Coagulation analyzers—point of care, self-monitoring

Part 1 of 6 *See accompanying article on page 27*	**Abbott Point of Care** **Kevin Ball** kevin.ball@apoc.abbott.com **400 College Road East** **Princeton, NJ 08540** **609-454-9301**	**Abbott Point of Care** **Douglas W. Gavin** douglas.gavin@apoc.abbott.com **400 College Road East** **Princeton, NJ 08540** **609-454-9320**	**Alere** **Dennis Dalangin** **9975 Summers Ridge Road** **San Diego, CA 92121** **877-441-7440** www.alere.com
Instrument name	**i-STAT 1**	**CoaguSense PT/INR Monitoring System**	**INRatio/INRatio2 PT INR Monitor**
First year sold	**2000**	**2010**	**2003 (INRatio)/2008 (INRatio2)**
No. of units sold in U.S./Outside U.S.	**—**	**—**	**—**
No. of units sold in 2010	**—**	**—**	**—**
• 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 and self-monitoring**	**POC and self-monitoring analyzer**
Specimen type	**fresh whole blood from arterial, venous, or skin puncture**	**fingerstick, venipuncture (whole blood, plasma)**	**fingerstick**
Model type	**handheld/portable**	**handheld/portable**	**handheld/portable**
Dimensions in inches (H × W × D)/Weight	**9.25 × 3.03 × 2.85/18.34 oz**	**3 × 6.5 × 5.75/1.8 lb (with 4 AA 1.5V alkaline batteries)**	**5.9 × 2.9 × 1.8 in/9.3 oz with batteries**
Specimen volume needs	**20 µL–40 µL**	**accurate volume required ~10 µL (transfer tube or minipipette)**	**accurate volume not necessary (drop) ~15 µL**
Clotting-based tests for which device has FDA-cleared applications	**PT/INR, ACT kaolin, ACT celite**	**PT (reportable range: low 7 seconds, high 180 seconds; INR: low 0.8 seconds, high 8.0 seconds)**	**PT (reportable range: low 7 seconds, high 75 seconds; INR: low 0.7 seconds, high 7.5 seconds)**
Tests using other methodologies for which device has FDA-cleared applications	**chemistries/electrolytes (sodium, potassium, chloride, TCO_2, anion gap, ionized calcium, glucose, urea nitrogen, creatinine, lactate); hematology (hematocrit, hemoglobin); blood gases (pH, PCO_2, PO_2, TCO_2, HCO_3, base excess, sO_2); cardiac markers (cTnI, CK-MB, BNP)**	**—**	**—**
FDA-cleared tests but not yet clinically released	**—**	**—**	**—**
Tests submitted for 510(k) clearance	**—**	**—**	**—**
Tests in development but not yet submitted for clearance	**—**	**—**	**—**
Method of endpoint detection	**electrogenic**	**direct micro-mechanical clot detection, measures actual time required for clotting**	**electrochemical detection, change in impedance as sample clots**
Quality control methods			
• Electronic	**yes**	**no**	**no (not required, built-in two-level QC on each strip)**
• Liquid	**yes**	**yes**	**no (not required, built-in two-level QC on each strip)**
• Lyophilized	**yes (plasma)**	**yes**	**no**
• Integrated QC with each analysis	**yes**	**no**	**yes**
• Automatic lockout for QC failure	**yes**	**no**	**yes**
• Other	**lockout for QC failure is for failed electronic QC or per cartridge internal QC**	**visual confirmation of clot formation**	**—**
Time (in minutes) to perform control plus specimen test			
• PT:	**3+**	**<1**	**1**
• PT and PTT:	**—**	**—**	**—**
• ACT:	**3+**	**—**	**—**
Data-management capability	**optional add-on**	**no**	**yes**
Includes QC	**yes**	**—**	**yes**
System can automatically transfer data to information system			
• Patient data	**yes**	**no**	**yes**
• QC data	**yes**	**no**	**yes**
Interface supplied by instrument vendor	**yes (additional cost)**	**yes**	**yes**
LOINC codes transmitted with results	**no**	**no**	**—**
How labs get LOINC codes for reagent kit	**package insert**	**Web site, package insert, e-mail query**	**—**
Commercially available systems for which interfaces are up and running in active user sites	**Sunquest, Cerner, Soft, McKesson, Meditech, GE, Siemens, VistA, others**	**—**	**CoagClinic from Standing Stone; PPM from Alere**
Lab can control analyzer remotely	**yes**	**no**	**no**
Real-time wireless linkage to LIS or HIS	**yes**	**no**	**no**
Positive identification system (e.g. bar code) for:			
• Patient specimen	**yes**	**no**	**no**
• Reagent	**no**	**yes (each test strip has a bar code, which conveys calibration and control range information)**	**no**
Onboard system for automatic error detection	**yes**	**yes, for sample (volume), reagent stability**	**yes, for sample (volume), reagent stability**
Training provided with instrument purchase	**yes (on site)**	**yes (on site)**	**yes (on site)**
Approx. No. of training hours needed for:			
• Medical staff	**1**	**1**	**1**
• Patient	**—**	**1**	**1**
Patient self-testing program is available	**no**	**yes, available through IDTF**	**yes**
Instrument list price	**—**	**$1,062.50**	**$1,595 professional; $1,995 self-test**
Reagent rental or lease only	**no**	**no**	**no**
Cost per sample for:			
• PT: Cost per sample for reagent rental	**varies**	**—**	**depends on volume**
Cost per sample if device purchased	**—**	**—**	**$5.50 per strip professional; $10 per self-test**
• 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	**—**	**—**	**—**
CLIA '88 complexity rating	**moderate**	**CLIA-waived**	**test-strip waived**
Unique advantages (provided by the vendor)	**broad testing menu; many data-management and interfacing options; easy to use**	**measures actual time required for clotting; portable monitoring system that directly detects clotting endpoint; system that emulates the WHO reference tilt-tube method; uses fresh capillary whole blood, or venous or recalcified plasma samples; displays PT results in less than 1 minute**	**onboard QC—two levels of quantitative controls with reportable results; individually wrapped, non-refrigerated test strips; one-drop fingerstick sample; 12-month dating on test strips; 120-test memory, including QC values; simple three-step test process; human recombinant thromboplastin (ISI 1.0)**

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Survey editor: Raymond Aller, MD

Coagulation analyzers—point of care, self-monitoring

Part 2 of 6	Helena Point of Care David Pearman dpearman@helena.com 1530 Lindbergh Dr. Beaumont, TX 77707 800-231-5663 www.helena.com	Helena Point of Care David Pearman dpearman@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Point of Care David Pearman dpearman@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com
Instrument name	Cascade POC	Actalyke XL	Actalyke Mini II
First year sold	2008	2002	2004
No. of units sold in U.S./Outside U.S.	200/100	300+/200+	150+/1,500+
No. of units sold in 2010	—	—	—
• 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 and self-monitoring analyzer	POC	POC
Specimen type	fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma)	venipuncture (whole blood)	venipuncture (whole blood)
Model type	handheld/portable	portable	portable
Dimensions in inches (H × W × D)/Weight	3.9 × 6 × 10.5/4.25 lb	5.6 × 10.7 × 10.3/15 lb	6.25 × 6 × 5/6.3 lb
Specimen volume needs	accurate volume required (pipetted)	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, APTT, Celite ACT, low-molecular-weight heparin	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	—	—	—
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	direct thrombin inhibitor, fibrinogen, heparin/protamine titration	APTT (whole blood), PT (whole blood), LMWH, heparin, and protamine titration (AMK)	LMWH, APTT (whole blood), PT (whole blood), AMK
Method of endpoint detection	photo-mechanical	two-point electromechanical soft-clot detection principle	two-point electromechanical
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	no	yes	yes
• Lyophilized	yes (plasma)	yes	yes
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	yes	yes	no
• Other	—	data management for entering heparin dose, L-J chart generation for all controls	—
Time (in minutes) to perform control plus specimen test			
• PT:	2	—	—
• PT and PTT:	5	—	—
• ACT:	5–12	5	5
Data-management capability	onboard	yes	no
Includes QC	yes	yes	no
System can automatically transfer data to information system			
• Patient data	yes	yes	—
• QC data	yes	yes	—
Interface supplied by instrument vendor	yes (included)	interface specifications supplied, POCT1-A compliant	—
LOINC codes transmitted with results	no	no	no
How labs get LOINC codes for reagent kit	Web site	—	—
Commercially available systems for which interfaces are up and running in active user sites	—	—	—
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	yes	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	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	30 minutes	1–2	1
• Patient	—	—	—
Patient self-testing program is available	no	no	no
Instrument list price	$3,590	$3,805	$1,024 (battery only)–$1,334 (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	variable	—	—
Cost per sample if device purchased	$2.50–$3.24	—	—
• PTT: Cost per sample for reagent rental	variable	—	—
Cost per sample if device purchased	$2.25–$3.50	—	—
• ACT: Cost per sample for reagent rental	variable	—	—
Cost per sample if device purchased	$2.25–$3.50	$0.74–$1.76	$0.74–$1.76
CLIA '88 complexity rating	nonwaived	moderate	moderate
Unique advantages (provided by the vendor)	multiple tests, same device; eight-hour battery operation; low cost per test	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 (ECT) that simulates and mimics actual blood clot formation for accurate ECT 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; electronic clotting tube available

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Coagulation analyzers—point of care, self-monitoring

Part 3 of 6	Instrumentation Laboratory **Mike Wright** mwright@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4165 www.ilus.com	ITC Nexus Dx customerservice@itcmed.com 8 Olsen Avenue Edison, NJ 08820 732-548-5700 www.itcmed.com	ITC Nexus Dx customerservice@itcmed.com 8 Olsen Avenue Edison, NJ 08820 732-548-5700 www.itcmed.com
Instrument name	Gem PCL Plus	ProTime Microcoagulation System	Hemochron Signature Elite
First year sold	2003	ProTime Micro: 1995; ProTime 3: 2001; New ProTime: 2006	2005
No. of units sold in U.S./Outside U.S.	>250/>250	—/—	—/—
No. of units sold in 2010	—	—	—
• 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	fresh whole blood, citrated whole blood (fingerstick for PT only)	fingerstick	venipuncture, fingerstick, fresh whole blood, citrated blood
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	2.0 × 7.5 × 3.5/0.75 lb	2.7 × 4.5 × 8.5/3 lb	2 × 7.5 × 3.7/1.2 lb
Specimen volume needs	accurate volume not necessary (~50 µL), low sample volume error message if well not filled	small blood sample volume needed, ~25 µL	accurate volume not necessary, (low sample volume error message if well not filled)
Clotting-based tests for which device has FDA-cleared applications	PT and citrate PT (reportable range: 10–150 seconds; INR: 0.8–12 seconds), APTT (reportable range: 20–300 seconds), ACT (reportable range: 65–1,005 seconds), ACT–low range (reportable range: 67–400 seconds)	PT (reportable range: low 10 seconds, high 130 seconds; INR: low 0.8, high 9.9)	PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR
Tests using other methodologies for which device has FDA-cleared applications	—	—	—
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	mechanical endpoint clotting mechanism, monitored optically	mechanical clot detection	mechanical clot detection
Quality control methods			
• Electronic	yes	no (not required, onboard QC)	yes, internal automatic EQC
• Liquid	yes (simulated whole blood)	yes (available as an option but not required due to onboard controls)	yes (simulated whole blood)
• Lyophilized	no	no	yes (simulated whole blood)
• Integrated QC with each analysis	no	yes	no
• Automatic lockout for QC failure	yes	yes	yes
• Other	—	two levels of onboard QC integrated into each cuvette	operator lockout, certification lockout, audit trail, and patient identification lockout
Time (in minutes) to perform control plus specimen test			
• PT:	2	<5	2
• PT and PTT:	2	—	2
• ACT:	1–5	—	1–5
Data-management capability	onboard (via Gem Premier 3000)	yes	onboard
Includes QC	yes	yes (onboard controls)	yes
System can automatically transfer data to information system			
• Patient data	yes	yes	yes
• QC data	yes	yes	yes
Interface supplied by instrument vendor	—	communication cable available	yes
LOINC codes transmitted with results	no	—	—
How labs get LOINC codes for reagent kit	—	—	—
Commercially available systems for which interfaces are up and running in active user sites	—	—	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), reagent, and instrument	yes, for sample (volume) and reagent/cuvette 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	30 minutes	1	1
• Patient	—	1.5	—
Patient self-testing program is available	no	yes (training CD/Web-based training)	no
Instrument list price	$5,329 (volume-dependent)	$1,749 professional, $2,350 consumer	$7,900
Reagent rental or lease only	outright purchase, lease, reagent rental	yes	purchase and rental available
Cost per sample for:			
• PT: Cost per sample for reagent rental	varies with volume	volume-dependent	—
Cost per sample if device purchased	varies with volume	volume-dependent	—
• PTT: Cost per sample for reagent rental	varies with volume	—	—
Cost per sample if device purchased	varies with volume	—	—
• ACT: Cost per sample for reagent rental	varies with volume	—	—
Cost per sample if device purchased	varies with volume	—	—
CLIA '88 complexity rating	nonwaived	waived	moderate
Unique advantages (provided by the vendor)	used in conjunction with the Gem Premier 3000/3500 analyzer; consolidating blood gas/electrolytes/glucose/lactate/hematocrit/coagulation testing; comprehensive POC coagulation menu allows for POC coagulation analysis throughout an institution; whole blood PT, citrate PT, APTT, ACT, and ACT-low range; patient safety features: automatic QC lockout, mandatory operator and patient ID options, database management (patient history query), fully automated sample measuring and mixing, inaccurate sample volume detection and optical monitoring	two levels of 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 five minutes; 16-hour room-temperature open-pouch stability of cuvette; bar-coded cuvette—no coding neccessary; accepts and stores patient/operator ID; automatically sends test results to printer, computer, LIS; onboard and external controls	integrated bar-code scanner; compliance technology; QC, PID, and OID; lockout and tracking; data-management storage and printing; optimal connectivity options; 15-µL blood volume; ease of use; Ethernet and RS232 ports; standardizes anticoagulation therapy monitoring across the continuum of care, while enhancing compliance and patient safety and maximizing efficiencies

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Coagulation analyzers—point of care, self-monitoring

Part 4 of 6	ITC Nexus Dx customerservice@itcmed.com 8 Olsen Avenue Edison, NJ 08820 732-548-5700 www.itcmed.com	ITC Nexus Dx customerservice@itcmed.com 8 Olsen Avenue Edison, NJ 08820 732-548-5700 www.itcmed.com
Instrument name	Signature+	Hemochron Response
First year sold	Signature+ introduced in 2002	2000
No. of units sold in U.S./Outside U.S.	—/—	—/—
No. of units sold in 2010	—	—
• units sold to:	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC
Specimen type	venipuncture, fingerstick, fresh whole blood, citrated blood	venipuncture, fingerstick, fresh whole blood, citrated blood
Model type	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	2 × 7.5 × 3.75/12 oz	8.7 × 10.5 × 7.5/6.4 lb
Specimen volume needs	accurate volume not necessary (low sample volume error message if well not filled)	accurate volume required (fill line on tubes)
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, PDAO, PDAOK, PT, APTT, PT citrated, APTT citrated
Tests using other methodologies for which device has FDA-cleared applications	—	—
FDA-cleared tests but not yet clinically released	—	—
Tests submitted for 510(k) clearance	—	—
Tests in development but not yet submitted for clearance	—	—
Method of endpoint detection	mechanical clot detection	mechanical clot detection
Quality control methods		
• Electronic	yes	yes
• Liquid	yes (simulated whole blood)	yes (simulated whole blood)
• Lyophilized	yes (simulated whole blood)	yes (simulated whole blood)
• Integrated QC with each analysis	no	no
• Automatic lockout for QC failure	yes	yes
• Other	operator lockout	operator lockout
Time (in minutes) to perform control plus specimen test		
• PT:	2	2
• PT and PTT:	2	2
• ACT:	1–5	1–5
Data-management capability	onboard	onboard
Includes QC	yes	yes
System can automatically transfer data to information system		
• Patient data	yes	yes
• QC data	yes	yes
Interface supplied by instrument vendor	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
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	no	no
• Reagent	yes	yes
Onboard system for automatic error detection	yes, for sample (volume)	yes, for sample (volume) and reagent/expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)
Approx. No. of training hours needed for:		
• Medical staff	—	1–2
• Patient	—	—
Patient self-testing program is available	no	no
Instrument list price	$5,280	$4,055
Reagent rental or lease only	purchase and rental available	no
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	—	—
CLIA '88 complexity rating	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; standardizes anticoagulation therapy monitoring across the continuum of care	QC lockout; data-management storage; connectivity options; RxDx heparin/protamine dosing system

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Coagulation analyzers—point of care, self-monitoring

Part 5 of 6	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	HMS Plus	ACT Plus
First year sold	1999	2003
No. of units sold in U.S./Outside U.S.	—/—	—
No. of units sold in 2010	—	—
• units sold to:	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC
Specimen type	venipuncture (whole blood)	venipuncture (whole blood)
Model type	benchtop	benchtop
Dimensions in inches (H × W × D)/Weight	15.7 × 15 × 13/34 lb	11 × 8 × 13/11.5 lb
Specimen volume needs	accurate volume required (automated dispensing)	accurate volume required (fill line on cuvette and optional easy fill accessory)
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)
Tests using other methodologies for which device has FDA-cleared applications	—	—
FDA-cleared tests but not yet clinically released	—	—
Tests submitted for 510(k) clearance	—	—
Tests in development but not yet submitted for clearance	—	—
Method of endpoint detection	mechanical clot detection	mechanical clot detection
Quality control methods		
• Electronic	yes	yes
• Liquid	no	no
• Lyophilized	yes	yes
• Integrated QC with each analysis	no	no
• Automatic lockout for QC failure	optional (user defined)	optional (user defined)
• Other	optional operator lockout	optional operator lockout
Time (in minutes) to perform control plus specimen test		
• PT:	—	—
• PT and PTT:	—	—
• ACT:	up to 12 (depending on patient sample)	up to 12 (depends on patient sample)
Data-management capability	yes	yes
Includes QC	yes	yes
System can automatically transfer data to information system		
• Patient data	yes	yes
• QC data	yes	yes
Interface supplied by instrument vendor	no	no
LOINC codes transmitted with results	—	—
How labs get LOINC codes for reagent kit	Web site	Web site
Commercially available systems for which interfaces are up and running in active user sites	Telcor, RALS-Plus, Aegis POC	Telcor, RALS-Plus, Aegis POC
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	yes
• Reagent	yes	yes
Onboard system for automatic error detection	yes	yes
Training provided with instrument purchase	yes (on site)	yes (on site)
Approx. No. of training hours needed for:		
• Medical staff	6	1
• Patient	—	—
Patient self-testing program is available	no	no
Instrument list price	$26,000	$4,200
Reagent rental or lease only	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
CLIA '88 complexity rating	moderate (nonwaived)	moderate (nonwaived)
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; HMS Plus Education Program CD	data-management software application; duplicate test results; optional bar-code scanner; optional easy filling accessory; ACT Plus Education Program CD

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Coagulation analyzers—point of care, self-monitoring

Part 6 of 6	Roche Diagnostics Jill Downey jill.downey@roche.com 9115 Hague Road Indianapolis, IN 46250 317-521-1829 or 317-902-6014 www.poc.roche.com	Roche Diagnostics Jill Downey jill.downey@roche.com 9115 Hague Road Indianapolis, IN 46250 317-521-1829 or 317-902-6014 www.poc.roche.com	Roche Diagnostics Jill Downey jill.downey@roche.com 9115 Hague Road Indianapolis, IN 46250 317-521-1829 or 317-902-6014 www.poc.roche.com
Instrument name	CoaguChek XS PT Test System	CoaguChek XS Plus PT Test System	CoaguChek XS Pro PT Test System
First year sold	2006 (international)/2007 (U.S.)	2007	2010
No. of units sold in U.S./Outside U.S.	—/—	—/—	—/—
No. of units sold in 2010	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Is instrument POC or self-monitoring analyzer?	POC and self-monitoring	POC	POC
Specimen type	fresh whole blood (venous or fingerstick capillary)	fresh whole blood (venous or fingerstick capillary)	fresh whole blood (venous or fingerstick capillary)
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	5.43 × 3.07 × 1.10/4.48 oz	7.28 × 3.89 × 1.65/350 g	9.09 × 3.89 × 1.65/350 g
Specimen volume needs	8 µL	8 µL	8 µL
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 9.6 seconds, high 96 seconds; INR: low 0.8 seconds, high 8.0 seconds)	PT (reportable range: low 9.6 seconds, high 96 seconds; INR: low 0.8 seconds, high 8.0 seconds)	PT (reportable range: low 9.6 seconds, high 96 seconds; INR: low 0.8 seconds, high 8.0 seconds)
Tests using other methodologies for which device has FDA-cleared applications	—	—	—
FDA-cleared tests but not yet clinically released	—	—	—
Tests submitted for 510(k) clearance	—	—	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	amperometric detection	amperometric detection	amperometric detection
Quality control methods			
• Electronic	no (not required, onboard QC)	no (not required, onboard QC)	no (not required, onboard QC)
• Liquid	no	yes (available as an option but not required due to onboard controls)	yes (available as an option but not required due to onboard controls)
• Lyophilized	no	no	no
• Integrated QC with each analysis	yes	yes	yes
• Automatic lockout for QC failure	no	yes	yes
• Other	—	optional operator lockout	optional operator lockout
Time (in minutes) to perform control plus specimen test			
• PT:	<1	<1	<1
• PT and PTT:	—	—	—
• ACT:	—	—	—
Data-management capability	no	yes	yes
Includes QC	no	yes	yes
System can automatically transfer data to information system			
• Patient data	no	yes	yes
• QC data	no	yes	yes
Interface supplied by instrument vendor	with license	POCT1-A	POCT1-A
LOINC codes transmitted with results	no	no	no
How labs get LOINC codes for reagent kit	—	—	—
Commercially available systems for which interfaces are up and running in active user sites	yes	RALS-Plus	RALS-Plus
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	no	no
Onboard system for automatic error detection	yes	yes	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	1.5	1.5
• Patient	trainer-dependent	—	—
Patient self-testing program is available	yes	no	no
Instrument list price	varies by distributor	varies by distributor	varies by distributor
Reagent rental or lease only	no	no	no
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	—	—	—
CLIA '88 complexity rating	CLIA-waived	moderate	moderate
Unique advantages (provided by the vendor)	performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; 18-month strip shelf life, no refrigeration needed; top or side dosing; results in one minute or less	performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; 18-month strip shelf life, no refrigeration needed; top or side dosing; results in one minute or less; memory of 1,000 patient and 500 optional liquid quality control tests, ability to add comments with each patient and liquid quality control test	performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; 18-month strip shelf life, no refrigeration needed; top or side dosing; results in one minute or less; memory of 1,000 patient and 500 optional liquid quality control tests, ability to add comments with each patient and liquid quality control test; integrated bar-code scanner able to scan both operator and patient IDs

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.