Coagulation analyzers (point of care, self-monitoring)

For home or POC use, a variety of options

Anne Ford

Something about springtime impels everyone to clean, organize, and consolidate. To wit: HemoSense's redesigned, streamlined test strip package for its INRatio PT/INR monitoring system. "A new packaging design will be introduced mid-2006," says David Phillips, vice president of marketing. "The reduced test strip box size will allow easier storage, handling, and convenience." Another change in the name of efficiency is the system's recently modified test strip dosing area, which, Phillips says, "provides increased visibility for users applying the test sample." Many of the other vendors in this month's instrumentation survey, which features point-of-care and self-monitoring coagulation analyzers, echo these sentiments of efficiency.

Roche's CoaguChek System family of analyzers, says Randy Pritchard, manager of segment marketing for near-patient testing, "offers the fastest test time and lowest sample size available to the patient and professional markets." Recently added to the CoaguChek ranks in Europe is the CoaguChek XS; "we are actively working to make it available to the U.S. market," Pritchard says.

International Technidyne Corp. has scheduled the release of a new ProTime instrument for this spring. The product "has a new design along with several key software enhancements," says marketing manager Kathy Kornafel. "Several of these new features benefit the professional as well as the patient self-tester." Features include the ability to autosend results to a printer or computer; the new ProTime also accepts and stores patient and operator IDs. Kornafel says that the new ProTime is designed to enhance user ease and convenience, increase results-reporting efficiency, and reduce transcription errors.

She adds that the patient self-testing market is trending toward small instruments that are easy to use, require a small sample size, and provide quick results. "Not to forget low cost!" she adds. "I believe the glucose monitors have set the standard, and people expect Coumadin monitors to follow."

Meanwhile, Instrumentation Laboratory continues to offer its Gem PCL Plus Coagulation Laboratory, a portable, whole-blood system that can be used in point-of-care settings and in tandem with the company's Gem Premier 3000 analyzer in the laboratory. The company calls the PCL Plus easy to use and maintenance-free, adding that the system offers fully automated sample measuring and mixing and is designed to handle fresh or citrated whole-blood samples.

CAP TODAY's survey of point-of-care and self-monitoring coagulation analyzers includes products from the manufacturers cited above and from Abbott Point of Care, Helena Point of Care, and Medtronic Cardiac Surgery. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.

Anne Ford is a writer in Chicago.

Part 1 of 5	Abbott Point of Care Michael A. Saperstein michael.saperstein@i-stat.com Marketing Communications 104 Windsor Center Drive East Windsor, NJ 08520 609-469-0342
Instrument name	i-STAT 1
First year sold	2000
No. of units sold in U.S./Outside U.S.	4,000/2,900
No. of units sold in 2005	—
• units sold to:	—
Country where analyzer designed/Manufactured	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC
Specimen type	fingerstick, venipuncture (whole blood, anticoagulated whole blood)
Model type	handheld/portable
Dimensions in inches (H x W x D)/Weight	9.25 x 3.03 x 2.85/18.34 oz
Specimen volume needs	accurate volume required (fill line on cuvette)
Clotting-based tests for which device has FDA-cleared applications	PT/INR, Celite ACT, Kaolin ACT
Tests using other methodologies for which device has FDA-cleared applications	blood gases, electrolytes, chemistry, immunoassay (troponin), chem 8+
FDA-cleared tests but not yet clinically released	CK-MB
Tests submitted for 510(k) clearance	—
Tests in development but not yet submitted for clearance	BNP
Method of endpoint detection	electrogenic
Quality control methods	
• Electronic	yes
• Liquid	yes
• Lyophilized	yes
• Integrated QC with each analysis	yes
• Automatic lockout for QC failure	yes
• Other	—
Time (in minutes) to perform control plus specimen test	
• PT:	2 min
• PT & PTT:	—
• ACT:	2 min+
Data management capability	onboard & optional add-on (SW mftr: i-STAT)
Includes QC	yes
System can automatically transfer data to information system	
• Patient data	yes
• QC data	yes
Interface supplied by instrument vendor	yes (additional cost)
LOINC codes transmitted with results	yes
How labs get LOINC codes for reagent kit	package insert
Commercially available systems for which interfaces are up and running in active user sites	Cerner, Misys, McKesson, Citation, Meditech, others
Lab can control analyzer remotely	yes
Real-time wireless linkage to LIS or HIS	yes (infrared)
Positive identification system (e.g. bar code) for:	
• Patient specimen	yes
• Reagent	yes
Onboard system for automatic error detection	yes, for sample (volume), reagent/cartridge error
Training provided with instrument purchase	yes (on site)
Approx. No. of training hours needed for:	
• Medical staff	1 hr
• Patient	n/a
Patient self-testing program is available	no
Instrument list price	$6,000
Reagent rental or lease only	yes
Cost per sample for:	
• PT: Cost per sample for reagent rental	n/a
Cost per sample if device purchased	n/a
• PTT: Cost per sample for reagent rental	n/a
Cost per sample if device purchased	n/a
• ACT: Cost per sample for reagent rental	call for pricing
Cost per sample if device purchased	call for pricing
CLIA '88 complexity rating	moderate
Unique advantages (provided by the vendor)	• handheld portable device • QC lockout/operator lockout • menu: blood gas, chemistry, electrolytes, coagulation, immunoassay • bar-code scanner • downloader/recharger

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

Coagulation analyzers (point of care, self-monitoring)

Part 2 of 5

	Abbott Point of Care Michael A. Saperstein michael.saperstein@i-stat.com Marketing Communications 104 Windsor Center Drive East Windsor, NJ 08520 609-469-0342	Helena Point of Care Jim Campbell pointofcare@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Point of Care Jim Campbell pointofcare@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com
Instrument name	i-STAT	Actalyke XL	Actalyke Mini II
First year sold	1992	2002	2004
No. of units sold in U.S./Outside U.S.	—	200+/100+	75+/650+
No. of units sold in 2005	—	150+	250+
• units sold to:	—	operating room-40; cardiac cath lab-45; stat lab-15; NICU-15	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	fingerstick, venipuncture (whole blood, anticoagulated whole blood)	venipuncture (whole blood)	venipuncture (whole blood)
Model type	handheld/portable	portable	benchtop
Dimensions in inches (H x W x D)/Weight	8.25 x 2.52 x 2.05/18.34 oz	5.6 x 10.7 x 10.3/15 lb	6.25 x 6 x 5/6.3 lb
Specimen volume needs	accurate volume required (fill line on cartridge)	accurate volume required (fill line on cuvette)	accurate volume required (fill line on cuvette)
Clotting-based tests for which device has FDA-cleared applications	PT/INR, Celite ACT, Kaolin ACT	activated clotting time (ACT)–whole blood, MAX-ACT: maximum factor XII activation ACT, celite, kaolin, glass	ACT—MAX-ACT, C-ACT, K-ACT, G-ACT
Tests using other methodologies for which device has FDA-cleared applications	blood gases, electrolytes, chemistry	—	—
FDA-cleared tests but not yet clinically released	none	none	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	APTT	APTT (whole blood), PT (whole blood), LMWH, heparin & protamine titration (AMK)	LMWH, APTT (whole blood), PT (whole blood), AMK
Method of endpoint detection	electrogenic	two-point electromechanical soft-clot detection principle	two-point electromechanical
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes	yes (simulated whole blood)	yes (simulated whole blood)
• Lyophilized	yes	yes (simulated whole blood)	yes (simulated whole blood)
• Integrated QC with each analysis	yes	no	no
• Automatic lockout for QC failure	yes	yes	no
• Other	n/a	data management for entering heparin dose, L-J chart generation for all controls	—
Time (in minutes) to perform control plus specimen test			
• PT:	2 min	n/a	n/a
• PT & PTT:	—	n/a	n/a
• ACT:	2 min+	5	5
Data management capability	onboard & optional add-on (SW mftr: i-STAT)	yes	no
Includes QC	yes (L-J plots)	yes	yes (L-J charts by level/well)
System can automatically transfer data to information system			
• Patient data	yes	yes	—
• QC data	yes	yes	—
Interface supplied by instrument vendor	yes (additional cost)	interface specifications supplied, POCT1-A compliant	—
LOINC codes transmitted with results	—	no	no
How labs get LOINC codes for reagent kit	—	n/a	n/a
Commercially available systems for which interfaces are up and running in active user sites	Cerner, Misys, McKesson, Citation, Meditech, others	n/a	—
Lab can control analyzer remotely	yes	no	no
Real-time wireless linkage to LIS or HIS	yes (infrared)	yes	—
Positive identification system (e.g. bar code) for:			
• Patient specimen	yes	yes	no
• Reagent	yes	yes; all disposables have bar code for identification with use on any Actalyke model	no
Onboard system for automatic error detection	yes, for sample (volume), reagent/cartridge error	yes, stuck magnet, no tube; mechanical instrument parameters only; well rotation, temperature, and detection settings	yes, for stuck magnet, printer problems
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	—	1–2 hr	1 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	no
Instrument list price	$5,000	$3,595	$1,095 (battery only)–$1,249 (with printer and battery)
Reagent rental or lease only	yes	purchase, lease, or reagent rental	purchase, lease, or reagent rental
Cost per sample for:			
• PT: Cost per sample for reagent rental	n/a	n/a	—
Cost per sample if device purchased	n/a	n/a	—
• PTT: Cost per sample for reagent rental	n/a	n/a	—
Cost per sample if device purchased	n/a	n/a	—
• ACT: Cost per sample for reagent rental	call for pricing	n/a	—
Cost per sample if device purchased	call for pricing	$0.74–$1.76	$0.74–$1.76
CLIA '88 complexity rating	moderate	moderate	moderate
Unique advantages (provided by the vendor)	• handheld • QC lockout/operator lockout	• two-point electromechanical "soft-clot" detection principle • MAX-ACT: maximum factor XII activation ACT test, 0.5 mL blood volume, linear up to 10 units of heparin, safer plastic tube construction, for use on Actalyke and Hemochron instruments • electronic clotting tube (EQC) that simulates and mimics actual blood clot formation for accurate EQC challenges • integrated printer • 3.5-in diskette storage	• two-point electromechanical "soft-clot" detection • magnetic detection device—electronic QC/revolution • MAX-ACT tubes, 0.5 mL volume and linear to 6 U/mL • linear up to 6 U/mL of heparin

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

Coagulation analyzers (point of care, self-monitoring)

Part 3 of 5	HemoSense Inc. David Phillips 651 River Oaks Parkway San Jose, CA 95134 408-719-1393 www.hemosense.com	Instrumentation Laboratory Elizabeth Walsh ewalsh@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4165 www.ilus.com	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com
Instrument name	INRatio PT/INR	Gem PCL Plus (Portable Coagulation Laboratory)	ProTime Microcoagulation System
First year sold	2003	2003	ProTime Micro: 1995; ProTime 3: 2001; New ProTime: 2006
No. of units sold in U.S./Outside U.S.	n/a/n/a	—/—	—/—
No. of units sold in 2005	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC and self-monitoring analyzer	POC	POC
Specimen type	fingerstick	fresh whole blood, citrated whole blood (fingerstick for PT)	fingerstick
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	6.125 x 3 x 2.2 in/8.1 oz	5.5 x 2 x 3.5/0.75 lb	2.7 x 4.5 x 8.5/3 lb
Specimen volume needs	accurate volume not necessary (drop) ~15 µL	accurate volume not necessary (~50 µL), low sample volume error message if well not filled	small blood sample volume needed, ~25 µL
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5)	PT and citrate PT (reportable range: 10–150 sec; INR: 0.8–12), APTT (reportable range: 20–300 sec), ACT (65–1,005 sec), ACT–low range (67–400 sec)	PT (reportable range: low 10 sec, high 130 sec; INR: low 0.8, high 9.9)
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	none	none	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted for clearance	none	none	—
Method of endpoint detection	electrochemical detection, change in impedance as sample clots	mechanical endpoint clotting mechanism, monitored optically	mechanical clot detection
Quality control methods			
• Electronic	no (not required, built-in 2-level QC on each strip)	yes	no (not required, onboard QC)
• Liquid	no (not required, built-in 2-level QC on each strip)	yes (simulated whole blood)	yes (available as an option but not required due to onboard controls)
• Lyophilized	no	yes	no
• Integrated QC with each analysis	yes	no	yes
• Automatic lockout for QC failure	yes	yes	yes
• Other	—	n/a	2 levels of onboard QC integrated into each cuvette
Time (in minutes) to perform control plus specimen test			
• PT:	<2	2	<5
• PT & PTT:	—	2	n/a
• ACT:	—	1–5	n/a
Data management capability	optional add-on (CoagClinic from Standing Stone)	onboard (via Gem Premier 3000)	yes
Includes QC	no	yes	yes (onboard controls)
System can automatically transfer data to information system			
• Patient data	yes	yes	yes
• QC data	yes	yes	yes
Interface supplied by instrument vendor	no	n/a	communication cable available
LOINC codes transmitted with results	—	no	—
How labs get LOINC codes for reagent kit	n/a	n/a	—
Commercially available systems for which interfaces are up and running in active user sites	CoagClinic from Standing Stone; PPM from QAS	n/a	n/a
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	no
• Reagent	no	yes	yes
Onboard system for automatic error detection	yes, for sample (volume), reagent stability	yes, for sample (volume), reagent, and instrument	yes, for sample (volume) and reagent/cuvette expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	1 hr	0.5 hr	1 hr
• Patient	1 hr	n/a	1.5 hr
Patient self-testing program is available	yes	no	yes (training CD/Web-based training)
Instrument list price	$1,595 professional; $1,995 self-test	$5,329 (volume dependent)	$1,699 professional, $2,350 consumer
Reagent rental or lease only	no	outright purchase, lease, reagent rental	yes
Cost per sample for:			
• PT: Cost per sample for reagent rental	n/a	varies with volume	volume dependent
Cost per sample if device purchased	$5.50 per strip professional; $10 per self-test	varies with volume	volume dependent
• PTT: Cost per sample for reagent rental	n/a	varies with volume	n/a
Cost per sample if device purchased	n/a	varies with volume	n/a
• ACT: Cost per sample for reagent rental	n/a	varies with volume	n/a
Cost per sample if device purchased	n/a	varies with volume	n/a
CLIA '88 complexity rating	waived	non-waived	waived
Unique advantages (provided by the vendor)	• onboard QC—2 levels of quantitative controls with results • very simple test procedure • human recombinant thromboplastin (ISI 1.0) • non-refrigerated test strips	• Gem PCL Plus can be used in conjunction with the Gem Premier 3000; consolidating BG/lytes/glu/lac/Hct testing • comprehensive POC coagulation menu that allows for POC coagulation analysis throughout an institution; whole blood PT, citrate PT, APTT, ACT, and ACT-low range • onboard data management • mandatory operator ID and patient ID options	• 2 levels of integral reagent control automatically run with each patient • internal instrument checks verify optical, electrical, and mechanical functions—no further calibration required • sensitive thromboplastin reagent (ISI = 1.0), as recommended by AHA, CAP, and WHO • results in less than 5 min • 16-hour room temperature open pouch stability of cuvette • bar-coded cuvette—no coding neccessary • accepts and stores patient ID/operator ID • automatically sends test results to printer, computer, LIS • both onboard and external controls available

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

SURVEY OF INSTRUMENTS

Coagulation analyzers (point of care, self-monitoring)

Part 4 of 5	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com
Instrument name	HEMOCHRON Jr.—Signature/Signature+	HEMOCHRON Response	HEMOCHRON Signature Elite
First year sold	1998; Signature+ introduced in 2002	2000	2005
No. of units sold in U.S./Outside U.S.	—/—	—/—	—/—
No. of units sold in 2005	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	venipuncture, fingerstick, fresh whole blood, citrated blood	venipuncture, fingerstick, fresh whole blood, citrated blood	venipuncture, fingerstick, fresh whole blood, citrated blood
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	2 x 7.5 x 3.75/12 oz	8.7 x 10.5 x 7.5/6.4 lb	2 x 7.5 x 3.7/1.2 lb
Specimen volume needs	accurate volume needed (fill line in cuvette sample well)	accurate volume required (fill line on tubes)	accurate volume needed (fill line in cuvette sample well)
Clotting-based tests for which device has FDA-cleared applications	PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR	ACT, (FTCA510, KACT, P214), HITT, TT, fib, HRT, KHRT, PRT, KPRT, PDA0, PDA0K, PT, APTT, PT citrated, APTT citrated	PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	none	none	none
Tests submitted for 510(k) clearance	—	none	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	optical detection of clot	mechanical clot detection	optical detection of clot
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes (simulated whole blood)	yes (simulated whole blood)	yes (simulated whole blood)
• Lyophilized	yes (simulated whole blood)	yes (simulated whole blood)	yes (simulated whole blood)
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	Signature, no; Signature+, yes	yes	yes
• Other	operator lockout	operator lockout	operator lockout
Time (in minutes) to perform control plus specimen test			
• PT:	2	2	2
• PT & PTT:	2	2	2
• ACT:	1–5	1–5	1–5
Data management capability	onboard	onboard	onboard
Includes QC	yes	yes	yes
System can automatically transfer data to information system			
• Patient data	yes	yes	yes
• QC data	yes	yes	yes
Interface supplied by instrument vendor	yes	yes	yes
LOINC codes transmitted with results	—	—	—
How labs get LOINC codes for reagent kit	—	—	—
Commercially available systems for which interfaces are up and running in active user sites	yes	yes	yes
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	no
• Reagent	yes	yes	yes
Onboard system for automatic error detection	yes, for sample (volume)	yes, for sample (volume) and reagent/expiration date	yes, for sample (volume) and reagent/expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	1 hr	1–2 hr	1 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	no
Instrument list price	Signature, $3,825; Signature+, $5,100	$4,055	$7,900
Reagent rental or lease only	no	no	no
Cost per sample for:			
• PT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	—	—	—
• PTT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	—	—	—
• ACT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	—	—	—
CLIA '88 complexity rating	moderate	moderate	moderate
Unique advantages (provided by the vendor)	• blood volume—15 µL • ease of use • data management storage and printing • connectivity options • configurable QC and operator lockout for Signature+	• QC lockout • data storage and management • connectivity options • RxDx heparin/protamine dosing system	• new compliance technology • QC lockout • data management storage and printing • connectivity options • blood volume—15 µL • ease of use • configurable QC and operator lockout

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

Coagulation analyzers (point of care, self-monitoring)

Part 5 of 5	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com	Roche Diagnostics Corp. Point of Care 9115 Hague Rd., Bldg. H Indianapolis, IN 46250 800-852-8766 www.roche.com
Instrument name	HMS Plus	ACT Plus	CoaguChek S System for Prothrombin Time Testing (professional use)
First year sold	1999	2003	2001
No. of units sold in U.S./Outside U.S.	—/—	—/—	30,000/100,000
No. of units sold in 2005	89	336	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.	Germany/Germany
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	venipuncture (whole blood)	venipuncture (whole blood)	fresh whole blood (venous or fingerstick capillary)
Model type	benchtop	benchtop	handheld/portable
Dimensions in inches (H x W x D)/Weight	15.7 x 15 x 13/34 lb	11 x 8 x 13/11.5 lb	1.8 x 4.9 x 6.8/1.0 lb
Specimen volume needs	accurate volume required (automated dispensing)	accurate volume required (fill line on cuvette and optional easy fill accessory)	accurate volume not necessary (drop), minimum 10 µL
Clotting-based tests for which device has FDA-cleared applications	ACT, heparin dose response, heparin protamine titration	ACT (high range, low range, recalcified, high range heparinase)	PT (reportable range: low 9.6 sec, high 33.9 sec; INR: low 0.6, high 8.0)
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	—	—	none
Tests submitted for 510(k) clearance	—	—	none
Tests in development but not yet submitted for clearance	—	—	none
Method of endpoint detection	mechanical clot detection	mechanical clot detection	iron particles mixed with the sample move in magnetic fields; reflectance photometry detects change in particle movement with clot formation
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	no	no	yes
• Lyophilized	yes	yes	no
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	optional (user defined)	optional (user defined)	no
• Other	—	—	n/a
Time (in minutes) to perform control plus specimen test			
• PT:	n/a	—	1 min for either test or QC result; QC not required with every sample
• PT & PTT:	n/a	—	n/a
• ACT:	up to 12 (depending on patient sample)	up to 12 min (depends on patient sample)	n/a
Data management capability	yes	yes	yes, external software programs
Includes QC	yes	yes	no
System can automatically transfer data to information system			
• Patient data	yes	yes	yes
• QC data	yes	yes	yes
Interface supplied by instrument vendor	no	no	software vendor
LOINC codes transmitted with results	—	—	n/a
How labs get LOINC codes for reagent kit	Web site	Web site	n/a
Commercially available systems for which interfaces are up and running in active user sites	yes	connectivity applications in development	Coag Clinic from Standing Stone Inc.
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	yes	yes	no
• Reagent	yes	yes	no
Onboard system for automatic error detection	yes	yes	yes, for sample (volume) and reagent/cuvette expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	6 hr	1 hr	1 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	no
Instrument list price	$26,000	$4,200	$1,149
Reagent rental or lease only	rental and purchase available	rental and purchase available	contact Roche Diagnostics sales
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	—	contact Roche Diagnostics sales
Cost per sample if device purchased	—	—	$5
• PTT: Cost per sample for reagent rental	—	—	n/a
Cost per sample if device purchased	—	—	n/a
• ACT: Cost per sample for reagent rental	—	—	n/a
Cost per sample if device purchased	customer dependent, per contract	customer dependent, per contract	n/a
CLIA '88 complexity rating	moderate (non-waived)	moderate (non-waived)	CLIA waived for professional use
Unique advantages (provided by the vendor)	• automated sample dispensing • constant temperature control • multiple testing capability • HDR: heparin dose response • HPT: heparin protamine titration • high-range ACT • optional bar-code scanner • optional data management software	• data management software application • duplicate test results • optional bar-code scanner • optional easy filling accessory	• fast test time—results in 1 minute • small sample: 10 µL from fingerstick • automatic calibration and system checks for consistent reliability • simple one-button operation makes training easy • alliance partnerships with University of Southern Indiana: continuing education—your time, your place

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