New analyzers, assays, controls, and PEP

Anne Ford

With the new year come fresh offerings from coagulation analyzer manufacturers, of which at least two have launched entirely new testing systems.

Instrumentation Laboratory's ACL AcuStar hemostasis system has been "met with great enthusiasm for its speed, accuracy, and comprehensive line of high performance chemiluminescent assays," says Venita C. Shirley, director of marketing for commercial operations in North America. The system, which she terms "the first hemostasis analyzer to incorporate chemiluminescence technology," features the HemosIL AcuStar anticardiolipin (IgG and IgM) and anti-β_2GP-I (IgG and IgM) assays for antiphospholipid syndrome.

Also new from the company are the HemosIL protein S activity and factor VIII assays. The first, a second-generation assay, offers increased onboard stability of eight hours on ACL TOP systems, while the second is a factor VIII-deficient plasma that features 24-hour stability. In addition, "Instrumentation Laboratory is working toward the release of several new assays in the United States," Shirley says. Those include HemosIL VWD:RCo Activity and HemosIL HIT-$Ab_{(PF4\text{-}H)}$, both already available in Europe and Canada.

Fresh from Diagnostica Stago: the STA Compact Max benchtop analyzer, "suitable for use in routine and specialty hemostasis testing," says marketing director Hamid Erfanian. "It combines powerful and proven viscosity-based clot-detection technology with easy-to-use expert module software." Innovative features of this new instrument's software, he adds, are multi-dilution management for factor assays; electronic lot conversion; autoverification rules; automatic management of dilutions, reruns, and reflex testing; advanced USB export capabilities; and customizable database queries.

This launch, Erfanian says, will be followed in the first quarter of this year by the STA-R Evolution Plus, a high-volume instrument-software combination that will perform simultaneous clotting, chromogenic, and immunological assays. In a manner similar to the new STA Compact Max, "the STA-R Evolution Plus provides enhanced software capabilities to allow users to manage patient results with autovalidation, delta check, and the ability to incorporate expert rules to perform multi-dilution factor testing," he says. "QC management features include Levey-Jennings graphs and value tables as well as Westgard rules and instant access to up to 500,000 archived patient results."

He adds that early 2014 should also see the launch of the STA Coag Control N and ABN Plus 24-hour controls for use with Stago's clotting assays for prothrombin time, activated partial thromboplastin time, fibrinogen, and thrombin time, with added values for the chromogenic antithrombin assay. Finally, forthcoming for research use only are the STA–Apixaban calibrator and controls, which Erfanian calls "highly specific, automation-ready products for determining the apixaban concentration in plasma," as well as dabigatran calibrators and controls for measuring direct thrombin inhibitors using the Ecarin Chromogenic Assay.

Bio/Data, meanwhile, marks the new year with not an introduction but a reintroduction—that of its non-activated partial thromboplastin time reagent, known as UPTT. "UPTT is used to perform required tests for evaluating hemocompatibility on medical devices that have in vivo contact with blood, regardless of how short the contact interval is," explains William M. Trolio, vice president and CSO. He adds that the UPTT has been formulated to meet an ANSI/ISO biocompatibility guideline specifying that a test with established sensitivity to the degree of activation of the intrinsic coagulation pathway be used in the development and pre-approval clinical tests of a medical device.

In his view, three paradigm shifts are underway in platelet studies. "Studies of platelet structure and function at the molecular and sub-molecular level are yielding new insights that may point the way to longer term storage of functional platelets for transfusion and improved applications for PRP therapy," he says. "In addition, potential targets for new therapeutic agents are being identified and studied. The search for new antiplatelet agents that can be tailored to individual needs and whose effect can be reversed follows along the same trajectory."

Finally, Siemens has developed an education solution it calls the Personalized Education Plan, or PEP. "For example, this past year we introduced on-demand webinars related to coagulation testing, and this series will continue with new topics in the coming months," hemostasis marketing director Jackie Hauser says. "We are also adding new instrument-based courses that integrate online and in-person training to help operators achieve the necessary competencies to ensure laboratory quality. In addition, PEP Administrator is available to support customer compliance needs by providing the visibility, administration, and reporting tools to ensure educational competence, quality, and compliance verification throughout the entire organization."

CAP TODAY's guide to coagulation analyzers includes products from the aforementioned manufacturers and from American Labor/Lab A.C.M., Chrono-Log, Helena Laboratories, and LABiTec. Companies supplied the information listed. Readers interested in a product should confirm it has the stated features and capabilities. □

Anne Ford is a writer in Evanston, Ill.

Part 1 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**American Labor/Lab A.C.M.** **Mike Shiflett** mshiflett@americanlabor.org **3329 Durham Chapel Hill Blvd., Suite 200, Durham, NC 27707** **919-286-0726 or (tech support) 800-424-0443** www.americanlabor.org and www.labitec.de
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 1/1/13 and 11/30/13	**—**
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. with mixers in trays: 11.6¢ ea., bulk 11¢; 500 macrocuv. with mixers in trays: 12¢ ea., bulk 10.6¢; 2,304 pipette tips-trayed: 5.1¢ ea., 3,000 tips bulk: 3.9¢ ea.**
Supports direct-from-track sampling/Primary tube sampling supported/Pierces caps on primary tubes	**no/no/no**
Sample/Reagent bar-code reading capability	**no/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**
• Incubation 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	**—**
Automatic transfer of QC results to LIS	**no**
Data-management capability	**no**
Interface supplied by instrument vendor	**no**
Interfaces in active user sites for:	**—**
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**
Distinguishing features (supplied by company)	**smaller clinic; office, private, vet labs; low acquisition and service cost, low maintenance; refurbished units available at reduced prices; can handle turbid and colored samples**
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 2 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**Bio/Data Corp.** **Kay Callahan** kay.callahan@biodatacorp.com **155 Gibraltar Road, Horsham, PA 19044** www.biodatacorp.com	**Chrono-Log Corp.** **Kathy Jacobs** jacobs@chronolog.com **Havertown, PA 19083** **610-853-1130** www.chronolog.com	**Diagnostica Stago** **Richard Peluso** richard.peluso@us.stago.com **5 Century Drive, Parsippany, NJ 07054** **800-220-2624** www.stago-us.com
Instrument name/First year sold	**Platelet Aggregation Profiler PAP-8E/2005**	**Whole Blood Optical Lumi-Aggregation System 700-2 and 700-4/2006**	**STA-R Evolution Plus/2012**
Number of units installed in U.S./Outside U.S.	>500 worldwide	160/205	—
Number of contracts signed between 1/1/13 and 11/30/13	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	France/France
Operational type	batch, random access	batch, random access	continuous random access
Reagent type	open reagent system, assay kits, reagents, controls, dilutents, buffer, specialty products, others	open reagent system, assay kits, reference plasmas, controls (lyophilized reconstituted manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	whole blood, spun plasma	spun plasma
Sample handling system	programmable electronic pipette, optional bar-code scanner	manual	rack with continuous specimen access
Model type	benchtop	benchtop	floor standing
Dimensions (H × W × D)/Weight/Instrument footprint	22.5 × 14.0 × 21.7 inches/45 lbs/2.2 square feet	8.5 × 14.0 × 18.0 inches/40 lbs/ M700-2: 1.75 square feet; M700-4: 3.5 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, protein C and S, lupus anticoagulants, DRVVT (screen and confirm), heparin (UFH & LMWH), protein C, AT, plasminogen, antiplasmin
FDA-cleared chromogenic tests	—	—	D-dimer, VWF, total and free protein S, AT antigen
FDA-cleared immunologic tests	—	—	—
Other FDA-cleared tests	ristocetin cofactor assay, ristocetin and heparin-induced platelet aggregation, platelet aggregation (ADP, EPI, arachidonic acid, trap, collagen), spontaneous aggregation, sticky platelets, dose response, EC, IC50, others	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	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	turbidimetric, platelet dense granule secretion, whole blood impedance aggreg., LTA aggreg., ristocetin cofactor assay	clot detection, mechanical; chromogenic; immunologic
Operator must load sep. reagent pack per specimen/Test run	no/no	no/—	no/no
Number of different measured assays onboard simultaneously	8	2–4	200
Number of different assays programmed and calib. at one time	>8	4–8	200
Number of user-definable (open) channels	8	2–4	200
Of those defined, number active simultaneously	8	2–4	200
Factor assays require manual manipulation or dilutions	yes	yes	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	2 stirred, adapters for various sized vials/varies/no	no/—/no	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	no	yes
Maximum time same lot number of reagents can be used	up to 18 months	12–30 months	18 months
Walkaway capacity: Number of specimens/Number of tests	8/8	2–4/4–8	215/32
Minimum sample volume aspirated precisely at one time	25 µL	—	5 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	—	225 µL PRP-lumi aggregation 450 µL; 450 µL whole blood-lumi aggregation 450 µL/25 µL ristocetin cofactor 50 µL	50 µL/50 µL
Disposables used/Price of each	siliconized test tubes: 100@$30.75; plastic-coated stir bars: 50 @ $16.25; pipette tips: 960@$42.25; MagneTubes: 50@$43.00	cuvettes: 144 @ $34, stir bars: 144 @ $30, impedance probes: 25 @ $130, pipette tips: 1,000 @ $73, $55 and $60	cuvettes, wash solution/—
Supports direct-from-track sampling/Primary tube sampling supported/Pierces caps on primary tubes	no/no/no	no/no/no	yes (Beckman Coulter, Siemens, Roche)/yes/yes
Sample/Reagent bar-code reading capability	yes/yes	no/no	yes/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	no	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	yes/no	yes/yes
Lag time during which hypercoagulable sample not detected	no	—	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
• Incubation times/Reading times	yes/yes	yes/yes	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	V2.1 hardware/software update adds optical calibration	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	—	—	<6 minutes/~300 specimens
• PT, PTT	—	—	7 minutes/~150 specimens
• Fibrinogen	—	—	7 minutes/~180 specimens
• Factor VIII activity assay	—	—	7 minutes/~180 specimens
Time delay from ordering stat to aspiration of sample	—	—	<15 seconds
Automatic transfer of QC results to LIS	no	no	yes
Data-management capability	yes (onboard, includes QC: L-J plots, Westgard Multirules)	yes (onboard)	onboard (includes QC: L-J plots, Westgard Multirules)
Interface supplied by instrument vendor	no	yes	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	no	yes (broadcast download, host query)
Results transferred to LIS as soon as test time complete	no	no	yes
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	yes
Modem servicing	no	no	—
Time required for maintenance by lab personnel	weekly: 15 minutes; monthly: 30 minutes	30 minutes when optical calibration required	daily: <5 min.; weekly: <30 min.; monthly: <30 min.
Onboard maintenance records	yes	yes	yes
Training provided with purchase	1.5 days on site	1.5 days on site	yes (varies on site, 4 days at vendor offices)
Approximate number of training hours needed per tech	4–6	8	3–6
List price	$19,990	M700-2: $19,500; M700-4: $32,000	$161,900
Annual service contract cost (24/7)/Warranty with purchase	$1,990 for 1 year, $2,990 for 2 years/—	M700-2: $1,804; M700-4: $3,008 for 3 years/1 year	—/1 year
Distinguishing features (supplied by company)	two-year warranty; no-charge software upgrades during warranty period; optional PDQ platelet function centrifuge standardizes sample preparation, reduces preparation time to five minutes; on-demand optical calibration; unlimited user-defined test types; selectable washed platelet sample test type; adjustable temperature settings	tests platelet aggregation; measures ATP release in four samples simultaneously using whole blood, PRP, washed, or gel-filtered platelets; continuously monitors temp. and stirring speed; optical calibration by lab personnel; dedicated software packages calculate amplitude, slope, lag time, and more	viscosity-based, mechanical clot detection system; connectivity to all major lab auto. systems; manages patient/QC results with autovalidation; delta check, offers expert rules to make complicated tests such as factor assays, multi-dilution factors, LA easy; abnormal results flagged; auto rerun capability w/rules; L-J charts, QC graphs, QC priorities, Westgard rules, auto-upload to Stago Clarity Check online QAP program

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

Coagulation analyzers

Part 3 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**Diagnostica Stago** **Barry Ray** barry.ray@us.stago.com **5 Century Drive** **Parsippany, NJ 07054** **800-222-2624** www.stago-us.com	**Diagnostica Stago** **Claudia Escobar** claudia.escobar@us.stago.com **5 Century Drive** **Parsippany, NJ 07054** **800-222-2624** www.stago-us.com	**Diagnostica Stago** **Richard Peluso** richard.peluso@us.stago.com **5 Century Drive** **Parsippany, NJ 07054** **888-222-2624** www.stago-us.com
Instrument name/First year sold	**STA Compact Max/2013**	**STA Satellite/2010**	**Destiny Plus/2005**
Number of units installed in U.S./Outside U.S.	4/71	—	—
Number of contracts signed between 1/1/13 and 11/30/13	18	—	—
Country where analyzer designed/Manufactured	France/France	France/France	Germany and U.S./Germany
Operational type	continuous random access	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	continuous load sample drawer	carousel (primary tubes)	continuous rack loading
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	27.75 × 38.18 × 28.73 inches/309 lbs/7 square feet	27.4 × 21.1 × 25.5 inches/72 lbs/4 square feet	22 × 33 × 27 inches/165 lbs/6.8 square feet
FDA-cleared clotting-based tests	PT, APTT, TT, fibrinogen, reptilase, factors, protein C and S, lupus anticoagulants, DRVVT (screen and confirm)	PT, APTT, fibrinogen	open system: all clottable assays (PT, PTT, FIB, TT, factors, venom time, proteins C and S, aPCR, lupus screen and confirm)
FDA-cleared chromogenic tests	heparin (UFH & LMWH), protein C, AT, plasminogen, antiplasmin	heparin (UFH, LMWH), AT	open system: all chromogenic assays (prot C, AT IIa and Xa based), heparin Xa, plasminogen
FDA-cleared immunologic tests	D-dimer, VWF, total and free protein S, AT antigen	D-dimer	open system: all latex immunoassays (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	—	—	—
Methodologies supported	clot detection, mechanical, chromogenic, immunologic	clot detection, mechanical, chromogenic, immunologic	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	—	80	10
Number of different assays programmed and calib. at one time	80	80	unlimited
Number of user-definable (open) channels	80	70	unlimited
Of those defined, number active simultaneously	80	70	10
Factor assays require manual manipulation or dilutions	no	—	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	45/varies/yes (15°–19°C)	16/varies/yes (15°–19°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 third-party reagent used	yes	yes	yes
Maximum time same lot number of reagents can be used	18 months	18 months	varies by reagent (routine reagents 12 months)
Walkaway capacity: Number of specimens/Number of tests	96/12	20/12 per specimen	50/240
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/—	25 µL/10 µL
Disposables used/Price of each	cuvettes, wash solution/varies	cuvettes, wash solution/varies	reaction trays, ProWash
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	yes/no	yes (all standard, pediatric, micro)/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	yes	in development
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 (not necessary for mechanical detection technology)	not necessary
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/no	yes/yes
Lag time during which hypercoagulable sample not detected	no	no	no
Read time extended for prolonged clotting times	yes	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
• Incubation 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 (not necessary)/no (not necessary)	yes/yes
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<6 minutes/150 specimens	7 minutes/52 specimens	<3 minutes/180 tests
• PT, PTT	<6 minutes/75 specimens	7 minutes/36 specimens	<6 minutes/90 tests
• Fibrinogen	<6 minutes/75 specimens	7 minutes/36 specimens	<6 minutes/105 tests
• Factor VIII activity assay	<6 minutes/70 specimens	—	<6 minutes/58 tests
Time delay from ordering stat to aspiration of sample	<15 seconds	<15 seconds	varies by test
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots, Westgard Multirules)	onboard (includes QC: L-J plots)	onboard (includes QC: L-J plots, Westgard Multirules)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	Cerner Classic, Cerner Millenium, Sunquest, Meditech, SOFT, others	Cerner, Misys, Meditech, others	all major LIS vendors
Bidirectional interface capability	yes (broadcast download, host query)	yes (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	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	yes	no	yes
Time required for maintenance by lab personnel	weekly: <30 minutes; monthly: 30 minutes	weekly: <30 minutes; monthly: 30 minutes	daily: <5 minutes; weekly: <30 minutes; monthly: <30 minutes
Onboard maintenance records	yes	yes	yes
Training provided with purchase	yes (varies on site, 3 days at vendor offices)	2 days on site	2–4 days on site, 3 days at vendor offices
Approximate number of training hours needed per tech	2 for basic operator	2	8
List price	$137,500	$45,000	$71,760
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—/1 year	—/1 year
Distinguishing features (supplied by company)	viscosity-based, mechanical clot detection system (exclusive to Stago) provides Interference-free testing for all clot-based assays; expert rules for routine and special coagulation testing, including multi-dilution factor assay rules; coagulation expertise built in; features such as electronic lot conversion and remote QC to maximize lab efficiency	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

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Coagulation analyzers

Part 4 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**Diagnostica Stago** **Barry Ray** barry.ray@us.stago.com **5 Century Drive** **Parsippany, NJ 07054** **800-222-2624** www.stago-us.com	**Diagnostica Stago** **Barry Ray** barry.ray@us.stago.com **5 Century Drive** **Parsippany, NJ 07054** **800-222-2624** www.stago-us.com	**Diagnostica Stago** **Richard Peluso** richard.peluso@us.stago.com **5 Century Drive** **Parsippany, NJ 07054** **800-222-2624** www.stago-us.com
Instrument name/First year sold	**STA Compact Hemostasis System/1996**	**STA Compact CT/2001**	**STA-R Evolution Expert Series/2005**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/13 and 11/30/13	—	—	—
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	open reagent system (lyophilized, reconstituted manually)	open reagent system
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	continuous specimen access (primary tube)	continuous 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, screen and confirm	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
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 chromogenic and immunological tests with user-defined applications	APCR, other clotting tests can have 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	clotting, chromogenic, immunologic assays	clot detection, mechanical	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	80	80	200
Number of different assays programmed and calib. at one time	80	80	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/varies/yes (15°–19°C)	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, wash solution/varies with volume	cuvettes, wash solution/varies with volume	cuvettes, 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/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
• Incubation 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	<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)	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 (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 offices	varies on site, 3 days at vendor office	varies on site, 4 days at vendor offices
Approximate number of training hours needed per tech	2 (basic)	2 (basic)	3–5
List price	$75,000	$50,000	$161,900
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—/1 year	—/1 year
Distinguishing features (supplied by company)	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; can standardize with other STA analyzers	viscosity-based detection system; walkaway testing for routine and specialty hemostasis assays; able to standardize with other STA analyzers	viscosity-based detection system; connectivity to lab automation systems; software for password protection and result traceability; can standardize with other STA analyzers

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

Coagulation analyzers

Part 5 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**Diagnostica Stago** **Richard Peluso** richard.peluso@us.stago.com **5 Century Drive, Parsippany, NJ 07054** **888-222-2624** www.stago-us.com	**Diagnostica Stago** **Paul Riley, PhD** paul.riley@us.stago.com **5 Century Drive, Parsippany, NJ 07054** **973-671-1200 ext. 4238** www.stago-us.com	**Diagnostica Stago** **Richard Peluso** richard.peluso@us.stago.com **5 Century Drive, Parsippany, NJ 07054** **800-222-2624** www.stago-us.com
Instrument name/First year sold	**Destiny Max/2009**	**Calibrated Automated Thrombogram/2006**	**STart 4 Hemostasis Analyzer/1998**
Number of units installed in U.S./Outside U.S.	—	—	—
Number of contracts signed between 1/1/13 and 11/30/13	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	The Netherlands/Finland	France/France
Operational type	continuous random access	batch, discrete	batch
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
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	4.7 × 16.1 × 16.5 inches/12.5 lbs/1.8 square feet
FDA-cleared clotting-based tests	open system: all clottable assays (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
FDA-cleared chromogenic tests	open system: all chromogenic assays (prot C, AT IIa and Xa based), heparin Xa, plasminogen	—	—
FDA-cleared immunologic tests	open system: all latex immunoassays (D-dimer)	—	—
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	all coagulation tests	fluorescence-based detection of thrombin generation and microparticle determination	—
Methodologies supported	clot detection, mechanical and optical; chromogenic; immunologic	quartz-halogen, fluorescence-based detection of thrombin generation	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	unlimited	5	1
Number of different assays programmed and calib. at one time	unlimited	5	20
Number of user-definable (open) channels	unlimited	16	4
Of those defined, number active simultaneously	unlimited	16	1
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	4/varies/no
Multiple reagent configurations supported	yes	—	yes
Reagents, consumables loaded without interrupting testing	yes	—	no
Same capabilities when third-party reagent used	no	—	yes
Maximum time same lot number of reagents can be used	varies, routine reagents 12 months	—	18 months
Walkaway capacity: Number of specimens/Number of tests	120/71,000	16/16	4/1
Minimum sample volume aspirated precisely at one time	25 µL	—	25 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	25 µL/10 µL	—	50 µL/5 µL
Disposables used/Price of each	reaction trays, ProWash	—	cuvettes, balls/varies
Supports direct-from-track sampling	yes	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes	no/no	no/no (not applicable)
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	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 (not necessary for mechanical detection technology)
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	no
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
• Incubation 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/—
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/~350 tests	—	<1 minute/up to 120 specimens
• PT, PTT	<6 minutes/~232 tests	—	—
• Fibrinogen	<6 minutes/~200 tests	—	<1 minute/up to 120 specimens
• Factor VIII activity assay	<6 minutes/~200 tests	—	varies/varies
Time delay from ordering stat to aspiration of sample	<3 minutes	—	<15 seconds
Automatic transfer of QC results to LIS	yes	no	no
Data-management capability	onboard (includes QC: L-J plots, Westgard Multirules)	onboard	no
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	no
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: <10 minutes; monthly: <30 minutes	weekly: 15 minutes	weekly: <5 minutes; monthly: <5 minutes
Onboard maintenance records	yes	no	no
Training provided with purchase	3–5 days on site, 5 days at vendor offices	1 day on site	1 day on site
Approximate number of training hours needed per tech	5	5	1
List price	$134,160	$38,500	$9,600
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	$1,550/1 year	—/1 year
Distinguishing features (supplied by company)	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	dynamic determination of thrombin generation during clot formation by fluorescence detection (for research use only; not for use in diagnostic procedures); sample-specific calibrator corrects for plasma color, turbidity, inner filter effect, substrate depletion	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

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

Coagulation analyzers

Part 6 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**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	**Helena Laboratories** **David Pearman** dpearman@helena.com **1530 Lindbergh Drive** **Beaumont, TX 77704** **409-842-3714 ext. 265** www.helena.com
Instrument name/First year sold	**AggRAM/2005**	**Cascade M-4/1992**	**Cascade M/1991**
Number of units installed in U.S./Outside U.S.	100+/500+	200+/40	300+/100
Number of contracts signed between 1/1/13 and 11/30/13	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	batch, random access	random access	batch
Reagent type	open reagent system	open reagent system	open reagent system
Operates on whole blood or spun plasma	spun plasma, platelet rich plasma	spun plasma	spun plasma
Sample handling system	manual	manual	manual
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	6 × 10 × 17 inches/15 lbs/—	8 × 15 × 13 inches/25 lbs/1.4 square feet	8 × 15 × 13 inches/25 lbs/1.4 square feet
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	ristocetin cofactor and platelet aggregation	—	—
User-defined tests in clinical use	ristocetin cofactor, platelet aggregation–ADP, EPI, COL, ristocetin, arachidonic acid	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	—	—	—
Tests in development but not yet submitted	lumi, chromogenics, HIT	DRVVT	DRVVT
Methodologies supported	ristocetin cofactor, platelet aggregation	clot detection, optical, turbidimetric	clot detection, optical, turbidimetric
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	4–8	4	1
Number of different assays programmed and calib. at one time	4–8	4	1
Number of user-definable (open) channels	12	4	2
Of those defined, number active simultaneously	4–8	2	1
Factor assays require manual manipulation or dilutions	yes	yes	yes
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	—/—/no	0/—/no	—
Multiple reagent configurations supported	no	no	—
Reagents, consumables loaded without interrupting testing	no	no	no
Same capabilities when third-party reagent used	—	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	no	no	no
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	platelet aggregation: 225 uL PRP; ristocetin cofactor: 50 uL/ platelet aggregation: 225 uL PRP; ristocetin cofactor: 50 uL	100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted)	100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted)
Disposables used/Price of each	cuvettes: 200 @ $55.65; pipette tips: 1,000 @ $82; stir bars: 30 @ $62.25	cuvettes: 500 @ $54; pipette tips: 1,000 @ $82	cuvettes: 500 @ $54; pipette tips: 1,000 @ $82
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/—	no/—	no/—
Sample bar-code reading capability	no	no	no
Reagent bar-code reading capability	no	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	—	—	—
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 (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	yes/yes
• No. and sources of reagent	yes	yes	yes
• Incubation 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	—	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 aspiration of sample	—	—	—
Automatic transfer of QC results to LIS	yes	yes	no
Data-management capability	onboard (includes QC: L-J plots, Westgard Multirules)	no (includes QC: L-J plots)	no (includes QC: L-J plots)
Interface supplied by instrument vendor	no	no	no
Interfaces in active user sites for:	—	—	—
Bidirectional interface capability	no	no	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	—	—	—
Electronic interface available (or will be) to automated (or robotic) specimen handling system	no	no	—
Modem servicing	—	no	no
Time required for maintenance by lab personnel	daily: 15 minutes; weekly: 15 minutes; monthly: 1 hour	daily: 10 minutes; weekly: 10 minutes; monthly: 30 minutes	daily: 10 minutes; weekly: 10 minutes; monthly: 20 minutes
Onboard maintenance records	yes	no	no
Training provided with purchase	2 days on site	1 day on site	1 day on site
Approximate number of training hours needed per tech	4–8	2	2–4
List price	$14,995	$9,635	$7,127
Annual service contract cost (24/7)/Warranty with purchase	$1,800/1 year	$966/1 year	$714/1 year
Distinguishing features (supplied by company)	specialized coagulation instrument intended for platelet aggregation and ristocetin cofactor	four-channel manual analyzer, QC program onboard, singles or duplicates	QC program onboard, curve storage, suitable for office lab or as backup analyzer

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

Coagulation analyzers

Part 7 of 10 *See* captodayonline.com/productguides *for an interactive version of guide*	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road, Bedford, MA 01730 800-955-9525 www.ilus.com	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road, Bedford, MA 01730 800-955-9525 www.ilus.com	Instrumentation Laboratory Venita Shirley vshirley@ilww.com 180 Hartwell Road, Bedford, MA 01730 800-955-9525 www.ilus.com
Instrument name/First year sold	ACL TOP 700 Series/2004	ACL TOP 500 CTS/2008	ACL TOP 300 CTS/2012
Number of units installed in U.S./Outside U.S.	4,000+/8,000+ (all ACL models combined)	4,000+/8,000+ (all ACL models combined)	4,000+/8,000+ (all ACL models combined)
Number of contracts signed between 1/1/13 and 11/30/13	32	228	128
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Operational type	continuous 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	racks, continuous loading of primary tubes	racks, continuous loading of primary tubes	racks, continuous loading of primary tubes
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	29 × 60 × 35/331 lbs/21 square feet	29 × 43 × 35 inches/312 lbs/14 square feet	29 × 32 × 33 inches/200 lbs/8 square feet
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVVT), APCR-V, protein C/S, FVIII (with VWF)	PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVVT), APCR-V, protein C/S, FVIII (with VWF)	PT, APTT, fibrinogen, TT, factors, FVIII (with VWF)
FDA-cleared chromogenic tests	Anti-Xa, protein C, AT, plasminogen, plasmin inhibitor	Anti-Xa, protein C, AT, plasminogen, plasmin inhibitor	Anti-Xa, AT
FDA-cleared immunologic tests	D-Dimer, D-Dimer HS, 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	D-Dimer, D-Dimer HS
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	VWF (RCo), HIT, global protein C pathway	VWF (RCo), HIT, global protein C pathway	VWF (RCo), HIT, global protein C pathway
Methodologies supported	LED optical detection: clotting, chromogenic, and immunologic	LED optical detection: clotting, chromogenic, and immunologic	LED optical detection: clotting, chromogenic, and 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	500	500
Number of different assays programmed and calib. at one time	500	500	500
Number of user-definable (open) channels	250	250	250
Of those defined, number active simultaneously	30	30	30
Factor assays require manual manipulation or dilutions	no	no	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	60/varies by assay/yes	40/varies by assay/yes	24/varies by assay/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	120/800	80/800	40/800
Minimum sample volume aspirated precisely at one time	4 µL	4 µL	4 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/25 µL	50 µL/25 µL	50 µL/—
Disposables used/Price of each	cuvettes/varies	cuvettes/varies	cuvettes/varies
Supports direct-from-track sampling	yes (model available)	no	no
Primary tube sampling supported/Pierces caps on primary tubes	yes/yes (optional)	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	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	no	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
• Incubation 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	not needed	not needed	not needed
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	<3 minutes/360 specimens	<3 minutes/240 specimens	<3 minutes/110 specimens
• PT, PTT	<6 minutes/165 specimens	<6 minutes/90 specimens	<6 minutes/55 specimens
• Fibrinogen	<3 minutes/108 specimens	<3 minutes/78 specimens	<6 minutes/60 specimens
• Factor VIII activity assay	8 minutes/100 specimens	8 minutes/77 specimens	<11 minutes/38 specimens
Time delay from ordering stat to aspiration of sample	0 seconds	0 seconds	0 seconds
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	yes	no	no
Modem servicing	in development	in development	in development
Time required for maintenance by lab personnel	daily: <10 minutes; weekly: 10 minutes; monthly: none	daily: <10 minutes; weekly: 10 minutes; monthly: none	daily: <10 minutes; weekly: 10 minutes; monthly: none
Onboard maintenance records	yes	yes	yes
Training provided with purchase	4 days at vendor offices	4 days at vendor offices	4 days at vendor offices
Approximate number of training hours needed per tech	24–40	24–40	24–40
List price	—	—	—
Annual service contract cost (24/7)/Warranty with purchase	—/1 year	—/1 year	—/1 year
Distinguishing features (supplied by company)	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 Anti-Xa with universal calibration curve for UFH and LMWH	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 Anti-Xa with universal calibration curve for UFH and LMWH	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 Anti-Xa 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.

Coagulation analyzers

Part 8 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**Instrumentation Laboratory** **Venita Shirley** vshirley@ilww.com **180 Hartwell Road** **Bedford, MA 01730** **800-955-9525** www.ilus.com	**Instrumentation Laboratory** **Venita Shirley** vshirley@ilww.com **180 Hartwell Road** **Bedford, MA 01730** **800-955-9525** www.ilus.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	**ACL ELITE Series/2006**	**ACL AcuStar/2010**	**CoaLAB 1000/2009**
Number of units installed in U.S./Outside U.S.	4,000+/8,000+ (all ACL models combined)	4,000+/8,000+ (all ACL models combined)	—/300
Number of contracts signed between 1/1/13 and 11/30/13	83	3	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	Germany/Germany
Operational type	modified random access	random access	batch, random access
Reagent type	open reagent system	multi-use reagent cartridges-liquid	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	tray, primary tubes	rack	two fixed racks of 11 samples each plus 3 stat
Model type	benchtop	benchtop	benchtop
Dimensions (H × W × D)/Weight/Instrument footprint	24 × 37 × 24 inches/139 lbs/6 square feet	21 × 34 × 24 inches/170 lbs/15 square feet	78 × 58 × 50 cm/30 kg/—
FDA-cleared clotting-based tests	PT, APTT, fibrinogen, TT, factors	—	—
FDA-cleared chromogenic tests	Anti-Xa	—	—
FDA-cleared immunologic tests	D-dimer, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine	anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM	—
Other FDA-cleared tests	—	—	—
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted	—	VWF (RCo), VWF (Ag.), HIT IgG, HIT total ab	—
Methodologies supported	clot detection, LED optical (nephelometric), chromogenic, immunologic	immunologic (chemiluminescent)	optical (LED), turbidimetric for clot detection, immunologic, chromogenic and aggregation tests
Operator must load sep. reagent pack per specimen/Test run	no/no	no/no	no/no
Number of different measured assays onboard simultaneously	22	20	15 maximum
Number of different assays programmed and calib. at one time	300	20	50
Number of user-definable (open) channels	100	0	2
Of those defined, number active simultaneously	20	—	2
Factor assays require manual manipulation or dilutions	no	—	no
Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard	22/varies by test/yes	20/varies by assay/yes (4°C)	15/200 maximum/no
Multiple reagent configurations supported	yes	no	yes
Reagents, consumables loaded without interrupting testing	yes	no	no
Same capabilities when third-party reagent used	yes	no	yes
Maximum time same lot number of reagents can be used	18 months	—	1 year
Walkaway capacity: Number of specimens/Number of tests	40/260	30/280	25 maximum/>10
Minimum sample volume aspirated precisely at one time	5 µL	—	2 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	60 µL/18 µL	—	PT: 100µl reagent, 50µL sample; APTT: 50µL reagent, 50µL sample, 50µL CACl2/Factor VIII: 50µL APTT, 50µL deficient plasma, 50µl sample, 50µL CACl2
Disposables used/Price of each	cuvettes/varies	cuvettes/varies	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	yes/no	yes/no	yes (1.7–4 mL)/no
Sample bar-code reading capability	yes	yes	yes
Reagent bar-code reading capability	yes	yes	no
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	yes	yes
Auto. detects adequate reagents for aspiration and analysis	yes	yes	yes
Hemolysis/Turbidity detection-quantitation	no/no	no/no	no/yes
Dilution of patient samples onboard	yes	yes	yes
Automatic rerun capability/Auto reflex testing capability	yes/yes	yes/yes	yes/no
Lag time during which hypercoagulable sample not detected	yes (PT and PTT: 3 seconds)	—	yes (PT: <10 seconds; PTT: <20 seconds)
Read time extended for prolonged clotting times	yes	—	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
• Incubation times/Reading times	yes/yes	no/no	yes/yes
Autocalib. or autocalib. alert/Multipoint calib. supported	no/yes	yes/yes	yes/yes
Auto shutdown/Auto startup programmable	not needed	not needed	no/no
Stat time to complete all analytes/Throughput per hour for:			
• PT alone	4 minutes/175 specimens	—	<2 minutes/108
• PT, PTT	8 minutes/270 specimens	—	<5 minutes/60
• Fibrinogen	4 minutes/175 specimens	—	<5 minutes/90
• Factor VIII activity assay	8 minutes/125 specimens	—	depends on assay
Time delay from ordering stat to aspiration of sample	15 seconds	<1 minute	3 minutes
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	yes	onboard (includes QC: L-J plots and Westgard Multirules)	onboard (includes QC: L-J plots and Westgard Multirules)
Interface supplied by instrument vendor	no	no	yes (included)
Interfaces in active user sites for:	most major vendors	—	via LAN, Windows OS, Linux OS
Bidirectional interface capability	yes (broadcast download and 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	no	no
Modem servicing	no	no	no
Time required for maintenance by lab personnel	daily: <5 minutes; weekly: 10 minutes; monthly: 5 minutes	daily: 5 minutes; weekly: 5 minutes	per shift: <1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: calibration 15 minutes
Onboard maintenance records	yes	no	no
Training provided with purchase	4 days at vendor offices	—	3 days at vendor offices, on site on request
Approximate number of training hours needed per tech	24	6 on site	—
List price	—	—	—
Annual service contract cost (24/7)/Warranty with purchase	various options available/1 year	—	—/1 year
Distinguishing features (supplied by company)	test menu featuring D-Dimer; barcoded reagent management; ACL family harmonization; HemosIL INR plasma sets for INR test system validation or calibration, or both; HemosIL liquid Anti-Xa with universal calibration curve for UFH and LMWH	easy to use, uses sensitive chemiluminescent technology, throughput of 60 tests per hour (<30 minutes to first test result); reagent cartridges stable up to 12 weeks onboard; reagents are precalibrated; replaces the need to run manual, time-consuming ELISA assays	standalone device, requires no additional PC-monitor to control, onboard software, 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

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Coagulation analyzers

Part 9 of 10 *See* captodayonline.com/productguides ***for an interactive version of guide***	**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 **511 Benedict Ave.** **Tarrytown, NY 10591** **847-267-5383** www.siemens.com/diagnostics	**Siemens Healthcare Diagnostics** **Jackie Hauser** jacqueline.k.hauser@siemens.com **511 Benedict Ave.** **Tarrytown, NY 10591** **847-267-5383** www.siemens.com/diagnostics
Instrument name/First year sold	**CoaData 2004 and 4004/—**	**Sysmex CA-600 systems/2012**	**BFT II/1999**
Number of units installed in U.S./Outside U.S.	—/>500	—	—
Number of contracts signed between 1/1/13 and 11/30/13	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Japan/Japan	Germany/Germany
Operational type	discrete	continuous random access	batch
Reagent type	open reagent system	open reagent system (reconstituted manually)	open reagent system (reconstituted manually)
Operates on whole blood or spun plasma	spun plasma	spun plasma	spun plasma
Sample handling system	semiautomated manual pipette-auto start	10-tube position sample rack	manual
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	22.5 × 19.5 × 19.5 inches/~94.6 lbs/~3.05 square feet	3.9 × 7.9 × 11.8 inches/8.4 lbs/0.65 square feet
FDA-cleared clotting-based tests	—	PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays	PT, APTT, fibrinogen
FDA-cleared chromogenic tests	—	Innovance AT, Berichrom AT, protein C chromo, heparin	—
FDA-cleared immunologic tests	—	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	—	—	—
Methodologies supported	clot detection, optical; turbodensitometric	clot detection, optical; turbidimetric; chromogenic; immunologic	turbodensitometric
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	3	7	3
Number of user-definable (open) channels	—	7	—
Of those defined, number active simultaneously	1	5	1
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	11/varies, up to 200/yes (15°C)	4/up to 200/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	yes	yes
Maximum time same lot number of reagents can be used	reagent manufacturer defined	12 months	12 months
Walkaway capacity: Number of specimens/Number of tests	18 incubational positions/2	10/50	1/1
Minimum sample volume aspirated precisely at one time	50 µL (150 µL total volume)	5 µL	50 µL
Standard specimen volume required to run PT or PTT/Factor VIII activity	50 µL/—	50 µL/5 µL	50 µL/—
Disposables used/Price of each	micro single cuvette, printer paper/—	reaction tubes, CA-clean I, CA-clean II, thermal paper/varies with volume	cuvettes, printer paper/varies with volume
Supports direct-from-track sampling	no	no	no
Primary tube sampling supported/Pierces caps on primary tubes	no/no	yes (2.7–5.0 mL)/no	no/no
Sample bar-code reading capability	no	yes	no
Reagent bar-code reading capability	no	no	no
Onboard test automatic inventory	no	yes	no
Measures No. of tests remaining/Short sample detection	no/no	yes/yes	no/no
Clot detection as preanalytical variable in plasma sample	no	no	no
Auto. detects adequate reagents for aspiration and analysis	no	yes	no
Hemolysis/Turbidity detection-quantitation	no/no	no/yes	no/no
Dilution of patient samples onboard	no	yes	no
Automatic rerun capability/Auto reflex testing capability	no/no	no/no	no/no
Lag time during which hypercoagulable sample not detected	no	yes (PT: <7 seconds, PTT: <15 seconds)	yes (PT: 5 seconds, APTT: 15 seconds)
Read time extended for prolonged clotting times	yes, selectable on operator menus	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
• Incubation 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/60 results	1 minute/—, manual
• PT, PTT	—	8 minutes/48 results	<5 minutes/—, manual
• Fibrinogen	—	7 minutes/60 results	<1 minute/—, manual
• Factor VIII activity assay	—	—	—
Time delay from ordering stat to aspiration of sample	—	2 minutes	—
Automatic transfer of QC results to LIS	no	yes	no
Data-management capability	no	onboard (includes QC: L-J plots)	no
Interface supplied by instrument vendor	no	no	—
Interfaces in active user sites for:	no	all major LIS vendors	—
Bidirectional interface capability	no	yes (host query)	no
Results transferred to LIS as soon as test time complete	no	yes	no
LOINC codes transmitted with all results	no	no	no
How labs get LOINC codes for reagent kits	—	upon request	upon request
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 (cleaning housing); daily: <1 minute (cleaning housing); weekly: <5 minutes (cleaning housing and incubating block)	daily: <10 minutes; quarterly: <5 minutes	daily: 1 minute
Onboard maintenance records	no	no	no
Training provided with purchase	1 day, on request	2 days on site, personalized education plan online training	quick reference guide
Approximate number of training hours needed per tech	4	2	2
List price	—	CA-620: $42,000; CA-660: $55,000	$8,685
Annual service contract cost (24/7)/Warranty with purchase	12 months	—	—
Distinguishing features (supplied by company)	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	maximizes counter space with compact footprint in low-volume labs; increases uptime and reduces service expenses; two models to meet individual laboratory needs: CA-620 system for routine clotting-based testing, CA-660 system for clotting, chromogenic, and immunologic testing needs	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; effective for low-volume testing, backup to larger systems

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Coagulation analyzers

Part 10 of 10 *See* captodayonline.com/productguides *for an interactive version of guide*	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 847-267-5383 www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Jackie Hauser jacqueline.k.hauser@siemens.com 511 Benedict Ave. Tarrytown, NY 10591 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 1/1/13 and 11/30/13	—	—	—
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/8.5 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	Innovance D-dimer	Innovance D-dimer	Innovance D-dimer
Other FDA-cleared tests	—	—	BC VWF-ristocetin cofactor assay (agglutination of fixed platelets)
User-defined tests in clinical use	—	—	—
Tests submitted for 510(k) clearance	—	—	—
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/up to 200/yes (15°C)	90/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	1 year	1 year	1 year
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/5 µL	50 µL/5 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	no/yes	no/yes	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
• Incubation 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, ~>5 minutes
Automatic transfer of QC results to LIS	yes	yes	yes
Data-management capability	onboard (includes QC: L-J plots and Westgard Multirules)	onboard (includes QC: L-J plots and Westgard Multirules)	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, personalized education plan online training course	3 days at vendor offices for 2 key operators, personalized education plan online training course	3 days at vendor offices for 2 key operators, personalized education plan 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	—	—	—
Distinguishing features (supplied by company) *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