:	HL7 and ASTM compatible	—	—
Bidirectional interface capability	yes (broadcast download and host query)	no	no
Results transferred to LIS as soon as test time complete	yes	no	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	no	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 5 minutes; weekly: 15 minutes; monthly: 60 minutes	30 minutes when optical calibration required	weekly: 15 minutes
Onboard maintenance records	no	yes	no
Training provided with purchase	1 day on site	1.5 days on site	1 day on site
Approximate number of training hours needed per tech	2	8	5
List price	GX IV: $78,200	M700-2: $19,500; M700-4: $32,000	$38,500
Annual service contract cost (24/7)/Warranty with purchase	$9,150/12 months	M700-2: $1,804; M700-4: $3,008 for 3 years/12 months	$1,550/1 year
Unique advantages (provided by vendors)	walkaway real-time PCR system; self-contained assay cartridges perform sample clean-up and extraction; contains PCR reagents, primers, and probes; internal controls; integrated detection tube; bar codes identify sample test cartridge; <2 minutes hands-on per sample	tests platelet aggregation; measures ATP release in 4 samples simult. using whole blood, PRP, washed, or gel-filtered platelets; continuously monitors temp. and stirring speed; optical calibration by lab personnel; dedicated software pkgs. calculate amplitude, slope, lag time and more	determination of thrombin generation by fluorescence detection; sample-specific calibrator corrects for plasma color, turbidity, inner filter effect, substrate depletion; examine thrombin generation in a dynamic process while clot formation is occurring

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Coagulation analyzers

Part 3 of 11	Diagnostica Stago Inc. Ron Evancheck ronald.evancheck@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Barry Ray barry.ray@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Barry Ray barry.ray@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	STA Satellite/2010	STA-R Evolution Expert Series/2005	STA Compact CT/2001
Number of units installed in U.S./Outside U.S.	—/—	—/—	—/—
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	France/France	France/France	France/France
Operational type	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	carousel	rack with continuous specimen access	continuous specimen access—primary tube
Model type	benchtop	floor standing	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	27.4 × 21.1 × 25.5 in/72 lbs/4 sq ft	49.2 × 50.3 × 32.2 in/507 lbs/26.8 sq ft	25.2 × 38.8 × 25.8 in/351 lbs/25.6 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT, screeen and confirm	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT
FDA-cleared chromogenic tests	heparin (UFH, LMWH), AT	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin	—
FDA-cleared immunologic tests	D-dimer	D-dimer, VWF, total and free protein S, AT antigen	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	APCR, other clotting chromogenic & immunological tests with user-defined applications	APCR, other clotting tests can have user-defined applications
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	—
Methodologies supported	clot detection, mechanical; chromogenic; immunologic	clot detection: mechanical; chromogenic; immunologic	clot detection, mechanical
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	up to 80	up to 200	up to 80
Number of different assays programmed and calib. at one time	up to 80	up to 200	up to 80
Number of user-definable (open) channels	70	200	70
Of those defined, number active simultaneously	70	200	70
Factor assays require manual manipulation or dilutions	—	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	16/varies/yes (15°–19°C)	70/varies/yes (15°–19°C)	45/varies/yes (15°–19°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	no	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Maximum time same lot number of reagents can be used	18 months	18 months	18 months
Walkaway capacity: Number of specimens/Number of tests	20/12 per specimen	215/32	96/12 per specimen
Minimum sample volume aspirated precisely at one time	5 µL	5 µL	5 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/5 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes & wash solution/varies with volume	cuvettes & wash solution/varies with volume	cuvettes & wash solution/varies with volume
Supports direct-from-track sampling	no	yes (Beckman Coulter, Bayer LabCell, Roche MPA)	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes/yes	yes/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	yes	yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for mechanical detection technology)	no/no (not necessary for mechanical detection technology)	no/no (not necessary for mechanical detection technology)
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/no	yes/no	yes/no
Lag time during which hypercoagulable sample not 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:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	no (not necessary)/no (not necessary)	no (not necessary)/no (not necessary)	no (not necessary)/no (not necessary)
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	7 minutes/52 specimens	<6 minutes/~300 specimens	<6 minutes/150 specimens
• PT, PTT	7 minutes/36 specimens	7 minutes/~150 specimens	7 minutes/75 specimens
• Fibrinogen	7 minutes/36 specimens	7 minutes/~180 specimens	7 minutes/75 specimens
• Factor VIII activity assay	—/—	7 minutes/~180 specimens	7 minutes/70 specimens
Time delay from ordering stat to aspir. of sample	<15 seconds	<15 seconds	<15 seconds
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots)	onboard (L-J plots)	onboard (incl. QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others	Cerner, Misys, Meditech, others
Bidirectional interface capability	yes (host query)	yes (host query)	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	yes (Beckman Coulter, Bayer LabCell, Roche MPA)	no
Modem servicing	no	yes	no
Time required for maintenance by lab personnel	weekly: <30 minutes; monthly: 30 minutes	weekly: <30 minutes; monthly: <30 minutes	weekly: <30 minutes; monthly: <30 minutes
Onboard maintenance records	yes	yes	yes
Training provided with purchase	2 days on site	varies on site, 4 days at vendor offices	varies on site, 3 days at vendor office
Approximate number of training hours needed per tech	2	~3–5	2 (basic)
List price	$45,000	$161,900	$50,000
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	prices available upon request/1 year	prices available on request/1 year
Unique advantages (provided by vendors)	viscosity-based detection system; standardization across all STA analyzers allows consistent reporting throughout hospital groups; complete walkaway automation for low-volume coagulation laboratories	viscosity-based detection system; connectivity to lab automation systems; software for password protection and result traceability; able to standardize with other STA analyzers	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; able to standardize with other STA systems

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Part 4 of 11	Diagnostica Stago Inc. Ron Evancheck ronald.evancheck@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Barry Ray barry.ray@stago-us.com Five Century Dr. Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com
Instrument name/first year sold	**STart 4 Hemostasis Analyzer/1998**	**STA Compact Hemostasis System/1996**	**AggRAM/2005**
Number of units installed in U.S./Outside U.S.	—/—	—/—	85/100+
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	France/France	France/France	U.S./U.S.
Operational type	batch	continuous random access	batch, random access
Reagent type	open reagent system (lyoph., reconst. manually)	open reagent system (lyoph., reconst. manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma, PRP
Sample handling system	manual	continuous specimen access—primary tube	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	4.7 × 16.1 × 16.5 in/12.5 lbs/1.8 sq ft	25.2 × 38.8 × 25.8 in/351 lbs/25.6 sq ft	6 × 10 × 17 in/15 lbs/—
FDA-cleared clotting-based tests	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT, screeen and confirm	—
FDA-cleared chromogenic tests	—	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin	—
FDA-cleared immunologic tests	—	D-dimer, VWF, total and free protein S, AT antigen	—
Other FDA-cleared tests	—	—	ristocetin cofactor and platelet aggreg.
User-defined tests in clinical use	DRVVT screen and confirm assays, APCR, other clotting tests with user-defined applications	APCR, other clotting chromogenic and immunological tests with user-defined applications	ristocetin cofactor, platelet aggreg.–ADP, EPI, COL, ristocetin, arach. acid
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	lumi, chromogenics, HIT
Methodologies supported	clotting tests	clotting, chromogenic, & immunologic assays	ristocetin cofactor, platelet aggreg.
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	1	up to 80	4–8
Number of different assays programmed and calib. at one time	20	up to 80	4–8
Number of user-definable (open) channels	4	70	12
Of those defined, number active simultaneously	1	70	4–8
Factor assays require manual manipulation or dilutions	yes	no	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	4/varies/no	45/varies/yes (15°–19°C)	—/—/no
Multiple reagent configurations supported	yes	yes	no
Reagents, consumables loaded without interrupting testing	no	yes	no
Same capabilities when 3rd-party reag. used	yes	yes	—
Maximum time same lot number of reagents can be used	18 months	18 months	12 months
Walkaway capacity: Number of specimens/Number of tests	4/1	96/12 per specimen	no
Minimum sample volume aspirated precisely at one time	25 µL	5 µL	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/5 µL	50 µL/5 µL	Plt. aggreg.: 225 µL PRP, Risto cofactor: 50 µL
Disposables used/Price of each	cuvettes, balls/varies	cuvettes and wash solution/varies with volume	cuvettes/200 @ $55.65; pipette tips/1,000 @ $82; stir bars/30 @ $62.25
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no (not applicable)	yes/yes	no
Sample bar-code reading capability	no	yes	no
Reagent bar-code reading capability	no	yes	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 preanalytical variable in plasma sample	no	no	—
Auto. detects adequate reagents for aspiration and analysis	no	yes	no
Hemolysis/Turbidity detection-quantitation	no/no (not necessary for mechanical detection technology)	no/no (not necessary for mechanical detection technology)	no/no
Dilution of patient samples onboard	no	yes	no
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	no/no
Lag time during which hypercoagulable sample not detected	no	no	—
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	—
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	no	no (not necessary)/no (not necessary)	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<1 minute/up to 120 specimens	<6 minutes/150 specimens	—
• PT, PTT	—/—	7 minutes/75 specimens	—
• Fibrinogen	<1 minute/up to 120 specimens	7 minutes/75 specimens	—
• Factor VIII activity assay	varies/varies	7 minutes/70 specimens	—
Time delay from ordering stat to aspir. of sample	<15 seconds	<15 seconds	—
Auto. transfer of QC results to LIS	no	yes	yes
Data management capability	no	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	Cerner, Misys, Meditech, others	—
Bidirectional interface capability	no	yes (host query)	no
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	—
Time required for maintenance by lab personnel	weekly: <5 minutes; monthly: <5 minutes	weekly: <30 minutes; monthly: <30 minutes	daily: 15 minutes; weekly: 15 minutes; monthly: 1 hour
Onboard maintenance records	no	yes	yes
Training provided with purchase	1 day on site	varies on site, 3 days at vendor offices	2 days on site
Approximate number of training hours needed per tech	1	2 (basic)	4–8
List price	$9,600	$75,000	$14,995
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	prices available on request/1 year	$1,800/1 year
Unique advantages (provided by vendors)	viscosity-based detection system; effective for low-volume testing or backup for optical system; programmable and preprogrammed assays with curve storage plus four independently timed measurement wells	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; able to standardize with other STA analyzers	specialized coag instrument intended for platelet aggreg. and ristocetin cofactor

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Coagulation analyzers

Part 5 of 11	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com	Instrumentation Laboratory Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea, CA 92821 714-961-4252 www.beckmancoulter.com
Instrument name/first year sold	**Cascade M-4/1992**	**Cascade M/1991**	**ACL AcuStar/2010**
Number of units installed in U.S./Outside U.S.	200+/30	300+/100	0/10
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
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	self-contained multi-use cartridges-packages-slides (liquid)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	8 × 15 × 13 in/25 lbs/1.4 sq ft	8 × 15 × 13 in/25 lbs/1.4 sq ft	21 × 34 × 24 in/170 lbs/15 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TCT, factor assays II, V, VII–XII	PT, APTT, fib., TCT, factor assays II, V, VII–XII	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	PT, APTT, fib., TCT, factor assays II, V, VII–XII	PT, APTT, fib., TCT, factor assays II, V, VII–XII	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	DRVVT	DRVVT	HIT IgG, HIT total
Methodologies supported	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric	immunologic (chemiluminescent)
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	4	1	20
Number of different assays programmed and calib. at one time	4	1	20
Number of user-definable (open) channels	4	2	0
Of those defined, number active simultaneously	2	1	—
Factor assays require manual manipulation or dilutions	yes	yes	—
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	0/—/no	—	20/varies by assay/yes (4°C)
Multiple reagent configurations supported	no	—	no
Reagents, consumables loaded without interrupting testing	no	no	no
Same capabilities when 3rd-party reag. used	yes	yes	no
Maximum time same lot number of reagents can be used	12 months	12 months	—
Walkaway capacity: Number of specimens/Number of tests	no	no	30/—
Minimum sample volume aspirated precisely at one time	manual, 50 µL	manual, 50 µL	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	100 µL, minimum 50 µL/100 µL (dil.), minimum 50 µL (dil.)	100 µL, minimum 50 µL/100 µL (dil.), minimum 50 µL (dil.)	—/—
Disposables used/Price of each	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvettes/price available upon request
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/—	no/—	yes (most tubes validated)/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/Short sample detection	no/no	no/no	yes/yes
Clot detection as preanalytical variable in plasma sample	—	—	no
Auto. detects adequate reagents for aspiration and analysis	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	yes/no
Lag time during which hypercoagulable sample not detected	yes (PT: 4 seconds, PTT: 14 seconds)	yes (PT: 4 seconds, PTT: 14 seconds)	—
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	—
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	no/no
• No. and sources of reagent	yes	yes	no
• Incub. times/Reading times	yes/yes	yes/yes	no/no
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	yes/yes
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	3 minutes/140 specimens	3 minutes/120 specimens	—
• PT, PTT	7 minutes/80 specimens	7 minutes/50 specimens	—
• Fibrinogen	3 minutes/160 specimens	3 minutes/140 specimens	—
• Factor VIII activity assay	7 minutes/80 specimens	7 minutes/50 specimens	—
Time delay from ordering stat to aspir. of sample	—	—	<1 minute
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	no (includes QC: L-J plots)	no (includes QC: L-J plots)	onboard (includes QC: L-J plots and Westgard multirule)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	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
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	—	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: 10 minutes; weekly: 10 minutes; monthly: 30 minutes	daily: 10 minutes; weekly: 10 minutes; monthly: 20 minutes	daily: 10 minutes; weekly: 10 minutes
Onboard maintenance records	no	no	no
Training provided with purchase	1 day on site	1 day on site	—
Approximate number of training hours needed per tech	2	2–4	6
List price	$9,635	$7,127	—
Annual service contract cost (24/7)/Warranty with purchase	$966/1 year	$714/1 year	—
Unique advantages (provided by vendors)	four-channel manual analyzer; QC program onboard; singles or duplicates	QC program onboard; curve storage; suitable for office lab or as backup analyzer	easy to use, utilizing sensitive chemilumiescent technology, providing results <1 hour; for many complex coag assays, replaces the need to run manual, time-consuming ELISA assays; test menu will include assays whose rapid results will improve patient care and lab efficiences

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Coagulation analyzers

Part 6 of 11	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea 92821 714-961-4252 www.beckmancoulter.com	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea 92821 714-961-4252 www.beckmancoulter.com	Instrumentation Laboratory/ Beckman Coulter Inc. Venita Shirley vcshirley@beckman.com 250 S. Kraemer Blvd., Brea 92821 714-961-4252 www.beckmancoulter.com
Instrument name/first year sold	**ACL TOP 500 CTS/2008**	**ACL ELITE Series/2006**	**ACL TOP 700 Series/2004**
Number of units installed in U.S./Outside U.S.	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)	4,000+/8,000+ (all models combined)
Number of contracts signed between 1/1/10 and 11/30/10	175	250	48
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	continuous random access	modified random access	continuous random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	racks, allowing continuous loading of samples	tray-primary tubes	racks, continuous loading of primary tubes
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 43 × 35 in/312 lbs/14 sq ft	24 × 37 × 24/139 lbs/6 sq ft	29 × 60 × 35/331 lbs/21 sq ft
FDA-cleared clotting-based tests	PT, APTT, fib., TT, factors, lupus (SCT and DRVVT), protein C/S, APCR-V	PT, APTT, fib., TT, factors, protein C/S, lupus (SCT and DRVVT), APCR-V	PT, APTT, fib., TT, factors, lupus (SCT and DRVVT), APCR-V, protein C/S
FDA-cleared chromogenic tests	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor	heparin Xa, protein C, AT plasminogen, plasmin inhibitor, factor VIII	heparin Xa, protein C, AT, plasminogen, plasmin inhibitor
FDA-cleared immunologic tests	D-dimer, D-dimer HS, vWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer, vWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine	D-dimer, D-dimer HS, vWF (Act. & Ag.), free protein S, factor XIII Ag., homocysteine
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	heparin-induced thrombocytopenia	—	heparin-induced thrombocytopenia
Tests in development but not yet submitted	global protein C pathway	—	global protein C pathway
Methodologies supported	clot detection, LED optical, chromogenic; immunologic (turbidimetric)	clot detection, LED optical (nephelometric); chromogenic; immunologic	clot detection, LED optical, chromogenic; immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	500	22	500
Number of different assays programmed and calib. at one time	500	300	500
Number of user-definable (open) channels	250	100	250
Of those defined, number active simultaneously	30	20	30
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	40/varies by assay/yes	22/varies by test/yes	60/varies/yes
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Maximum time same lot number of reagents can be used	18 months	18 months	18 months
Walkaway capacity: Number of specimens/Number of tests	80/800	40/260	120/800
Minimum sample volume aspirated precisely at one time	4 µL	5 µL	4 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	PT and PTT: 50 µL; FVIII: 25 µL	PT and PTT: 60 µL; FVIII: 18 µL	PT and PTT: 50 µL; FVIII: 25 µL
Disposables used/Price of each	cuvettes/varies	cuvettes/varies	cuvettes/varies
Supports direct-from-track sampling	no	no	yes (model available)
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes/yes (optional)
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	yes	yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	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/yes	yes/yes
Lag time during which hypercoagulable sample not detected	no	yes (PT and PTT: 3 seconds)	no
Read time extended for prolonged clotting times	yes	yes	yes
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	not needed	not needed	not needed
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/240 specimens	4 minutes/175 specimens	<3 minutes/360 specimens
• PT, PTT	8 minutes/90 specimens	8 minutes/270 specimens	8 minutes/165 specimens
• Fibrinogen	<3 minutes/78 specimens	4 minutes/175 specimens	<3 minutes/108 specimens
• Factor VIII activity assay	8 minutes/77 specimens	8 minutes/125 specimens	8 minutes/100 specimens
Time delay from ordering stat to aspir. of sample	minimal	15 seconds	minimized
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes	yes	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	most major vendors	most major vendors	most major vendors
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	yes
Modem servicing	In development	no	In development
Time required for maintenance by lab personnel	daily: <10 minutes; weekly: 10 minutes	daily: <5 minutes; weekly: 10 minutes; monthly: 5 minutes	daily: <10 min.; wkly: 10 minutes; no monthly maintenance
Onboard maintenance records	yes	yes	yes
Training provided with purchase	5 days at vendor offices	5 days at vendor offices	5 days at vendor offices
Approximate number of training hours needed per tech	24–40	24	24–40
List price	$130,900	$54,900	$145,000
Annual service contract cost (24/7)/Warranty with purchase	various options available/1 year	various options available/1 year	various options available/1 year
Unique advantages (provided by vendors)	complete assay menu including D-dimer and D-dimer HS with VTE exclusion; 671-nm LED detection, which minimizes interference from lipemia, hemoglobin, and bilirubin; HemosIL plasma sets for validation of INR test system; HemosIL liquid hep with universal cal curve for UFH and LMWH	test menu featuring D-dimer; bar-code reagent management; ACL family harmonization; HemosIL INR plasma sets for INR test system validation and/or calibration; HemosIL liq. hep with universal cal curve for UFH and LMWH	features clot signature curve analysis; continuous operation w/o interruption to workflow; minimized operator intervention using intuitive Windows XP software; 2D bar code for reagent, calibration, and control assay value import; HemosIL INR plasma sets for INR test system validation and/or calibration; HemosIL liq. hep with universal cal curve for UFH and LMWH

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Coagulation analyzers

Part 7 of 11	LABiTec GmbH **Matthias Schramm** matthias.schramm@labitec.de An der Strusbek 6 Ahrensburg, Germany 22926 011-49-4102-47950 www.labitec.com	Siemens Healthcare Diagnostics **Jackie Hauser** jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.siemens.com/diagnostics	Siemens Healthcare Diagnostics **Jackie Hauser** jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.siemens.com/diagnostics
Instrument name/first year sold	**CoaLAB 1000/2009**	**BFT II/U.S.: 1999**	**Sysmex CA-530/2006**
Number of units installed in U.S./Outside U.S.	—/150	—/—	—/—
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	Japan/Japan
Operational type	batch, random access	batch	continuous random access
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)	open reagent system (reconstituted manually), optimized for Siemens instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	two fixed racks of 11 samples each plus 3 stat	manual	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	78 × 58 × 50 cm/30 kg (shipping)/—	3.9 × 7.9 × 11.8 in/8.4 lbs/1.5 sq ft	19 × 21 × 18.5 in/99 lbs/9 sq ft
FDA-cleared clotting-based tests	—	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, reptilase time, protien C clot, factor assays
FDA-cleared chromogenic tests	—	—	Innovance AT, Berichrom AT, protein C chromo, heparin
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	PT/APTT/fibrinogen	—	—
Tests in development but not yet submitted	—	—	PT multicalibrators
Methodologies supported	clot detection (optical), nephelometric, trubidimetric, chromogenic, immunologic (agglutination/aggregation)	turbodensitometric	clot detection: optical; turbidimetric, chromogenic; immunol.
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	15 maximum	1	5
Number of different assays programmed and calib. at one time	50	3	7
Number of user-definable (open) channels	2	—	7
Of those defined, number active simultaneously	2	1	5
Factor assays require manual manipulation or dilutions	no	—	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	15/200 maximum/no	4/up to 200/no	11/varies, up to 200/yes (15°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	no	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	yes	yes	yes
Maximum time same lot number of reagents can be used	1 year	12 months	12 months
Walkaway capacity: Number of specimens/Number of tests	25 maximum/>10	1/1	10/50
Minimum sample volume aspirated precisely at one time	2 µL	50 µL	10 µL/50 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	100µl reagent/50 µL sample/50 µL APTT; 50 µL sample; 50 µL/3 reagents and 1-sample	50 µL	50 µL/—
Disposables used/Price of each	cuvette ring (32 single cuvettes per ring)/sample cups	cuvettes, printer paper/varies with volume	reaction tubes, CA clean I, thermal paper/varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (1.7–4 mL)/no	no/no	yes (3–5 mL)/no
Sample bar-code reading capability	yes	no	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	yes	no	yes
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	yes/yes
Clot detection as preanalytical variable in plasma sample	yes	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	no	yes
Hemolysis/Turbidity detection-quantitation	no/yes	no/no	yes/no
Dilution of patient samples onboard	yes	no	yes
Automatic rerun capability/Auto reflex testing capability	yes/no	no/no	no/no
Lag time during which hypercoagulable sample not detected	yes (PT: <10 seconds; PTT: <20 seconds)	yes (PT: 5 seconds, APTT: 15 seconds)	yes (<7 seconds for PT; <15 seconds for APTT)
Read time extended for prolonged clotting times	yes	no	yes (selectable on menus)
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<2 minutes/108 per hour	1 minute/—, manual	7 minutes/54 results
• PT, PTT	<5 minutes/60 per hour	—, manual	8 minutes/43 results
• Fibrinogen	<5 minutes/90 per hour	<1 minute/—, manual	7 minutes/54 results
• Factor VIII activity assay	depends on assay	—	—
Time delay from ordering stat to aspir. of sample	3 minutes	—	2 minutes
Auto. transfer of QC results to LIS	yes	no	yes
Data management capability	onboard (includes QC: Levy-Jennings plots and Westgard multirule)	no	onboard (incl. QC: L-J plots)
Interface supplied by instrument vendor	yes (included)	—	no
Interfaces in active user sites for:	via LAN, Windows OS, Linux OS	—	all major LIS vendors
Bidirectional interface capability	yes (host query)	no	yes (host query after manual ID input)
Results transferred to LIS as soon as test time complete	yes	no	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
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	per shift: <1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: calibration 15 minutes	daily: 1 minute	daily: <5 minutes; weekly: 1 minute; quarterly: <5 minutes
Onboard maintenance records	no	no	no
Training provided with purchase	3 days at vendor offices; on site on request	Web CD training course	2 days on site, online training course, Web CD training
Approximate number of training hours needed per tech	—	2	2
List price	—	$8,685	$34,812
Annual service contract cost (24/7)/Warranty with purchase	—/12 months	—	—
Unique advantages (provided by vendors)	standalone device, requires no additional PC/monitor to control system, software onboard, only external printer; flexible and extendable by software add-ons; like QC/Bi-Di, different wavelength available; optimized for small- to midsized labs; special hemostasis of diagnostic assays	two-channel micro reagent volume clot-based technology; opto-mechanical detection accurate on lipemic, icteric samples; automatic INR calculation, curve storage, built-in thermal printer; perfect for low-volume testing/backup to larger systems	small footprint; onboard quality control package; primary tube sampling and removable reagent trays

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Coagulation analyzers

Part 8 of 11	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics
Instrument name/first year sold	Sysmex CA-560/U.S.: 2003	Sysmex CA-1500/U.S.: 2000; worldwide: 1999	Sysmex CA-7000/2002
Number of units installed in U.S./Outside U.S.	—/—	—/—	—/—
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	Japan/Japan	Japan/Japan	Japan/Japan
Operational type	continuous random access	continuous random access	continuous random access
Reagent type	open reagent system (reconstituted manually), optimized for Siemens instruments	open reagent system (lyoph., reconstituted manually), optimized for Siemens instruments	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack	10-tube position sample rack × 5	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	19 × 21 × 18.5 in/99 lbs/9 sq ft	20 × 31.2 × 31.2 in/186 lbs/6.8 sq ft	24.8 × 42 × 43.8 in/345.4 lbs/12.78 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays	PT, APTT, fibrinogen, TT, reptilase time, factor assays, DRVVT screen and confirm, factor V Leiden, protein C clot, protein S activity	PT, APTT, fibrinogen, TT, reptilase time, factor assays, DRVVT screen and confirm, factor V Leiden, protein C clot, protein S activity
FDA-cleared chromogenic tests	Innovance AT, Berichrom AT, protein C chromo, heparin	Innovance AT, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin	Innovance AT, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin
FDA-cleared immunologic tests	Advanced D-dimer, Innovance D-dimer	Advanced D-dimer, Innovance D-dimer	Advanced D-dimer, Innovance D-dimer
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	PT multicalibrators	PT multicalibrators	PT multicalibrators
Methodologies supported	clot detect., optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	5	15	20
Number of different assays programmed and calib. at one time	7	25	40
Number of user-definable (open) channels	7	25	40
Of those defined, number active simultaneously	5	15	20
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	11/varies, up to 200/yes (15°C)	39/up to 200/yes (15°C)	58/varies up to 200/yes (15°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	consumables yes, reagents no	some consumables yes, reagents no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Maximum time same lot number of reagents can be used	12 months	12 months	12 months
Walkaway capacity: Number of specimens/Number of tests	10/50	50/up to 1,000	100/550 per hour PT and APTT, 300 per hour PT
Minimum sample volume aspirated precisely at one time	10 µL	5 µL	5 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/10 µL	50 µL/10 µL
Disposables used/Price of each	reaction tubes, CA clean I, thermal paper/varies with volume	reaction tubes, sample plates, CA clean I and II, system buffer, halogen lamp, closed container sample replacement needles/varies with volume	reaction tubes, CA clean I and II, system buffer, halogen lamp, closed container sample replacement needles/varies with volume
Supports direct-from-track sampling	no	yes (Sysmex CST series)	yes (custom automation solutions available)
Primary tube sampling supported/Pierces caps on primary tubes	yes (3–5 mL)/no	yes (3–5 mL)/yes	yes (3–5 mL)/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	no	yes	yes
Onboard test automatic inventory	yes	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	yes/no	yes/no	yes/no
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/yes	yes/yes
Lag time during which hypercoagulable sample not detected	yes (PT: <7 seconds, APTT: <15 seconds)	yes (PT: 7 seconds, APTT: 15 seconds)	yes (PT: 7 seconds, APTT: 15 seconds)
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:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	7 minutes/54 results	7 minutes/120 results	7 minutes/280 results
• PT, PTT	8 minutes/43 results	8 minutes/80 results	8 minutes/480 results
• Fibrinogen	7 minutes/54 results	8 minutes/120 results	8 minutes/280 results
• Factor VIII activity assay	—	8 minutes/—	8 minutes/300 results
Time delay from ordering stat to aspir. of sample	2 minutes	2 minutes	2 minutes
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	onboard (incl. QC: L-J plots)	onboard (incl. QC: L-J plots & Westgard)	onboard (incl. QC: L-J plots & Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	all major LIS vendors	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	yes (host query)	yes (host query)	yes (host query)
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	yes (Sysmex CST series)	custom automated connectivity with StreamLab
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: 1 minute; quarterly: < 5 minutes	daily: <5 minutes; weekly: 1 minute; quarterly: <5 minutes	daily: <10 minutes; weekly: 1 minute; monthly: <5 minutes; quarterly: <5 minutes
Onboard maintenance records	no	no	no
Training provided with purchase	2 days on site, online training course, Web CD training	3 days at vendor offices for key operator, online training course, Web CD training	3 days at vendor offices for 2 key operators, Web CD training course
Approximate number of training hours needed per tech	2	6	8 (on site)
List price	$47,634	$97,529 standard model; $110,544 cap-piercing model	$196,451
Annual service contract cost (24/7)/Warranty with purchase	—	—	—
Unique advantages (provided by vendors)	five-parameter true random-access clotting/chromogenic/immunologic technology; complete automation, specialty assay capability; low operating expense	simultaneous curve calibrating and patient testing; ability to load multiple bottles or multiple lots of reagent; user-definable, repeat, redilute, and reflex testing	fast throughput for routine testing; continuous loading of reagents, consumables, and patient samples without interruption; connectivity to lab automation system

Coagulation analyzers

Part 9 of 11	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 1717 Deerfield Road Deerfield, IL 60015-0778 847-267-5383 www.usa.siemens.com/diagnostics	Tcoag US Kevin McGlinchey kevin.mcglinchey@tcoag.com Marketing Manager 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.com	Tcoag US Kevin McGlinchey kevin.mcglinchey@tcoag.com Marketing Manager 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.com
Instrument name/first year sold	BCS XP/2006	KC1△/2001	KC4△/2001
Number of units installed in U.S./Outside U.S.	—/—	>250/>100	>100/>100
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Operational type	batch, continuous random access	semiautomatic, single channel	semiautomatic, 4 channels
Reagent type	open reagent system (reconst. manually), optimized for Siemens instruments	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	37 × 49 × 25 in/330 lbs/14 sq ft	3.25 × 5.5 × 8.25 in/2.5 lbs/<1 sq ft	4.7 × 13.9 × 17.7 in/14 lbs/1.7 sq ft
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, reptilase time, factor assays, DRVVT screen and confirm, factor V Leiden, protein C clot, protein S activity	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, atroxin, intrinsic and extrinsic factors
FDA-cleared chromogenic tests	Innovance AT, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin,	—	—
FDA-cleared immunologic tests	Advanced D-dimer, Innovance D-dimer	—	—
Other FDA-cleared tests	BC von Willebrand-risto. cofactor assay (agglut of fixed plts)	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	ETP (for research use only), PT multicalibrators	—	—
Methodologies supported	clot detection, optical (xenon flasher lamp); chromogenic; immunologic	clot detection, mechanical	clot detection, mechanical
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	>100 tests/samples	1	5
Number of different assays programmed and calib. at one time	99	manual	1/1
Number of user-definable (open) channels	7,999	—	—
Of those defined, number active simultaneously	>100	—	up to 4
Factor assays require manual manipulation or dilutions	no	yes	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	90/varies, up to 200/yes (<15°C)	1/varies for each assay/no	5/varies for test kit/no
Multiple reagent configurations supported	yes	no	no
Reagents, consumables loaded without interrupting testing	yes	—, manual	—, manual
Same capabilities when 3rd-party reag. used	yes	yes	yes
Maximum time same lot number of reagents can be used	12 months	12–18 months	12–18 months
Walkaway capacity: Number of specimens/Number of tests	100 samples/400 cuvettes	—, manual	—, manual
Minimum sample volume aspirated precisely at one time	3 µL	—	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/20 µL, min 100 µL (incl. dead vol)/50 µL, min 100 µL	50 µL/—	50 µL/10 µL
Disposables used/Price of each	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/varies with volume	cuvettes and ball dispenser/available on request	cuvettes & ball dispenser/available on request
Supports direct-from-track sampling	no	—	—
Primary tube sampling supported/Pierces caps on primary tubes	yes (all up to 100 mm long, ext. diam. 11–16 mm)/no	—	—
Sample bar-code reading capability	yes	—	—
Reagent bar-code reading capability	yes	—	—
Onboard test automatic inventory	yes	—	—
Measures No. of tests remaining/Short sample detection	yes/yes	—	—
Clot detection as preanalytical variable in plasma sample	no	—	—
Auto. detects adequate reagents for aspiration and analysis	yes	—	—
Hemolysis/Turbidity detection-quantitation	yes/no	—	—
Dilution of patient samples onboard	yes	—	—
Automatic rerun capability/Auto reflex testing capability	yes/yes	—	—
Lag time during which hypercoagulable sample not detected	yes (7 seconds for PT and APTT)	yes (PT and PTT: 4.5 seconds)	yes (PT and PTT: 4.5 seconds)
Read time extended for prolonged clotting times	yes	yes	yes
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	no/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<5 minutes/~380 results (including abnormals)	75 seconds/48 tests	75 seconds/48 tests
• PT, PTT	<5 minutes/~325 results (including abnormals)	350 seconds/10 tests	350 seconds/10 tests
• Fibrinogen	<5 minutes (if curve available)~315 results	65 seconds/55 tests	65 seconds/55 tests
• Factor VIII activity assay	<5 minutes (if curve available)~280 results	275 seconds/13 tests	275 seconds/13 tests
Time delay from ordering stat to aspir. of sample	varies by test in progress, appox. >5 minutes	—	—
Auto. transfer of QC results to LIS	yes	yes	yes
Data management capability	yes, onboard (incl. QC: L-J plots)	yes	yes
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	all major LIS vendors	—	—
Bidirectional interface capability	yes (host query)	—	—
Results transferred to LIS as soon as test time complete	yes	yes	yes
LOINC codes transmitted with all results	no	—	—
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	—	—
Modem servicing	yes	—	—
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: <10 minutes.; monthly: 15 minutes	—	—
Onboard maintenance records	yes	—	—
Training provided with purchase	3 days at vendor offices for 2 key operators, online training course	as needed on site	as needed on site
Approximate number of training hours needed per tech	8 (on site)	2	2
List price	$171,921	$2,206	$9,660
Annual service contract cost (24/7)/Warranty with purchase	—	—	—
Unique advantages (provided by vendors)	user-definable calibration curve expiration and prewarning alerts; user-definable bar-code utility enables customizable reagent protocols; user-friendly Windows XP software	patented ball technology for reproducible and reliable results; provides significant cost savings when used with Tcoag's reagents and controls	four test positions can be used simultaneously; patented ball method for reproducible and reliable results; provides significant cost savings when used with Tcoag's reagents and controls

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Coagulation analyzers

Part 10 of 11	Tcoag US Kevin McGlinchey kevin.mcglinchey@tcoag.com Marketing Manager 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.com	Tcoag US Kevin McGlinchey kevin.mcglinchey@tcoag.com Marketing Manager 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.com	Tcoag US Kevin McGlinchey kevin.mcglinchey@tcoag.com Marketing Manager 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.com
Instrument name/first year sold	**Coag-A-Mate XM/1989**	**Coag-A-Mate MTX/1997**	**Destiny Plus/2005**
Number of units installed in U.S./Outside U.S.	>2,000 worldwide	>500 worldwide	>175/>500
Number of contracts signed between 1/1/10 and 11/30/10	—	—	—
Country where analyzer designed/manufactured	U.S./U.S.	Germany & U.S./Germany	Germany & U.S./Germany
Operational type	discrete	random access	continuous random access
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual pipetting into cuvette (4 wells at a time)	rotor (32 positions)	continuous rack loading
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	4.6 × 14.7 × 20 in/20 lbs/2 sq ft	19.7 × 30.7 × 21.3 in/100 lbs/5 sq ft, 8 w/ PC	22 × 33 × 27 in/165 lbs/6.8 sq ft
FDA-cleared clotting-based tests	PT, APTT, TT, fibrinogen, PT and APTT factor assays	PT, APTT, TT, fibrinogen, PT and APTT factor assays	PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, XII
FDA-cleared chromogenic tests	—	AT III, hep. antifactor Xa, protein C	AT, heparin Xa
FDA-cleared immunologic tests	none (latex immunologic assay in development)	none (latex immunologic assay in development)	D-dimer
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	alpha-2 antiplasmin, plasminogen, PT mix, APTT mix, LMWH (antifactor Xa)	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	quantitative D-dimer immunoassay	—
Methodologies supported	clotting assays; photo-optical	clotting, chromogenic assays; photo-optical	clot detection, mechanical and optical (turbidimetric); chromogenic; immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	2	8	10
Number of different assays programmed and calib. at one time	16	32	unlimited
Number of user-definable (open) channels	16	up to 32	unlimited
Of those defined, number active simultaneously	2	8	10
Factor assays require manual manipulation or dilutions	yes	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	4/30–100/no	16 cooled, 12 room temp. total 28/25–200/yes (15°C)	31–51/varies/yes (12°–16°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	no	yes
Same capabilities when 3rd-party reag. used	yes	yes	yes
Maximum time same lot number of reagents can be used	12–18 months	12–18 months	varies by reagent—routine reagents 12 months
Walkaway capacity: Number of specimens/Number of tests	4/4	32/32	50/240
Minimum sample volume aspirated precisely at one time	—	2 µL	5 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	100 µL/10 µL, minutes 10 µL	50 µL/5 µL, minutes 2 µL	25 µL/10 µL
Disposables used/Price of each	cuvettes, stir bars, optional: printer & paper/available on request	cuvette rings, pipettor wash solution, cleaning solution/available on request	reaction trays, ProWash
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes/no	yes (all standard, pediatric, micro)/no
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	no	in development
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/no	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	no	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	not necessary
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/no	yes/yes
Lag time during which hypercoagulable sample not detected	yes (PT: 7 seconds, APTT: 20 seconds)	yes (PT: 3 seconds, APTT: 5 seconds)	no
Read time extended for prolonged clotting times	yes	yes	
User can set different-than-standard:			yes
• Reagent volumes/Sample volumes	yes/yes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incub. times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes	no/yes
Auto shutdown/Auto startup programmable	no/no	no/no	yes/yes
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	2 minutes/200 results (manual)	2 minutes/90 results	<3 minutes/180 tests
• PT, PTT	5 minutes/50 PTT results (manual)	5 minutes/60 results	<6 minutes/90 tests
• Fibrinogen	2–3 minutes/100 results (manual)	2 minutes/75 results	<6 minutes/105 tests
• Factor VIII activity assay	5 minutes/50 results (manual)	5 minutes/60 results	<6 minutes/58 tests
Time delay from ordering stat to aspir. of sample	≤2 minutes	30–60 seconds	varies by test
Auto. transfer of QC results to LIS	no	yes	yes
Data management capability	no	yes (incl. QC: L-J plots)	onboard (incl. QC: LJ plots, Westgard)
Interface supplied by instrument vendor	no	yes (additional cost)	no
Interfaces in active user sites for:	—	all commonly used LISs in North America	all major LIS vendors
Bidirectional interface capability	no	yes	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	no	yes	yes
LOINC codes transmitted with all results	no	no	yes
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	weekly: ~5 minutes	daily: ~5 minutes; weekly: ~1 minute; monthly: ~5 minutes	daily: <5 minutes; weekly: <30 minutes; monthly: <30 minutes
Onboard maintenance records	no	no	yes
Training provided with purchase	half day on site	3 days at vendor offices	2-4 days on site; 3 days at vendor offices
Approximate number of training hours needed per tech	1–2	2–3	8
List price	$5,173	$52,500	$79,500
Annual service contract cost (24/7)/Warranty with purchase	—	—	—
Unique advantages (provided by vendors)	simple to operate: clot detection starts automatically on addition of start reagent; flexibility; test params. can be modified to accommodate various reagent systems	normalization of PT and APTT results between Tcoag automated systems; stat results within 2–5 minutes; flexibility; MTX supports new assays easily through user-programmable method files; internal bar-code reader for sample and test identification	¼-volume patient sample and reagent usage for PT, PTT, fib; mechanical and optical clot detection in one platform; easy to learn and retain IntuiTouch software

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Coagulation analyzers

Part 11 of 11	Tcoag US Kevin McGlinchey kevin.mcglinchey@tcoag.com Marketing Manager 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.com	Tcoag US Kevin McGlinchey kevin.mcglinchey@tcoag.com Marketing Manager 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.com
Instrument name/first year sold	Destiny Max/2009	MDA II/1999
Number of units installed in U.S./Outside U.S.	>25/>25	>400 worldwide
Number of contracts signed between 1/1/10 and 11/30/10	0	—
Country where analyzer designed/manufactured	Germany/Germany	U.S./U.S.
Operational type	continuous random access	continuous random access
Reagent type	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma
Sample handling system	continuous rack loading	racks
Model type	benchtop	floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	29.5 × 59 × 27 in/340 lbs/11.03 sq ft	58 × 75 × 31 in/840 lbs/18 sq ft w/PC
FDA-cleared clotting-based tests	Open system: All clottable assays can be run on the Destiny Max (PT, PTT, FIB, TT, factors, venom time, prot C, prot S, aPCR, lupus screen and confirm)	PT screening (moderate and low ISI), PT factors, quick%, APTT screening, APTT factors, PT mix, APTT mix, TT, fib.
FDA-cleared chromogenic tests	Open System: All chromogenic assays can be run on the Destiny Max (prot C, AT IIa and Xa based), heparin Xa, plasminogen	hep. antifactor Xa, AT III, protein C, plasminogen, alpha-2 antiplasmin, lupus (DRVVT screen and confirm), APCR
FDA-cleared immunologic tests	Open System: All latex immunoassays can be run on the Destiny Max (D-dimer)	D-dimer (latex immunoassay)
Other FDA-cleared tests	—	—
User-defined tests in clinical use	—	clottable C and S, PNP, P and P (1 and 2), vWF, open assays—user definable for clotting, chrom. and microlatex assays
Tests submitted for 510(k) clearance	—	—
Tests in development but not yet submitted	all coagulation tests	—
Methodologies supported	clot detection, mechanical and optical; chromogenic; immunologic	clotting; chromogenic; immunoassay; photo-optical
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no
Number of different measured assays onboard simultaneously	unlimited	16
Number of different assays programmed and calib. at one time	unlimited	72
Number of user-definable (open) channels	unlimited	20
Of those defined, number active simultaneously	unlimited	16
Factor assays require manual manipulation or dilutions	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	—/varies by test/yes (12°–16°C)	30/25–400/yes (8°–15°C)
Multiple reagent configurations supported	yes	yes
Reagents, consumables loaded without interrupting testing	yes	consumables yes, reagents no
Same capabilities when 3rd-party reag. used	no	yes
Maximum time same lot number of reagents can be used	varies—routine reagents 12 months	12–18 months
Walkaway capacity: Number of specimens/Number of tests	120/71,000	170/480
Minimum sample volume aspirated precisely at one time	25 µL	5 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	25 µL/10 µL	50 µL/10 µL
Disposables used/Price of each	reaction trays, ProWash	cuvettes, bar-code labels, MDA probe cleaner/available on request
Supports direct-from-track sampling	yes	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/yes
Sample bar-code reading capability	yes	yes (internal bar-code scanner)
Reagent bar-code reading capability	yes	yes
Onboard test automatic inventory	yes	yes
Measures No. of tests remaining/Short sample detection	yes/yes	yes/yes
Clot detection as preanalytical variable in plasma sample	no	no
Auto. detects adequate reagents for aspiration and analysis	yes	yes
Hemolysis/Turbidity detection-quantitation	not necessary/not necessary	yes/yes (detects bilirubin, corrects for lipemia)
Dilution of patient samples onboard	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	no/no
Lag time during which hypercoagulable sample not detected	no	yes (PT: default 3 sec, APTT: default 5 sec)
Read time extended for prolonged clotting times	yes	yes (selectable on menus)
User can set different-than-standard:	yes	
• Reagent volumes/Sample volumes	yes/yes	yes/yes
• No. and sources of reagent	yes	yes
• Incub. times/Reading times	yes/yes	no/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	yes/yes	yes/yes
Stat time to complete all analytes/Throughput per hour for:		
• PT alone	<3 minutes/~350 tests	12 minutes/180 results
• PT, PTT	<6 minutes/~232 tests	12 minutes/180 results
• Fibrinogen	<6 minutes/~200 tests	12 minutes/180 results
• Factor VIII activity assay	<6 minutes/~200 tests	12 minutes/180 results
Time delay from ordering stat to aspir. of sample	<3 minutes	<1 minute
Auto. transfer of QC results to LIS	yes	yes
Data management capability	onboard (incl. QC: LJ plots, Westgard)	onboard (incl. QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	yes (additional cost)
Interfaces in active user sites for:	—	all commonly used LISs in North America
Bidirectional interface capability	yes (broadcast download & host query)	yes (broadcast download & host query)
Results transferred to LIS as soon as test time complete	yes	yes
LOINC codes transmitted with all results	no	no
How labs get LOINC codes for reagent kits	package insert, e-mail	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	yes	yes
Modem servicing	yes	yes
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: <10 minutes; monthly: <30 minutes	daily: ~35 minutes; weekly: 45 minutes; monthly: 10 minutes
Onboard maintenance records	yes	no
Training provided with purchase	3–5 days on site; 5 days at vendor offices	3–5 days on site, 4 days at vendor offices
Approximate number of training hours needed per tech	5	4–5
List price	$129,000	$92,295
Annual service contract cost (24/7)/Warranty with purchase	—	—
Unique advantages (provided by vendors)	mechanical clot detection via the patented ball method; ¼-volume patient sample and reagent usage for PT, PTT, fib; waveform analysis, dyes in routine reagents for vol. delivery check, factor parallelism; normalization of PT and PTT results between Tcoag automated instruments	patented waveform analysis tech. with flags for ident. abnormal waveforms (for example, biphasic samples); sensitive quantitative D-dimer assay for use in VTE diagnosis; dyes in routine reagents for vol. delivery chk; throughput same, regardless of test mix

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