Coagulation product guide

From the new to the improved

Brendan Dabkowski

New to CAP TODAY's annual coagulation analyzers product guide are Beckman Coulter/Instrumentation Laboratory's ACL AcuStar and ACL TOP 300 CTS systems and Diagnostica Stago's STA Compact Plus analyzer. Other companies have enhanced their established systems.

Stago plans to launch its STA Compact Plus during the first quarter. The analyzer incorporates the mechanical clot detection technology used in the company's STA Compact product and simultaneously performs clotting, chromogenic, and immunological assays in true random access, says Robert Bachkosky, Diagnostica Stago's director of marketing. "Perhaps in conjunction with the introduction of new anticoagulation therapies and increased use of blood substitute products that affect the color of the sample, the U.S. market has seen a significant shift of laboratories moving from optical to mechanical clot detection analyzers," Bachkosky notes. The STA Compact Plus serves as an interface between a laboratory information system and the lab's coagulation instruments. The analyzer can archive up to 500,000 patient test results.

Stago will launch this year a new line of liquid ready-to-use reagents, including the STA liquid anti-Xa assay for heparin monitoring and a liquid fibrinogen reagent. The company is also working on an automated test for factor XIII antigen. And the company introduced in 2010 Qualiris by Stago, a Web-based hemostasis proficiency testing program that provides real-time peer group reports and advanced technical support.

Also in the following pages are Stago's Calibrated Automated Thrombogram, STA Satellite, STA-R Evolution Expert Series, STA Compact, Start 4 Hemostasis Analyzer, STA Compact Hemostasis System, KC1, KC4, Destiny Plus, and Destiny Max.

Beckman Coulter/IL in December launched the ACL AcuStar hemostasis testing system, which uses chemiluminescent technology and automates ACA (IgG and IgM) and B2GP1 (IgG and IgM) assays for antiphospholipid syndrome. The company in October launched its HemosIL lupus anticoagulant quality controls for assessing precision and accuracy in lupus anticoagulant testing, says Venita C. Shirley, Beckman's director of U.S. hospitals marketing.

Slated for release in March is the ACL TOP 300 CTS system, which automates many of the manual-oriented tasks associated with hemostasis testing. The instrument is standardized with other TOP analyzers, offering the same operating system, reagents, prothrombin time International Sensitivity Index values, and normal ranges. Most importantly, Shirley says, the ACL TOP 300 CTS uses 671-nm LED technology, which allows clotting assays to be read at a 671-nm wavelength—"outside the range influenced by the typical preanalytical variables of lipemia, hemoglobin, and bilirubin, so the correct result gets reported out the first time it is run."

Siemens Healthcare Diagnostics' Innovance D-dimer assay last year was cleared by the FDA to exclude deep vein thrombosis and pulmonary embolism in patients in whom a pretest probability assessment indicates a non-high probability of embolism, says Michael Noeh, vice president of the company's global marketing hematology, hemostasis, and specialty business unit. And late last year Siemens announced that it could now connect its BCS XP automated hemostasis analyzer with the Advia CentraLink data-management middleware solution.

Siemens is developing a latex-based von Willebrand factor assay and will soon offer a prothrombin time multi-calibrator product that will allow labs to produce direct INR results that each lab calibrates and determines, Noeh says.

Bio/Data Corp. continues to offer its Platelet Aggregration Profiler 8E instrument. The company last year enhanced the PAP 8E's optical hardware to accommodate more samples and test types, says vice president William M. Trolio. Bio/Data also updated the system's software by reducing the time required to perform touchscreen applications and strengthening system security.

At Helena Laboratories, most of the focus is on developing rapid and point-of-care testing products that provide "lab-like hemostasis results," says Dave Pearman, global product manager of hemostasis/point of care. For coagulation labs, the company has updated its AggRAM Platelet Aggregometer software to meet custom reporting needs. Profiled in the following pages are the AggRAM, Cascade M, and Cascade M-4 systems.

CAP TODAY's coagulation analyzers product guide includes systems from the aforementioned companies and from American Labor/Lab A.C.M., Cepheid, Chrono-Log Corp., and LABiTec GmbH. Companies supplied the information listed. Readers interested in a particular system should confirm it has the stated features and capabilities. □

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Instrument name/first year sold	CD2000/1986
Number of units installed in U.S./Outside U.S.	>500/>1,000
Number of contracts signed between 1/1/11 and 11/30/11	—
Country where analyzer designed/manufactured	Germany/Germany
Operational type	batch, discrete
Reagent type	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma
Sample handling system	cuvette, semiautomated
Model type	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	5 × 12 × 8.5 inches/9.2 lbs/1 square foot
FDA-cleared clotting-based tests	PT, PTT, fibrinogen, any citrated plasma clot-based assay
FDA-cleared chromogenic tests	—
FDA-cleared immunologic tests	—
Other FDA-cleared tests	—
User-defined tests in clinical use	—
Tests submitted for 510(k) clearance	—
Tests in development but not yet submitted	—
Methodologies supported	clot detection, optical; turbodensitometry stir bar mixing–optical detection
Operator must load sep. reagent pack per specimen/Test run	no/no
Number of different measured assays onboard simultaneously	2 (PT, APTT)
Number of different assays programmed and calib. at one time	1 (fibrinogen)
Number of user-definable (open) channels	2
Of those defined, number active simultaneously	2
Factor assays require manual manipulation or dilutions	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	5 or more/reagent manufacturer defined/no
Multiple reagent configurations supported	yes
Reagents, consumables loaded without interrupting testing	yes
Same capabilities when third-party reagent used	yes
Maximum time same lot number of reagents can be used	laboratory dependent
Walkaway capacity: Number of specimens/Number of tests	—/—
Minimum sample volume aspirated precisely at one time	manual pipetting
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL, minimum 50 µL/50 µL, minimum 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.
Supports direct-from-track sampling	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no
Sample bar-code reading capability	no
Reagent bar-code reading capability	no
Onboard test automatic inventory	no
Measures No. of tests remaining/Short sample detection	no/no
Clot detection as preanalytical variable in plasma sample	no
Auto. detects adequate reagents for aspiration and analysis	no
Hemolysis/Turbidity detection-quantitation	no/no
Dilution of patient samples onboard	no
Automatic rerun capability/Auto reflex testing capability	no/no
Lag time during which hypercoagulable sample not detected	yes (3 seconds)
Read time extended for prolonged clotting times	yes, up to 999 seconds
User can set different-than-standard:	
• Reagent volumes/Sample volumes	yes/yes
• No. and sources of reagent	yes
• Incub. times/Reading times	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/no
Auto shutdown/Auto startup programmable	no/no
Stat time to complete all analytes/Throughput per hour for:	
• PT alone	120 seconds/user defined
• PT, PTT	240 seconds/user defined
• Fibrinogen	300 seconds/user defined
• Factor VIII activity assay	300 seconds/user defined
Time delay from ordering stat to aspiration of sample	—, all preanalytical
Automatic transfer of QC results to LIS	no
Data-management capability	no
Interface supplied by instrument vendor	no
Interfaces in active user sites for:	call technical support for inquiry
Bidirectional interface capability	no
Results transferred to LIS as soon as test time complete	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	yes
Modem servicing	no
Time required for maintenance by lab personnel	daily: 30 seconds; weekly: 30 seconds; monthly: 5 minutes
Onboard maintenance records	no
Training provided with purchase	video; on-site training extra
Approximate number of training hours needed per tech	2
List price	$900, special pricing upon written request for quote
Annual service contract cost (24/7)/Warranty with purchase	add. 1-year init. contract $500 (opt.)/1 year, $300 renewal
Unique advantages (provided by vendors) *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	smaller clinic; office, private, vet labs; low acquisition and service cost, low maintenance; refurbished units available at reduced prices; can handle turbid/colored samples

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Survey Editor: Raymond Aller, MD

Coagulation analyzers

Part 2 of 11	American Labor/Lab A.C.M. Inc. Mike Shiflett mshiflett@americanlabor.org 1308 Broad Street, Durham, NC 27705 919-286-0726 or (tech support) 800-424-0443 www.americanlabor.org and www.labitec.de	Beckman Coulter Inc./ Instrumentation Laboratory Venita Shirley vcshirley@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-4252 www.beckmancoulter.com	Beckman Coulter Inc./ Instrumentation Laboratory Venita Shirley vcshirley@beckman.com 250 S. Kraemer Boulevard, Brea, CA 92821 714-961-4252 www.beckmancoulter.com
Instrument name/first year sold	CoaData 2004/4004/2010	ACL TOP 300 CTS/2012	ACL AcuStar/2010
Number of units installed in U.S./Outside U.S.	—/>500	0/25	—
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	Germany/Germany	U.S./U.S.	U.S./U.S.
Operational type	discrete	continuous random access	random access
Reagent type	open reagent system	open	self-contained multi-use cartridges-packages-slides (liquid)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	semiautomated manual pipette-auto start	racks, continuous loading of primary tubes	rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	10.7 × 13.7 × 4.9 inches/8.6 lbs/2 square feet	29 × 32 × 33 inches/200 lbs/8 square feet	21 × 34 × 24 inches/170 lbs/15 square feet
FDA-cleared clotting-based tests	PT, APTT	PT, APTT, fibrinogen, TT, factors, APCR-V, protein C	—
FDA-cleared chromogenic tests	—	heparin Xa, protein C, AT	—
FDA-cleared immunologic tests	—	D-dimer HS, free protein S	anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	PT, APTT, fibrinogen	heparin-induced thrombocytopenia	—
Tests in development but not yet submitted	—	global protein C pathway	HIT IgG, HIT total
Methodologies supported	clot detection, optical; turbodensitometric	clot detection (LED optical), chromogenic, immunologic	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	1	500	20
Number of different assays programmed and calib. at one time	3	500	20
Number of user-definable (open) channels	—	250	0
Of those defined, number active simultaneously	1	30	—
Factor assays require manual manipulation or dilutions	yes	no	—
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	4/reagent manufacturer defined/no	24/—/yes	20/varies by assay/yes (4°C)
Multiple reagent configurations supported	yes	yes	no
Reagents, consumables loaded without interrupting testing	yes	yes	no
Same capabilities when third-party reagent used	yes	yes	no
Maximum time same lot number of reagents can be used	reagent manufacturer defined	18 months	—
Walkaway capacity: Number of specimens/Number of tests	18 incubational positions/2	40/800	30/—
Minimum sample volume aspirated precisely at one time	50 µL (150 µL total volume)	4 µL	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/25 µL	—/—
Disposables used/Price of each	micro single cuvette, printer paper/—	—	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/yes	yes (most tubes validated)/no
Sample bar-code reading capability	no	yes	yes
Reagent bar-code reading capability	no	yes	yes
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	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	no/no
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	yes/yes	yes/no
Lag time during which hypercoagulable sample not detected	no	no	—
Read time extended for prolonged clotting times	yes, selectable on operator menus	yes	—
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	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	—	yes/yes
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	—	<3 minutes/110 specimens	—
• PT, PTT	—	<6 minutes/55 specimens	—
• Fibrinogen	—	<6 minutes/60 specimens	—
• Factor VIII activity assay	—	<11 minutes/38 specimens	—
Time delay from ordering stat to aspiration of sample	—	minimal	<1 minute
Automatic transfer of QC results to LIS	no	yes	yes
Data-management capability	no	onboard (includes QC: L-J plots, Westgard multirules)	onboard (includes QC: L-J plots and Westgard Multirules)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	not yet	most major vendors	—
Bidirectional interface capability	no	yes (broadcast download and host query)	yes (host query)
Results transferred to LIS as soon as test time complete	no	yes	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	no	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	no
Modem servicing	no	in development	no
Time required for maintenance by lab personnel	per shift: <1 minute (cleaning housing); daily: <1 minute (cleaning housing); weekly: <5 minutes (cleaning housing and incubating block)	daily: <10 minutes; weekly: 10 minutes	daily: 10 minutes; weekly: 10 minutes
Onboard maintenance records	no	yes	no
Training provided with purchase	1 day, on request	five days at vendor offices	—
Approximate number of training hours needed per tech	4	24–40	6
List price	—	$99,900	—
Annual service contract cost (24/7)/Warranty with purchase	12 months	—/1 year	—
Unique advantages (provided by vendors)	inexpensive two-channel (2004) and four-channel (4004) protime instruments with few moving parts; for small lab/physician office; updated version of CoaData/Accustasis; low maintenance and repair costs	complete standardization solution; 671-nm LED detection minimizes interferences from lipemia, hemoglobin, and billirubin; complete HemosIL assay menu, including D-dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid heparin with universal calibration curve for UFH and LMWH	easy to use, uses sensitive chemilumiescent technology, providing results in less than one hour; for many complex coagulation 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

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Coagulation analyzers

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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 1/1/11 and 11/30/11	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 inches/312 lbs/14 square feet	24 × 37 × 24inches/139 lbs/6 square feet	29 × 60 × 35/331 lbs/21 square feet
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVVT), protein C/S, APCR-V	PT, APTT, fibrinogen, TT, factors, protein C/S, lupus (SCT and DRVVT), APCR-V	PT, APTT, fibrinogen, 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. and 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 third-party reagent 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 aspiration of sample	minimal	15 seconds	minimized
Automatic 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 and host query)	yes (broadcast download and host query)	yes (broadcast download and 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 minutes; weekly: 10 minutes
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 heparin with universal calibration 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 or calibration, or both; HemosIL liquid heparin with universal calibration curve for UFH and LMWH	clot signature curve analysis; continuous operation without 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 or calibration, or both; HemosIL liquid heparin with universal calibration curve for UFH and LMWH

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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Coagulation analyzers

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Instrument name/first year sold	Platelet Aggregation Profiler, Model-PAP 8E/2005	GeneXpert/2005	Whole Blood-Optical Lumi-Aggregation System, Model 700-2/700-4/2006
Number of units installed in U.S./Outside U.S.	>200/>350	2,200 globally	160/205
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	batch, random access	batch, random access, continuous random access	batch, random access
Reagent type	open reagent system, assay kits, reagents, controls, diluents, buffer, specialty products, others	self-contained single-use catridges/packages/slides (lyophilized reconstituted manually)	open reagent system, assay kits, reference plasmas, controls (lyophilized reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	whole blood	whole blood, spun plasma
Sample handling system	programmable electronic pipette, optional bar-code scanner	self-contained cartridge	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	22.5 × 14.0 × 21.7 inches/45 lbs/2.2 square feet	GX IV: 14 × 11.75 × 12.25 inches/26 lbs/.999 square feet GX XVI: 30 × 21 × 15 inches/125 lbs/.999 square feet	8.5 × 14.0 × 18.0 inches/40 lbs/ M700-2: 1.75 square feet; M700-4: 3.5 square feet
FDA-cleared clotting-based tests	—	—	—
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	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	templates for user-defined tests included in software, specialty agonists, antiplatelet compounds, others	Xpert HemosIL Factor II/V (distributed exclusively by Instrumentation Labs)	platelet dense granule secretion, whole blood impedance aggregation, LTA aggregation with all standard reagents, ristocetin cofactor assay
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	proprietary	—	—
Methodologies supported	UV LED, platelet agglutination, platelet aggreg., turbidometric and rate reaction assays, digital circuitry and software	molecular PCR testing	turbidimetric, platelet dense granule secretion, whole blood impedance aggreg., LTA aggreg., ristocetin cofactor assay
Operator must load sep. reagent pack per specimen/Test run	no/no	yes, 1 assay per pack/—	no/—
Number of different measured assays onboard simultaneously	up to 8	GX IV: 4; GX XVI: 16	2–4
Number of different assays programmed and calib. at one time	>256	1 to 16	4–8
Number of user-definable (open) channels	8	—	2–4
Of those defined, number active simultaneously	8	GX IV: 4; GX XVI: 16	2–4
Factor assays require manual manipulation or dilutions	yes	no	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	2 stirred, adapters for various sized vials/varies/no	GX IV: 4; GX XVI: 16/1/no, temperature: 15° to 30°C	no/—/no
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when third-party reagent used	yes	no	no
Maximum time same lot number of reagents can be used	up to 18 months	—	12–30 months
Walkaway capacity: Number of specimens/Number of tests	8/8	GX-IV: 4; GX-XVI: 16/GX-IV: 4; GX-SVI: 16	2–4/4–8
Minimum sample volume aspirated precisely at one time	25 µL	—	—
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	siliconized test tubes: 100 @ $28.75; plastic-coated stir bars: 50 @ $14.75; pipette tips: 960 @ $36.00; MagneTubes: 50 @ $41.75	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	yes	no
Reagent bar-code reading capability	yes	yes	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
Dilution of patient samples onboard	no	no	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	yes/no
Lag time during which hypercoagulable sample not detected	no	—	—/—
Read time extended for prolonged clotting times	no	—	yes
User can set different-than-standard:			
• Reagent volumes/Sample volumes	yes/yes	no/no	yes/yes
• No. and sources of reagent	yes	no	yes
• Incub. times/Reading times	yes/yes	no/no	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	V2.1 hardware/software update adds optical calibration	yes/—	yes
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 aspiration of sample	—	—	—
Automatic transfer of QC results to LIS	yes	yes	no
Data-management capability	yes (onboard, includes QC: L-J plots, Westgard)	yes (onboard, includes QC)	yes (onboard)
Interface supplied by instrument vendor	no	no	yes
Interfaces in active user sites for:	—	HL7 and ASTM compatible	—
Bidirectional interface capability	yes (host query)	yes (broadcast download and 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
How labs get LOINC codes for reagent kits	e-mail query	—	—
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	weekly: 15 minutes; monthly: 30 minutes	daily: 5 minutes; weekly: 15 minutes; monthly: 60 minutes	30 minutes when optical calibration required
Onboard maintenance records	yes	no	yes
Training provided with purchase	1.5 days on site	1 day on site	1.5 days on site
Approximate number of training hours needed per tech	4–6	2	8
List price	$15,990	GX IV: $78,200	M700-2: $19,500; M700-4: $32,000
Annual service contract cost (24/7)/Warranty with purchase	$1,990 for 1 year, $2,990 for 2 years/—	$9,150/12 months	M700-2: $1,804; M700-4: $3,008 for 3 years/12 months
Unique advantages (provided by vendors)	two-year warranty; no-charge software upgrades during warranty period; optional PDQ platelet function centrifuge standardizes sample preparation, reduces preparation time to five minutes	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 simultaneously 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

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Coagulation analyzers

Part 5 of 11	Diagnostica Stago Inc. Kevin McGlinchey kevin.mcglinchey@tcoag.com 5 Century Drive Parsippany, NJ 07054 888-291-0415 www.tcoag.com	Diagnostica Stago Inc. Kevin McGlinchey kevin.mcglinchey@tcoag.com 5 Century Drive Parsippany, NJ 07054 888-291-0415 www.tcoag.com	Diagnostica Stago Inc. Ron Evancheck ronald.evancheck@stago-us.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	KC1△/2001	KC4△/2001	STart 4 Hemostasis Analyzer/1998
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany	France/France
Operational type	semiautomatic, single channel	semiautomatic, 4 channels	batch
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	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	3.25 × 5.5 × 8.25 inches/2.5 lbs/<1 square feet	4.7 × 13.9 × 17.7 inches/14 lbs/1.7 square feet	4.7 × 16.1 × 16.5 inches/12.5 lbs/1.8 square feet
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, atroxin, intrinsic, and extrinsic factors	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	DRVVT screen and confirm assays, APCR, other clotting tests with user-defined applications
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	—
Methodologies supported	clot detection, mechanical	clot detection, mechanical	clotting tests
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	1	5	1
Number of different assays programmed and calib. at one time	manual	1/1	20
Number of user-definable (open) channels	—	—	4
Of those defined, number active simultaneously	—	up to 4	1
Factor assays require manual manipulation or dilutions	yes	yes	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	1/varies for each assay/no	5/varies for test kit/no	4/varies/no
Multiple reagent configurations supported	no	no	yes
Reagents, consumables loaded without interrupting testing	—, manual	—, manual	no
Same capabilities when third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	12–18 months	12–18 months	18 months
Walkaway capacity: Number of specimens/Number of tests	—, manual	—, manual	4/1
Minimum sample volume aspirated precisely at one time	—	—	25 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/10 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes and ball dispenser/available on request	cuvettes and ball dispenser/available on request	cuvettes, balls/varies
Supports direct-from-track sampling	—	—	no
Primary tube sampling supported/Pierces caps on primary tubes	—	—	no/no (not applicable)
Sample bar-code reading capability	—	—	no
Reagent bar-code reading capability	—	—	no
Onboard test automatic inventory	—	—	no
Measures No. of tests remaining/Short sample detection	—	—	no/no
Clot detection as preanalytical variable in plasma sample	—	—	no
Auto. detects adequate reagents for aspiration and analysis	—	—	no
Hemolysis/Turbidity detection-quantitation	—	—	no/no (not necessary for mechanical detection technology)
Dilution of patient samples onboard	—	—	no
Automatic rerun capability/Auto reflex testing capability	—	—	no/no
Lag time during which hypercoagulable sample not detected	yes (PT and PTT: 4.5 seconds)	yes (PT and PTT: 4.5 seconds)	no
Read time extended for prolonged clotting times	yes	yes	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
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	75 seconds/48 tests	75 seconds/48 tests	<1 minute/up to 120 specimens
• PT, PTT	350 seconds/10 tests	350 seconds/10 tests	—/—
• Fibrinogen	65 seconds/55 tests	65 seconds/55 tests	<1 minute/up to 120 specimens
• Factor VIII activity assay	275 seconds/13 tests	275 seconds/13 tests	varies/varies
Time delay from ordering stat to aspiration of sample	—	—	<15 seconds
Automatic transfer of QC results to LIS	yes	yes	no
Data-management capability	yes	yes	no
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	—	—	no
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	—	—	no
Time required for maintenance by lab personnel	—	—	weekly: <5 minutes; monthly: <5 minutes
Onboard maintenance records	—	—	no
Training provided with purchase	as needed on site	as needed on site	1 day on site
Approximate number of training hours needed per tech	2	2	1
List price	$2,758	$6,978	$9,600
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	prices available on request/1 year	prices available on request/1 year
Unique advantages (provided by vendors)	one test position, mechanical clot detection via the ball method, reproducible and reliable results	four test positions can be used simultaneously, mechanical clot detection via the ball method, reproducible and reliable results	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

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Coagulation analyzers

Part 6 of 11	Diagnostica Stago Inc. **Ron Evancheck** ronald.evancheck@stago-us.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. **Kevin McGlinchey** kevin.mcglinchey@tcoag.com 5 Century Drive Parsippany, NJ 07054 888-291-0415 www.tcoag.com	Diagnostica Stago Inc. **Barry Ray** barry.ray@stago-us.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	**STA Satellite/2010**	**Destiny Plus/2005**	**STA Compact Hemostasis System/1996**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	France/France	Germany and U.S./Germany	France/France
Operational type	random access	continuous 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	carousel (primary tubes)	continuous rack loading	continuous specimen access—primary tube
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	27.4 × 21.1 × 25.5 inches/72 lbs/4 square feet	22 × 33 × 27 inches/165 lbs/6.8 square feet	25.2 × 38.8 × 25.8 inches/351 lbs/7 square feet
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	open system: all clottable assays can be run on the Destiny Plus (PT, PTT, FIB, TT, factors, venom time, proteins C and S, aPCR, lupus screen and confirm)	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT, screen and confirm
FDA-cleared chromogenic tests	heparin (UFH, LMWH), AT	open system: all chromogenic assays can be run on the Destiny Plus (prot C, AT IIa and Xa based), heparin Xa, plasminogen	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin
FDA-cleared immunologic tests	D-dimer	open system: all latex immunoassays can be run on the Destiny Plus (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 and immunological tests with 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 and optical (turbidimetric); chromogenic; immunologic	clotting, chromogenic, and immunologic assays
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	10	up to 80
Number of different assays programmed and calib. at one time	up to 80	unlimited	up to 80
Number of user-definable (open) channels	70	unlimited	70
Of those defined, number active simultaneously	70	10	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)	31 to 51/varies/yes (12°–16°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 third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	18 months	varies by reagent—routine reagents 12 months	18 months
Walkaway capacity: Number of specimens/Number of tests	20/12 per specimen	50/240	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/—	25 µL/10 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes and wash solution/varies with volume	reaction trays, ProWash	cuvettes and wash solution/varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/no	yes (all standard, pediatric, micro)/no	yes/yes
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	in development	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)	not necessary	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/yes	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)
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	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no (not necessary)/no (not necessary)	yes/yes	no (not necessary)/no (not necessary)
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	7 minutes/52 specimens	<3 minutes/180 tests	<6 minutes/150 specimens
• PT, PTT	7 minutes/36 specimens	<6 minutes/90 tests	7 minutes/75 specimens
• Fibrinogen	7 minutes/36 specimens	<6 minutes/105 tests	7 minutes/75 specimens
• Factor VIII activity assay	—/—	<6 minutes/58 tests	7 minutes/70 specimens
Time delay from ordering stat to aspiration of sample	<15 seconds	varies by test	<15 seconds
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots)	onboard (includes QC: LJ plots, Westgard)	onboard (includes QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner, Misys, Meditech, others	all major LIS vendors	Cerner, Misys, Meditech, others
Bidirectional interface capability	yes (host query)	yes (broadcast download and 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	yes	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	yes	no
Time required for maintenance by lab personnel	weekly: <30 minutes; monthly: 30 minutes	daily: <5 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	2 to 4 days on site; 3 days at vendor offices	varies on site, 3 days at vendor offices
Approximate number of training hours needed per tech	2	8	2 (basic)
List price	$45,000	$71,760	$75,000
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	prices available on 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	mechanical and optical clot detection on one platform; easy to learn and retain IntuiTouch software; standardize with Destiny Max; normalization of PT and PTT results	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; can standardize with other STA analyzers

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Coagulation analyzers

Part 7 of 11	Diagnostica Stago Inc. Barry Ray barry.ray@stago-us.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Barry Ray barry.ray@stago-us.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com	Diagnostica Stago Inc. Barry Ray barry.ray@stago-us.com 5 Century Drive Parsippany, NJ 07054 800-222-COAG www.stago-us.com
Instrument name/first year sold	STA Compact CT/2001	STA Compact Plus/—	STA-R Evolution Expert Series/2005
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
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 (lyophilized, reconstituted manually)	open	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	continuous specimen access (primary tube)	continous specimen access (primary tube)	rack with continuous specimen access
Model type	benchtop	benchtop	floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	25.2 × 38.8 × 25.8 inches/351 lbs/7 square feet	25.2 × 38.8 × 25.8 inches/351 lbs/7 square feet	49.2 × 50.3 × 32.2 inches/507 lbs/26.8 square feet
FDA-cleared clotting-based tests	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT screen and confirm	PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT, screen and confirm
FDA-cleared chromogenic tests	—	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin	heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin
FDA-cleared immunologic tests	—	D-dimer, VWF, total and free protein S, AT antigen	D-dimer, VWF, total and free protein S, AT antigen
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	APCR, other clotting tests can have user-defined applications	APCR, other clotting chromogenic and immunological tests with user-defined applications	APCR, other clotting chromogenic and immunological tests with user-defined applications
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	—	—
Methodologies supported	clot detection, mechanical	clot detection, mechanical, chromogenic, immunologic	clot detection, mechanical, 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	up to 80	up to 80	up to 200
Number of different assays programmed and calib. at one time	up to 80	up to 80	up to 200
Number of user-definable (open) channels	70	70	200
Of those defined, number active simultaneously	70	70	200
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	45/varies/yes (15°–19°C)	45/—/yes (15°–19°)	70/varies/yes (15°–19°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	yes	yes
Same capabilities when third-party reagent 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	96/12	96/12	215/32
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/5 µL	50 µL/5 µL	50 µL/5 µL
Disposables used/Price of each	cuvettes and wash solution/varies with volume	cuvettes and wash solution/—	cuvettes and wash solution/varies with volume
Supports direct-from-track sampling	no	no	yes (Beckman Coulter, Siemens LabCell, Roche MPA)
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes (multiple sizes)/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	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 (option selectable on operator menu)	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/no	no (not necessary)/no (not necessary)
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<6 minutes/150 specimens	<6 minutes/150 specimens	<6 minutes/~300 specimens
• PT, PTT	7 minutes/75 specimens	7 minutes/75 specimens	7 minutes/~150 specimens
• Fibrinogen	7 minutes/75 specimens	7 minutes/75 specimens	7 minutes/~180 specimens
• Factor VIII activity assay	7 minutes/70 specimens	7 minutes/70 specimens	7 minutes/~180 specimens
Time delay from ordering stat to aspiration of sample	<15 seconds	<15 seconds	<15 seconds
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots)	onboard (includes QC: L-J plots, Westgard multirules)	onboard (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 (broadcast download and 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	no	yes (Beckman Coulter, Siemens LabCell, Roche MPA)
Modem servicing	no	no	yes
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	varies on site, 3 days at vendor office	three days at vendor offices	varies on site, 4 days at vendor offices
Approximate number of training hours needed per tech	2 (basic)	24–32	3–5
List price	$50,000	$90,000	$161,900
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	—/1 year	prices available upon request/1 year
Unique advantages (provided by vendors)	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; able to standardize with other STA analyzers	performs simultaneous clotting (viscosity-based detection system), chromogenic, and immunological assays in true random access; manages patient results with autovalidation; delta check; incorporates expert rules to perform multi-dilution factors and lupus anticoagulant testing; abnormal results are flagged; auto rerun capability; quality control: L-J graphs, value tables, and Westgard rules	viscosity-based detection system; connectivity to lab automation systems; software for password protection and result traceability; can standardize with other STA analyzers

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Coagulation analyzers

Part 8 of 11	Diagnostica Stago Inc. Kevin McGlinchey kevin.mcglinchey@tcoag.com 5 Century Drive, Parsippany, NJ 07054 888-291-0415 www.tcoag.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	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	**Destiny Max/2009**	**Calibrated Automated Thrombogram/2006**	**AggRAM/2005**
Number of units installed in U.S./Outside U.S.	—	—	90/100+
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	Germany/Germany	The Netherlands/Finland	U.S./U.S.
Operational type	continuous random access	batch, discrete	batch, random access
Reagent type	open reagent system	self-contained single-use and multi-use cartridges-packages-slides, open reagent system (lyophilized, reconstituted manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma, PRP
Sample handling system	continuous rack loading	96-well plate pipetted manually, inserted into instrument where the last reagent is automatically dispensed	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29.5 × 59 × 27 in/340 lbs/11.03 square feet	34 × 42 × 42 cm/30 lbs/2 square feet	6 × 10 × 17 inches/15 lbs/—
FDA-cleared clotting-based tests	open system: all clottable assays can be run on the Destiny Max (PT, PTT, FIB, TT, factors, venom time, proteins C and S, aPCR, lupus screen and confirm)	—	—
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	—	—
FDA-cleared immunologic tests	open system: all latex immunoassays can be run on the Destiny Max (D-dimer)	—	—
Other FDA-cleared tests	—	—	ristocetin cofactor and platelet aggreg.
User-defined tests in clinical use	—	—	ristocetin cofactor, platelet aggregation–ADP, EPI, COL, ristocetin, arach. acid
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	all coagulation tests	fluorescence-based detection of thrombin generation and microparticle determination	lumi, chromogenics, HIT
Methodologies supported	clot detection, mechanical and optical; chromogenic; immunologic	quartz-halogen, fluorescence-based detection of thrombin generation	ristocetin cofactor, platelet aggregation
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	unlimited	5	4–8
Number of different assays programmed and calib. at one time	unlimited	5	4–8
Number of user-definable (open) channels	unlimited	16	12
Of those defined, number active simultaneously	unlimited	16	4–8
Factor assays require manual manipulation or dilutions	no	—	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	—/varies by test/yes (12°–16°C)	—/16/no	—/—/no
Multiple reagent configurations supported	yes		no
Reagents, consumables loaded without interrupting testing	yes		no
Same capabilities when third-party reagent used	no		—
Maximum time same lot number of reagents can be used	varies—routine reagents 12 months		12 months
Walkaway capacity: Number of specimens/Number of tests	120/71,000	16/16	no
Minimum sample volume aspirated precisely at one time	25 µL	—	—
Standard specimen volume required to run PT or PTT/Factor VIII activity	25 µL/10 µL	—	platelet aggregation: 225 µL PRP, ristocetin cofactor: 50 µL
Disposables used/Price of each	reaction trays, ProWash	—	cuvettes/200 @ $55.65; pipette tips/1,000 @ $82; stir bars/30 @ $62.25
Supports direct-from-track sampling	yes	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	no/no	no
Sample bar-code/Reagent bar-code reading capability	yes/yes	no/no	no/no
Onboard test automatic inventory	yes	no	no
Measures No. of tests remaining/Short sample detection	yes/yes	no/no	no/no
Clot detection as preanalytical variable in plasma sample	no	no	—
Auto. detects adequate reagents for aspiration and analysis	yes	no	no
Hemolysis/Turbidity detection-quantitation	not necessary/not necessary	no/no (not necessary for internal calibration technology)	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 sample not detected	no	no	—
Read time extended for prolonged clotting times	yes	no	—
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/no	no/yes
Auto shutdown/Auto startup programmable	yes/yes	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/~350 tests	—	—
• PT, PTT	<6 minutes/~232 tests	—	—
• Fibrinogen	<6 minutes/~200 tests	—	—
• Factor VIII activity assay	<6 minutes/~200 tests	—	—
Time delay from ordering stat to aspiration of sample	<3 minutes	—	—
Automatic transfer of QC results to LIS	yes	no	yes
Data-management capability	onboard (includes QC: LJ plots, Westgard)	onboard	onboard (includes QC: L-J plots, Westgard)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	yes (broadcast download and 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
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	no	no
Modem servicing	yes	no	—
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: <10 minutes; monthly: <30 minutes	weekly: 15 minutes	daily: 15 minutes; weekly: 15 minutes; monthly: 1 hour
Onboard maintenance records	yes	no	yes
Training provided with purchase	3–5 days on site; 5 days at vendor offices	1 day on site	2 days on site
Approximate number of training hours needed per tech	5	5	4–8
List price	$134,160	$38,500	$14,995
Annual service contract cost (24/7)/Warranty with purchase	prices available on request/1 year	$1,550/1 year	$1,800/1 year
Unique advantages (provided by vendors)	mechanical and optical clot detection; closed tube sampling; dyes in routine reagents for volume delivery check; factor parallelism; normalization of PT and PTT results; LAS ready	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	specialized coagulation instrument intended for platelet aggregation and ristocetin cofactor

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Coagulation analyzers

Part 9 of 11	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com	Helena Laboratories David Pearman dpearman@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 409-842-3714 ext. 265 www.helena.com	LABiTec GmbH Matthias Schramm matthias.schramm@labitec.de An der Strusbek 6 Ahrensburg, Germany 22926 011-49-4102-47950 www.labitec.com
Instrument name/first year sold	**Cascade M-4/1992**	**Cascade M/1991**	**CoaLAB 1000/2009**
Number of units installed in U.S./Outside U.S.	200+/30	300+/100	—/150
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	Germany/Germany
Operational type	random access	batch	batch, random access
Reagent type	open reagent system	open reagent system	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	manual	manual	two fixed racks of 11 samples each plus 3 stat
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	8 × 15 × 13 inches/25 lbs/1.4 square feet	8 × 15 × 13 inches/25 lbs/1.4 square feet	78 × 58 × 50 cm/30 kg (shipping)/—
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	—
FDA-cleared chromogenic tests	—	—	—
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII	—
Tests submitted for 510(k) clearance	—	—	PT, APTT, fibrinogen
Tests in development but not yet submitted	DRVVT	DRVVT	—
Methodologies supported	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric	clot detection (optical), nephelometric, trubidimetric, chromogenic, immunologic (agglutination/aggregation)
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	15 maximum
Number of different assays programmed and calib. at one time	4	1	50
Number of user-definable (open) channels	4	2	2
Of those defined, number active simultaneously	2	1	2
Factor assays require manual manipulation or dilutions	yes	yes	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	0/—/no	—	15/200 maximum/no
Multiple reagent configurations supported	no	—	yes
Reagents, consumables loaded without interrupting testing	no	no	no
Same capabilities when third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	12 months	12 months	1 year
Walkaway capacity: Number of specimens/Number of tests	no	no	25 maximum/>10
Minimum sample volume aspirated precisely at one time	manual, 50 µL	manual, 50 µL	2 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted)	100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted)	100µl reagent/50-µL sample/50 µL APTT; 50-µL sample; 50 µL/3 reagents and 1 sample
Disposables used/Price of each	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvettes/500 @ $54; pipette tips/1,000 @ $82	cuvette ring (32 single cuvettes per ring)/sample cups
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/—	no/—	yes (1.7–4 mL)/no
Sample bar-code reading capability	no	no	yes
Reagent bar-code reading capability	no	no	no
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	—	—	yes
Auto. detects adequate reagents for aspiration and analysis	no	no	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/yes
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)	yes (PT: <10 seconds; PTT: <20 seconds)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	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	no/yes	no/yes	yes/yes
Auto shutdown/Auto startup programmable	no/no	no/no	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	3 minutes/140 specimens	3 minutes/120 specimens	<2 minutes/108 per hour
• PT, PTT	7 minutes/80 specimens	7 minutes/50 specimens	<5 minutes/60 per hour
• Fibrinogen	3 minutes/160 specimens	3 minutes/140 specimens	<5 minutes/90 per hour
• Factor VIII activity assay	7 minutes/80 specimens	7 minutes/50 specimens	depends on assay
Time delay from ordering stat to aspiration of sample	—	—	3 minutes
Automatic 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	yes (included)
Interfaces in active user sites for:	—	—	via LAN, Windows OS, Linux OS
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	per shift: <1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: calibration 15 minutes
Onboard maintenance records	no	no	no
Training provided with purchase	1 day on site	1 day on site	3 days at vendor offices; on site on request
Approximate number of training hours needed per tech	2	2–4	—
List price	$9,635	$7,127	—
Annual service contract cost (24/7)/Warranty with purchase	$966/1 year	$714/1 year	—/12 months
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	standalone device, requires no additional PC/monitor to control system; software onboard, only external printer; flexible and extendable by software add-ons; different wavelength available; optimized for small to mid sized labs; special hemostasis of diagnostic assays

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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

Coagulation analyzers

Part 10 of 11	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	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	**BFT II/U.S.: 1999**	**Sysmex CA-530/2006**	**Sysmex CA-560/U.S.: 2003**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	Germany/Germany	Japan/Japan	Japan/Japan
Operational type	batch	continuous random access	continuous random access
Reagent type	open reagent system (reconstituted manually)	open reagent system (reconstituted manually), optimized for Siemens instruments	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	manual	10-tube position sample rack	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	3.9 × 7.9 × 11.8 inches/8.4 lbs/1.5 square feet	19 × 21 × 18.5 inches/99 lbs/9 square feet	19 × 21 × 18.5 inches/99 lbs/9 square feet
FDA-cleared clotting-based tests	PT, APTT, fibrinogen	PT, APTT, fibrinogen, TT, reptilase time, protien C clot, factor assays	PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays
FDA-cleared chromogenic tests	—	Innovance AT, Berichrom AT, protein C chromo, heparin	Innovance AT, Berichrom AT, protein C chromo, heparin
FDA-cleared immunologic tests	—	—	Advanced D-dimer, Innovance D-dimer
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	PT multi-calibrators	PT multi-calibrators, innovance VWF activity assay
Tests in development but not yet submitted	—	—	—
Methodologies supported	turbodensitometric	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	1	5	5
Number of different assays programmed and calib. at one time	3	7	7
Number of user-definable (open) channels	—	7	7
Of those defined, number active simultaneously	1	5	5
Factor assays require manual manipulation or dilutions	—	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	4/up to 200/no	11/varies, up to 200/yes (15°C)	11/varies, up to 200/yes (15°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	yes	consumables yes, reagents no	consumables yes, reagents no
Same capabilities when third-party reagent 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	1/1	10/50	10/50
Minimum sample volume aspirated precisely at one time	50 µL	10 µL/50 µL	10 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL	50 µL/—	50 µL/—
Disposables used/Price of each	cuvettes, printer paper/varies with volume	reaction tubes, CA clean I, thermal 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	no/no	yes (3–5 mL)/no	yes (3–5 mL)/no
Sample bar-code reading capability	no	no	yes
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	yes
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	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	yes/no	yes/no
Dilution of patient samples onboard	no	yes	yes
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable sample not detected	yes (PT: 5 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	no	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	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	1 minute/—, manual	7 minutes/54 results	7 minutes/54 results
• PT, PTT	—, manual	8 minutes/43 results	8 minutes/43 results
• Fibrinogen	<1 minute/—, manual	7 minutes/54 results	7 minutes/54 results
• Factor VIII activity assay	—	—	—
Time delay from ordering stat to aspiration of sample	—	2 minutes	2 minutes
Automatic transfer of QC results to LIS	no	yes	yes
Data-management capability	no	onboard (includes QC: L-J plots)	onboard (includes QC: L-J plots)
Interface supplied by instrument vendor	—	no	no
Interfaces in active user sites for:	—	all major LIS vendors	all major LIS vendors
Bidirectional interface capability	no	yes (host query after manual ID input)	yes (host query)
Results transferred to LIS as soon as test time complete	no	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	no
Time required for maintenance by lab personnel	daily: 1 minute	daily: <5 minutes; weekly: 1 minute; quarterly: <5 minutes	daily: <5 minutes; weekly: 1 minute; quarterly: < 5 minutes
Onboard maintenance records	no	no	no
Training provided with purchase	Web CD training course	2 days on site, online training course, Web CD training	2 days on site, online training course, Web CD training
Approximate number of training hours needed per tech	2	2	2
List price	$8,685	$34,812	$47,634
Annual service contract cost (24/7)/Warranty with purchase	—	—	—
Unique advantages (provided by vendors)	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	five-parameter true random-access clotting/chromogenic/immunologic technology; complete automation, specialty assay capability; low operating expense

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Coagulation analyzers

Part 11 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-1500/U.S.: 2000; worldwide: 1999	Sysmex CA-7000/2002	BCS XP/2006
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/11 and 11/30/11	—	—	—
Country where analyzer designed/manufactured	Japan/Japan	Japan/Japan	Germany/Germany
Operational type	continuous random access	continuous random access	batch, continuous random access
Reagent type	open reagent system (lyophilized, reconstituted manually), optimized for Siemens instruments	open reagent system	open reagent system (reconstructed manually), optimized for Siemens instruments
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	10-tube position sample rack × 5	rack	10-tube position sample rack
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	20 × 31.2 × 31.2 inches/186 lbs/6.8 square feet	24.8 × 42 × 43.8 inches/345.4 lbs/12.78 square feet	37 × 49 × 25 inches/330 lbs/14 square feet
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, 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, 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	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	—	—	BC von Willebrand-risto. cofactor assay (agglut of fixed plts)
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	PT multi-calibrators, innovance VWF activity assay	PT multi-calibrators, innovance VWF activity assay	PT multi-calibrators, innovance VWF activity assay
Tests in development but not yet submitted	—	—	ETP (for research use only)
Methodologies supported	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical, turbidimetric; chromogenic; immunologic	clot detection, optical (xenon flasher lamp); 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	15	20	>100 tests/samples
Number of different assays programmed and calib. at one time	25	40	99
Number of user-definable (open) channels	25	40	7,999
Of those defined, number active simultaneously	15	20	>100
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	39/up to 200/yes (15°C)	58/varies up to 200/yes (15°C)	90/varies, up to 200/yes (<15°C)
Multiple reagent configurations supported	yes	yes	yes
Reagents, consumables loaded without interrupting testing	some consumables yes, reagents no	yes	yes
Same capabilities when third-party reagent 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	50/up to 1,000	100/550 per hour PT and APTT, 300 per hour PT	100 samples/400 cuvettes
Minimum sample volume aspirated precisely at one time	5 µL	5 µL	3 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/10 µL	50 µL/10 µL	50 µL/20 µL, minimum 100 µL (includes dead volume)/50 µL, minimum 100 µL
Disposables used/Price of each	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	cuvette rotors, washing solution, terralin disinfectant, BC validation kit/varies with volume
Supports direct-from-track sampling	yes (Sysmex CST series)	yes (custom automation solutions available)	no
Primary tube sampling supported/Pierces caps on primary tubes	yes (3–5 mL)/yes	yes (3–5 mL)/yes	yes (all up to 100 mm long, ext. diameter 11–16 mm)/no
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	yes/no	yes/no	yes/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	yes (PT: 7 seconds, APTT: 15 seconds)	yes (PT: 7 seconds, APTT: 15 seconds)	yes (7 seconds for PT and APTT)
Read time extended for prolonged clotting times	yes (selectable on menus)	yes (selectable on menus)	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	no/yes	no/yes	yes/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/120 results	7 minutes/280 results	<5 minutes/~380 results (including abnormals)
• PT, PTT	8 minutes/80 results	8 minutes/480 results	<5 minutes/~325 results (including abnormals)
• Fibrinogen	8 minutes/120 results	8 minutes/280 results	<5 minutes (if curve available)~315 results
• Factor VIII activity assay	8 minutes/—	8 minutes/300 results	<5 minutes (if curve available)~280 results
Time delay from ordering stat to aspiration of sample	2 minutes	2 minutes	varies by test in progress, appox. >5 minutes
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots and Westgard)	onboard (includes QC: L-J plots and Westgard)	yes, onboard (includes QC: L-J plots)
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	yes (Sysmex CST series)	custom automated connectivity with StreamLab	no
Modem servicing	no	no	yes
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: 1 minute; quarterly: <5 minutes	daily: <10 minutes; weekly: 1 minute; monthly: <5 minutes; quarterly: <5 minutes	daily: <5 minutes; weekly: <10 minutes.; monthly: 15 minutes
Onboard maintenance records	no	no	yes
Training provided with purchase	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	3 days at vendor offices for 2 key operators, online training course
Approximate number of training hours needed per tech	6	8 (on site)	8 (on site)
List price	$97,529 standard model; $110,544 cap-piercing model	$196,451	$171,921
Annual service contract cost (24/7)/Warranty with purchase	—	—	—
Unique advantages (provided by vendors) *Note: a dash in lieu of an answer means company did not answer question or question is not applicable*	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	user-definable calibration curve expiration and prewarning alerts; user-definable bar-code utility enables customizable reagent protocols; user-friendly Windows XP software