PT/INR coverage

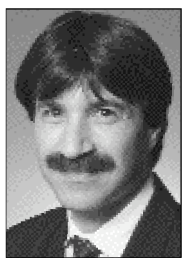
continued from page 22

for PT/INR self-testing, explaining why patients should test at home. Proponents of PT/INR self-testing may also examine why self-testing is flourishing in countries such as Germany, where more than 100,000 patients are performing PT/INR self-management.

The PST Industry Coalition is gathering data from a number of sources in an effort to determine where the true barriers to adoption of PT/INR home-monitoring lie. "We're trying to get a sense of which issues are hindering PT/INR home-monitoring, and based on that, we'll be coming up with a plan in the next few months to address the barriers," Dr. Radensky says.

The coalition hopes that the recent *Annals* study or data from The INR Study (THINRS) will help make the case for expanding coverage of PT/INR home-monitoring from only those with mechanical heart valves to all patients on warfarin anticoagulation therapy. The ongoing clinical trial, which is being conducted in more than 100 Veterans Affairs medical centers and seeks to enroll about 3,500 patients, is comparing outcomes in patient populations performing self-testing versus patient populations in which testing is performed in anticoagulation clinics. The study is not slated to end, however, for at least another year.

Although a clear strategy for removing the roadblocks to PT/INR home-monitoring has not yet emerged, Dr. Ansell and the coalition of manufacturers agree that the current reimbursement mechanism is not working. Says Dr. Radensky, "We will be meeting with CMS in the near future, and hopefully we will all be able to agree on reimbursement strategies that will encourage greater adoption of PT/INR home-monitoring." □



Dr. Radensky

Sue Parham is a writer in Edgewater, Md.

SURVEY OF INSTRUMENTS

Coagulation Analyzers

(Point of care, self-monitoring)

Part 1 of 5

See accompanying article on page 18

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**
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)**
FDA-cleared tests but not yet clinically released	**—**
Tests submitted for 510(k) clearance	**—**
Tests in development but not yet submitted for clearance	**APTT, CK-MB, BNP, Chem 8+**
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**

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Survey editor: Raymond D. Aller, MD

Coagulation Analyzers (Point of care, self-monitoring)

Part 2 of 5

See accompanying article on page 18

	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.	25,000/—	100+/100+	n/a/400+
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	—	none	—
Tests in development but not yet submitted for clearance	APTT	APTT (whole blood), PT (whole blood), heparin assay, protamine assay, therapeutic assessment kit (TAK), LMWH	LMWH, APTT (whole blood), PT (whole blood)
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	—
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 specimen placement
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

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Coagulation Analyzers (Point of care, self-monitoring)

Part 3 of 5

See accompanying article on page 18

	HemoSense Inc. Dale Clendon 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	Gem PCL Plus (Portable Coagulation Laboratory)	ProTime Microcoagulation System/ProTime 3
First year sold	cleared for professional and self-test use, 2002	2003	ProTime Micro: 1995; ProTime 3: 2001
No. of units sold in U.S./Outside U.S.	n/a/n/a	—/—	—/—
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	6.2 x 3 x 2.25 in/8.1 oz	5.5 x 2 x 3.5/0.75 lb	2.5 x 4.5 x 9/3 lb
Specimen volume needs	accurate volume not necessary (drop)	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	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	PT (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5)	none	none
Tests in development but not yet submitted for clearance	planned tests: APTT, ACT	none	—
Method of endpoint detection	change in impedance of the sample when clotting occurs	mechanical endpoint clotting mechanism, monitored optically	mechanical clot detection
Quality control methods			
• Electronic	no (not required, built-in QC on test strip)	yes	no (not required, onboard QC)
• Liquid	no (not required, built-in QC on test 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 (automatic self-check diagnosis)	no	yes
• Automatic lockout for QC failure	yes	yes	yes
• Other	impedance check strip	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:	n/a	2	n/a
• ACT:	n/a	1–5	n/a
Data management capability	onboard	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	computer cable option 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	n/a	n/a	n/a
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	planned	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 (programmed instruction/video/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	$10 per strip self-test	varies with volume	volume dependent
Cost per sample if device purchased	$5.50 per strip professional	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—no external QC needed; therefore the best value for clinician and patient • total test time <2 min • very simple test procedure • no special blood collection devices required • uses human recombinant thromboplastin • test strips can be stored at room temperature for 12 months	• 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	• two 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 • 8-hour room temperature open pouch stability of cuvette

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Coagulation Analyzers (Point of care, self-monitoring)

Part 4 of 5

See accompanying article on page 18

	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	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com
Instrument name	Hemochron Jr.—Signature/Signature+	Hemochron Response	HMS Plus
First year sold	1998; Signature+ introduced in 2002	2000	1999
No. of units sold in U.S./Outside U.S.	—/—	—/—	—/—
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)	venipuncture (whole blood, anticoagulated whole blood)	venipuncture (whole blood)
Model type	handheld/portable	handheld/portable	benchtop
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	15.7 x 15 x 13/34 lb
Specimen volume needs	accurate volume not necessary (drop)	accurate volume required (fill line on tubes)	accurate volume required (automated dispensing)
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 11.4 sec, high 129 sec; INR: low 0.8, high 12.0), PT (citrated), PTT (reportable range: low 20 sec, high 400 sec plasma equiv.), APTT (citrated), ACT low-range, ACT+	PT (reportable range: low 50 sec, high 340 sec; INR: low 1, high 6), PT (citrated), PTT (reportable range: low 24 sec, high 120 sec), APTT (citrated), ACT, (FTCA510, KACT, P214), HiTT, TT, HNTT, Fib., HRT, KHRT, PRT, KPRT, PDAO, KPDAO	ACT, heparin dose response, heparin protamine titration
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	none	none	—
Tests submitted for 510(k) clearance	none	none	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	optical detection of clot	mechanical clot detection	mechanical clot detection
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes (simulated whole blood)	yes (simulated whole blood)	no
• Lyophilized	yes (simulated whole blood)	yes (simulated whole blood)	yes
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	Signature, no; Signature+, yes	yes	optional (user defined)
• Other	operator lockout	operator lockout	—
Time (in minutes) to perform control plus specimen test			
• PT:	2	2	n/a
• PT & PTT:	2	2	n/a
• ACT:	1–5	1–5	up to 12 (depending on patient sample)
Data management capability	onboard	onboard	yes
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	no
LOINC codes transmitted with results	—	—	—
How labs get LOINC codes for reagent kit	—	—	Web site
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	yes
• Reagent	yes	yes	yes
Onboard system for automatic error detection	yes, for sample (volume)	yes, for sample volume and reagent/expiration date	yes
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	6 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	$26,000
Reagent rental or lease only	no	no	rental and purchase available
Cost per sample for:			
• PT: Cost per sample for reagent rental	n/a	n/a	—
Cost per sample if device purchased	—	—	—
• PTT: Cost per sample for reagent rental	n/a	n/a	—
Cost per sample if device purchased	—	—	—
• ACT: Cost per sample for reagent rental	n/a	n/a	—
Cost per sample if device purchased	—	—	customer dependent, per contract
CLIA '88 complexity rating	moderate	moderate	moderate (non-waived)
Unique advantages (provided by the vendor)	• blood volume—15 µL • ease of use • data management storing/printing • connectivity options • configurable QC and operator lockout for Signature+	• QC lockout • data storage and management • connectivity options • RxDx heparin/protamine dosing system	• 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

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SURVEY OF INSTRUMENTS

Coagulation Analyzers (Point of care, self-monitoring)

Part 5 of 5

See accompanying article on page 18

	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	Roche Diagnostics Corp. Point of Care 9115 Hague Rd., Bldg. H Indianapolis, IN 46250 800-852-8766 www.roche.com
Instrument name	ACT Plus	CoaguChek Pro DM System	CoaguChek S System for Prothrombin Time Testing (professional use)
First year sold	2003	1999	2001
No. of units sold in U.S./Outside U.S.	—/—	—/—	10,000/52,000
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	Germany/Germany
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	venipuncture (whole blood)	fresh whole blood (venous, arterial, or fingerstick capillary)	fresh whole blood (venous or fingerstick capillary)
Model type	benchtop	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	11 x 8 x 13/11.5 lb	8.1 x 4.5 x 2/1.5 lb	1.8 x 4.9 x 6.8/1.0 lb
Specimen volume needs	accurate volume required (fill line on cuvette and optional easy fill accessory)	accurate volume not necessary (drop), minimum of approx. 25 µL to 45 µL	accurate volume not necessary (drop), minimum 10 µL
Clotting-based tests for which device has FDA-cleared applications	ACT (high range, low range, recalcified, high range heparinase)	ACT, APTT, PT	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	none
Tests submitted for 510(k) clearance	—	none	none
Tests in development but not yet submitted for clearance	—	none	none
Method of endpoint detection	mechanical clot detection	laser photometry detects change in blood flow when clot forms	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	yes	yes
• Lyophilized	yes	yes (simulated whole blood)	no
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	optional (user defined)	yes	no
• Other	—	password protected QC lockouts by time of day, shift, or QC level	n/a
Time (in minutes) to perform control plus specimen test			
• PT:	—	within 4	1 min for either test or QC result; QC not required with every sample
• PT & PTT:	—	within 5 each	n/a
• ACT:	up to 12 min (depends on patient sample)	within 6	n/a
Data management capability	yes	onboard	yes, with Coag Clinic from Standing Stone Inc.
Includes QC	yes	yes (L-J plots and QC results report)	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	yes (via additional DataCare software)	software vendor
LOINC codes transmitted with results	—	n/a	n/a
How labs get LOINC codes for reagent kit	Web site	n/a	n/a
Commercially available systems for which interfaces are up and running in active user sites	connectivity applications in development	AccuChek HDM 3.2.1, Roche DataCare, MAS-RALS+	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, patient and operator IDs can be entered by bar-code reader	no
• Reagent	yes	yes, reagent type and expiration date contained on each test cartridge; lot-specific code key contains calibration data and expiration date	no
Onboard system for automatic error detection	yes	yes, for sample (volume), reagent expiration date, and internal monitor operation	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	1.5 hr	1 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	no
Instrument list price	$4,200	$3,795	$1,295
Reagent rental or lease only	rental and purchase available	contact Roche Diagnostics sales	contact Roche Diagnostics sales
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	usage dependent	contact Roche Diagnostics sales
Cost per sample if device purchased	—	usage dependent	$5
• PTT: Cost per sample for reagent rental	—	usage dependent	n/a
Cost per sample if device purchased	—	usage dependent	n/a
• ACT: Cost per sample for reagent rental	—	usage dependent	n/a
Cost per sample if device purchased	customer dependent, per contract	usage dependent	n/a
CLIA '88 complexity rating	moderate (non-waived)	moderate	CLIA waived for professional use
Unique advantages (provided by the vendor)	• data management software application • duplicate test results • optional bar-code scanner • optional easy filling accessory	• user-defined QC lockout, new lot lockout, and operator lockout options • can establish mandatory entry of operator IDs, patient IDs, and comment codes • monitor can interface with AccuChek HDM 3.2.1 data management software and with hospital LIS via RALS+ or DataCare software • 11 different types of reports can be directly printed from monitor	• fast results in 60 sec • small sample: 10 µL from fingerstick • automatic calibration and system checks for consistent reliability • simple one-button operation • alliance partnerships with Bristol Myers Squibb and Standing Stone for patient management software

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