Coagulation Analyzers (Point-of-care, self-monitoring)

Coagulation device makers giving users what they need

Anne Ford

If necessity is the mother of invention, desperation is its father. Ask the staff of any emergency department, in which the frequently frenzied pace is making more and more demands on point-of-care testing. "There aren't many clinicians that want to run diagnostics in their OR, CCU, ED, etc.," says Michael Corsello, Abbott point of care senior marketing manager. "Instead, many of these clinicians feel that they have to run these diagnostics to keep in pace with the throughput and therapy regimens assigned to critical patients." That puts all the more pressure on point-of-care coagulation analyzer manufacturers to offer products that, Corsello says, help the physician "aggressively manage the therapy of the patient in the unit."

The manufacturers of the point-of-care coagulation analyzers profiled in this month's instrumentation survey, on pages 35–42, aim to do just that with forthcoming or recently introduced products and features. Not to be outdone, the manufacturers of self-monitoring coagulation analyzers featured in the survey are stepping up to the plate as well.

Instrumentation Laboratory launched in November 2003 its GEM PCL Plus Coagulation Laboratory, a portable whole-blood coagulation system that can be used in point-of-care settings as a standalone system or in conjunction with IL's GEM Premier 3000 Critical Care analyzer. The GEM PCL Plus, says product manager Elizabeth Walsh, "is easy to use, maintenance-free, and offers fully automated sample measuring and mixing." The instrument's security features include a compulsory operator/patient identification function and QC lockout. Other new instruments on the market include Helena Laboratories' Actalyke XL activated clotting time test system, which features dual test wells, two-point clot detection, and battery backup for portability; and Medtronic's ACT Plus, which features a bar-code scanner and a data-management program.

Both Roche and Abbott have added or will soon add capabilities to their existing analyzers. Roche plans to launch a new PT-S test strip for use with the company's CoaguChek S analyzer. The new strip will feature simplified liquid controls, insensitivity to heparin or low-molecular-weight heparin, and an ISI of 1.0 (human recombinant tissue factor). "In addition to these new features," says Roche CoaguChek Systems manager Randy Pritchard, "it will continue to offer all the benefits of the current PT strip." Meanwhile, Abbott Point of Care has added a kaolin activated clotting time test to its point-of-care i-Stat system. Says Corsello: "Simply use the desired unitized test cartridge, add two drops of blood, and you can have the results in minutes at the patient bedside." Over the next 18 months, the company plans to expand the i-Stat's menu with parameters such as CK-MB, BNP, and APTT. New capabilities are on the horizon as well for an International Technidyne coagulation system that has onboard controls, says marketing manager Kathy Kornafel: "We anticipate continued improvements to the ProTime system in response to customer feedback in the very near future."

Several trends in POC and self-monitoring coagulation analyzers are emerging, say many manufacturers. HemoSense has been in the coag analyzer market for only a short time, notes executive vice president of sales and marketing Timothy Still, but he's learned already that onboard quality controls "are a major differentiating factor for doctors and patients." He adds, "HemoSense currently offers onboard QC with every test strip." And what about self-monitoring analyzers? International Technidyne's Kathy Kornafel sees nothing but growth in that area. "With patients taking a more active role in their health, self-monitoring at home is in demand," she says.

CAP TODAY's survey of point-of-care and self-monitoring coagulation analyzers includes products from the manufacturers listed here. 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.

SURVEY OF INSTRUMENTS

Coagulation Analyzers (Point-of-care, self-monitoring)

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**	**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
Instrument name	**i-STAT**	**i-STAT 1**	**Actalyke XL**
First year sold	**1992**	**2000**	**2002**
No. of units sold in U.S./Outside U.S.	**25,000/—**	**3,000/2,500**	**75+/50**
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**
Specimen type	**fingerstick, venipuncture (whole blood, anticoagulated whole blood)**	**fingerstick, venipuncture (whole blood, anticoagulated whole blood)**	**venipuncture (whole blood)**
Model type	**handheld/portable**	**handheld/portable**	**portable**
Dimensions in inches (H x W x D)/Weight	**8.25 x 2.52 x 2.05/18.34 oz**	**9.25 x 3.03 x 2.85/18.34 oz**	**5.6 x 10.7 x 10.3/15 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**	**PT/INR, Celite ACT, Kaolin ACT**	**activated clotting time (ACT)–whole blood, MAX-ACT: maximum factor XII activation ACT, celite, kaolin, glass**
Tests using other methodologies for which device has FDA-cleared applications	**blood gases, electrolytes, chemistry**	**blood gases, electrolytes, chemistry, immunoassay (troponin)**	**—**
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**	**APTT (whole blood), PT (whole blood), heparin assay, protamine assay, therapeutic assessment kit (TAK), LMWH**
Method of endpoint detection	**electrogenic**	**electrogenic**	**two-point electromechanical soft-clot detection principle**
Quality control methods			
• Electronic	**yes**	**yes**	**yes**
• Liquid	**yes**	**yes**	**yes (simulated whole blood)**
• Lyophilized	**no**	**no**	**yes (simulated whole blood)**
• Integrated QC with each analysis	**yes**	**yes**	**no**
• Automatic lockout for QC failure	**yes**	**yes**	**yes**
• 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**	**2 min**	**n/a**
• PT & PTT:	**—**	**—**	**n/a**
• ACT:	**2 min**	**2 min**	**5**
Data management capability	**onboard & optional add-on (SW mftr: i-STAT)**	**onboard & optional add-on (SW mftr: i-STAT)**	**yes**
Includes QC	**yes (L-J plots)**	**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 (additional cost)**	**yes (additional cost)**	**interface specifications supplied, POCT1-A compliant**
LOINC codes transmitted with results	**—**	**yes**	**no**
How labs get LOINC codes for reagent kit	**—**	**package insert**	**n/a**
Commercially available systems for which interfaces are up and running in active user sites	**Cerner, Misys, McKesson, Citation, Meditech, others**	**Cerner, Misys, McKesson, Citation, Meditech, others**	**n/a**
Lab can control analyzer remotely	**yes**	**yes**	**no**
Real-time wireless linkage to LIS or HIS	**yes (infrared)**	**yes**	**yes**
Positive identification system (e.g. bar code) for:			
• Patient specimen	**yes**	**yes**	**yes**
• Reagent	**yes**	**yes**	**yes; all disposables have bar code for identification with use on any Actalyke model**
Onboard system for automatic error detection	**yes, for sample (volume)**	**yes, for sample (volume), reagent/cuvette expiration date**	**yes, stuck magnet, no tube; mechanical instrument parameters only; well rotation, temperature, and detection settings**
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**
• Patient	**n/a**	**n/a**	**n/a**
Patient self-testing program is available	**no**	**no**	**no**
Instrument list price	**$5,000**	**$6,000**	**$3,595**
Reagent rental or lease only	**yes**	**yes**	**purchase, lease, or reagent rental**
Cost per sample for:			
• PT: Cost per sample for reagent rental	**n/a**	**n/a**	**n/a**
Cost per sample if device purchased	**n/a**	**n/a**	**n/a**
• PTT: Cost per sample for reagent rental	**n/a**	**n/a**	**n/a**
Cost per sample if device purchased	**n/a**	**n/a**	**n/a**
• ACT: Cost per sample for reagent rental	**call for pricing**	**n/a**	**n/a**
Cost per sample if device purchased	**call for pricing**	**n/a**	**$0.74–$1.76**
CLIA '88 complexity rating	**moderate**	**moderate**	**moderate**
Unique advantages (provided by the vendor)	**• handheld** **• QC lockout/operator lockout**	**• handheld portable device** **• QC lockout/operator lockout** **• menu: blood gas, chemistry, electrolytes, coagulation, immunoassay** **• bar-code scanner** **• downloader/recharger**	**• 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**

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Survey editor: Raymond D. Aller, MD

Coagulation Analyzers (Point-of-care or self-monitoring)

Part 2 of 5

See accompanying article on page 34

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Instrument name	Actalyke Mini II	INRatio	Gem PCL Plus (Portable Coagulation Laboratory)
First year sold	2004	cleared for professional and self-test use, 2002	2003
No. of units sold in U.S./Outside U.S.	n/a/400+	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	POC and self-monitoring analyzer	POC
Specimen type	venipuncture (whole blood)	fingerstick	fresh whole blood, citrated whole blood (fingerstick for PT)
Model type	benchtop	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	6.25 x 6 x 5/6.3 lb	6.2 x 3 x 2.25 in/8.1 oz	5.5 x 2 x 3.5/0.75 lb
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume not necessary (drop)	accurate volume not necessary (~50 µL), low sample volume error message if well not filled
Clotting-based tests for which device has FDA-cleared applications	ACT—MAX-ACT, C-ACT, K-ACT, G-ACT	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)
Tests using other methodologies for which device has FDA-cleared applications	—	none	none
FDA-cleared tests but not yet clinically released	—	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
Tests in development but not yet submitted for clearance	LMWH, APTT (whole blood), PT (whole blood)	planned tests: APTT, ACT	none
Method of endpoint detection	two-point electromechanical	change in impedance of the sample when clotting occurs	mechanical endpoint clotting mechanism, monitored optically
Quality control methods			
• Electronic	yes	no (not required, built-in QC on test strip)	yes
• Liquid	yes (simulated whole blood)	no (not required, built-in QC on test strip)	yes (simulated whole blood)
• Lyophilized	yes (simulated whole blood)	no	yes
• Integrated QC with each analysis	no	yes (automatic self-check diagnosis)	no
• Automatic lockout for QC failure	no	yes	yes
• Other	—	impedance check strip	n/a
Time (in minutes) to perform control plus specimen test			
• PT:	n/a	<2	2
• PT & PTT:	n/a	n/a	2
• ACT:	5	n/a	1–5
Data management capability	no	onboard	onboard (via Gem Premier 3000)
Includes QC	—	no	yes
System can automatically transfer data to information system			
• Patient data	—	yes	yes
• QC data	—	yes	yes
Interface supplied by instrument vendor	—	no	n/a
LOINC codes transmitted with results	no	—	no
How labs get LOINC codes for reagent kit	n/a	n/a	n/a
Commercially available systems for which interfaces are up and running in active user sites	—	n/a	n/a
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	—	planned	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	no
• Reagent	no	no	yes
Onboard system for automatic error detection	yes, for specimen placement	yes, for sample (volume), reagent stability	yes, for sample (volume), reagent, and instrument
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 hr	0.5 hr
• Patient	n/a	1 hr	n/a
Patient self-testing program is available	no	yes	no
Instrument list price	$1,095 (battery only)–$1,249 (with printer and battery)	$1,595 professional; $1,995 self-test	$5,329 (volume dependent)
Reagent rental or lease only	purchase, lease, or reagent rental	no	outright purchase, lease, reagent rental
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	$10 per strip self-test	varies with volume
Cost per sample if device purchased	—	$5.50 per strip professional	varies with volume
• PTT: Cost per sample for reagent rental	—	n/a	varies with volume
Cost per sample if device purchased	—	n/a	varies with volume
• ACT: Cost per sample for reagent rental	—	n/a	varies with volume
Cost per sample if device purchased	$0.74–$1.76	n/a	varies with volume
CLIA '88 complexity rating	moderate	waived	non-waived
Unique advantages (provided by the vendor)	• 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	• 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

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Coagulation Analyzers (Point-of-care or self-monitoring)

Part 3 of 5

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Instrument name	ProTime Microcoagulation System/ProTime 3	Hemochron Jr.—Signature/Signature+	Hemochron Response
First year sold	ProTime Micro: 1996; ProTime 3: 2001	1998; Signature+ introduced in 2002	2000
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?	—	—	—
Specimen type	fingerstick	fingerstick, venipuncture (whole blood)	venipuncture (whole blood, anticoagulated whole blood)
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	2.5 x 4.5 x 9/3 lb	2 x 7.5 x 3.75/12 oz	8.7 x 10.5 x 7.5/6.4 lb
Specimen volume needs	small blood sample volume needed, ~25 µL	accurate volume not necessary (drop)	accurate volume required (fill line on tubes)
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 10 sec, high 130 sec; INR: low 0.8, high 9.9)	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
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	—	—	—
Method of endpoint detection	optical detection of clot	optical detection of clot	mechanical clot detection
Quality control methods			
• Electronic	no (not required, onboard QC)	yes	yes
• Liquid	yes (available as an option but not required due to onboard controls)	yes (simulated whole blood)	yes (simulated whole blood)
• Lyophilized	no	yes (simulated whole blood)	yes (simulated whole blood)
• Integrated QC with each analysis	yes	no	no
• Automatic lockout for QC failure	yes	Signature, no; Signature+, yes	yes
• Other	2 levels of onboard QC integrated into each cuvette	Signature+, operator lockout	operator lockout
Time (in minutes) to perform control plus specimen test			
• PT:	<5	2	2
• PT & PTT:	n/a	2	2
• ACT:	n/a	1–5	1–5
Data management capability	yes	onboard	onboard
Includes QC	yes	yes (QC Data Management)	yes
System can automatically transfer data to information system			
• Patient data	no	yes	yes
• QC data	no	yes	yes
Interface supplied by instrument vendor	n/a	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	n/a	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) and reagent/cuvette expiration date	yes, for sample (volume)	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 hr	1–2 hr
• Patient	1.5 hr	n/a	n/a
Patient self-testing program is available	yes (programmed instruction/video/Web-based training)	no	no
Instrument list price	$1,699 professional, $2,350 consumer	Signature, $3,825; Signature+, $5,100	$4,055
Reagent rental or lease only	no	no	no
Cost per sample for:			
• PT: Cost per sample for reagent rental	volume dependent	n/a	n/a
Cost per sample if device purchased	volume dependent	—	—
• PTT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	n/a	—	—
• ACT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	n/a	—	—
CLIA '88 complexity rating	waived	moderate	moderate
Unique advantages (provided by the vendor)	• 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 • 30-day room storage of cuvettes	• blood volume—15 µL • ease-of-use • data management storing/printing • connectivity options • configurable QC and operator lockout for Signature+	• gold standard for ACT • QC lockout • data storage and management • connectivity options • RxDx heparin/protamine dosing system

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Coagulation Analyzers (Point-of-care or self-monitoring)

Part 4 of 5

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	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	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com
Instrument name	ACT II	HMS Plus	ACT Plus
First year sold	1994	1999	2003
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	venipuncture	venipuncture	venipuncture (whole blood, anticoagulated whole blood)
Model type	benchtop	benchtop	benchtop
Dimensions in inches (H x W x D)/Weight	6.5 x 6.5 x 9.5/8 lb	15.7 x 15 x 13/34 lb	11 x 8 x 13/11.5 lb
Specimen volume needs	0.2 to 0.4 cc/test, fill to line	accurate volume required (automated dispensing)	accurate volume required (fill line on cuvette)
Clotting-based tests for which device has FDA-cleared applications	ACT (high range, low range, recalcified, and heparinase test)	ACT, heparin dose response, heparin protamine titration, platelet function	ACT (high range, low range, recalcified, high range heparinase)
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	—	ATIII	—
Method of endpoint detection	mechanical clot detection	mechanical clot detection	mechanical clot detection
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	no	no	no
• Lyophilized	yes	yes	yes (simulated whole blood)
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	no	optional (user defined)	yes
• Other	n/a	n/a	—
Time (in minutes) to perform control plus specimen test			
• PT:	n/a	n/a	—
• PT & PTT:	n/a	n/a	—
• ACT:	up to 12 (depending on patient sample)	up to 12 (depending on patient sample)	up to 12 min (depends on patient sample)
Data management capability	yes	yes	onboard
Includes QC	yes	yes	yes (L-J plots)
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	no
LOINC codes transmitted with results	—	—	—
How labs get LOINC codes for reagent kit	Web site	Web site	Web site
Commercially available systems for which interfaces are up and running in active user sites	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	no	no	yes
Onboard system for automatic error detection	yes	yes	yes (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	2 hr	6 hr	1 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	no
Instrument list price	$2,900	$26,000	$4,200
Reagent rental or lease only	rental and purchase available	rental and purchase available	rental and purchase available
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	—	—
Cost per sample if device purchased	—	—	—
• PTT: Cost per sample for reagent rental	—	—	—
Cost per sample if device purchased	—	—	—
• ACT: Cost per sample for reagent rental	—	—	—
Cost per sample if device purchased	customer dependent, per contract	customer dependent, per contract	customer dependent, per contract
CLIA '88 complexity rating	moderate	moderate	moderate
Unique advantages (provided by the vendor)	• automated mixing of reagent and sample • constant temperature control • complete QC program	• automated sample dispensing • constant temperature control • multiple testing capability • HDR: heparin dose response • HPT: heparin protamine titration • high-range ACT	• data management software application • duplicate test results • optional bar-code scanner

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Coagulation Analyzers (Point-of-care or self-monitoring)

Part 5 of 5

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	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	CoaguChek Pro DM System	CoaguChek S System for Prothrombin Time Testing (professional use)
First year sold	1999	2001
No. of units sold in U.S./Outside U.S.	—/—	10,000/52,000
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany
Is instrument POC or self-monitoring analyzer?	POC	POC
Specimen type	fresh whole blood (venous, arterial, or fingerstick capillary)	fresh whole blood (venous or fingerstick capillary)
Model type	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/Weight	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 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, 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
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	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
• Liquid	yes	yes
• Lyophilized	yes (simulated whole blood)	no
• Integrated QC with each analysis	no	no
• Automatic lockout for QC failure	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:	within 6	n/a
Data management capability	onboard	yes, with Coag Clinic from Standing Stone Inc.
Includes QC	yes (L-J plots and QC results report)	no
System can automatically transfer data to information system		
• Patient data	yes	yes
• QC data	yes	yes
Interface supplied by instrument vendor	yes (via additional DataCare software)	software vendor
LOINC codes transmitted with results	n/a	n/a
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	AccuChek HDM 3.2.1, Roche DataCare, MAS-RALS+	Coag Clinic from Standing Stone Inc.
Lab can control analyzer remotely	no	no
Real-time wireless linkage to LIS or HIS	no	no
Positive identification system (e.g. bar code) for:		
• Patient specimen	yes, patient and operator IDs can be entered by bar-code reader	no
• Reagent	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, 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)
Approx. No. of training hours needed for:		
• Medical staff	1.5 hr	1 hr
• Patient	n/a	n/a
Patient self-testing program is available	no	no
Instrument list price	$3,795	$1,295
Reagent rental or lease only	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	$6
• 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	usage dependent	n/a
CLIA '88 complexity rating	moderate	CLIA waived for professional use
Unique advantages (provided by the vendor)	• 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: patient results in as little as 30 sec • small sample: 10 µL from fingerstick • alliance partnerships with Bristol Myers Squibb and Standing Stone for patient management software

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