2008 Grant Deadlines

CAP Foundation

APPLY TODAY

Grant Descriptions and Deadlines

Deadline June 1, 2008

NEW:

■ **CAP Foundation Conference Travel Stipend for Digital Pathology** for CAP Junior Members to attend the digital pathology conference, Pathology Visions on November 2- 4, 2008, in San Diego. Funding is provided by Aperio.

■ **CAP Foundation Pathology Informatics Grant** is a one month informatics elective for Junior Members. Three weeks in a business laboratory setting in Minnesota and one week visiting additional labs. Timeframe is between August 1 and November 1, 2008. Funding is provided by McKesson Information Solutions.

GRANTS:

■ **CAP Foundation/API Pathology Informatics Scholarship** for CAP Junior Members exposes pathologists-in-training to new developments in information technology. The scholarship includes a $5,000 grant for educational, living, and travel expenses incurred during the rotation.

■ **CAP Foundation Informatics Grants for Telepathology** for CAP Junior Members support developments in and the use of telepathology and information technology for the practice of pathology. Funding is provided by Olympus America and Nikon Instruments.

▼ **CAP Foundation Humanitarian Grants Program** funds projects up to $30,000 that deliver pathology and medical services to under-served patients and in underdeveloped areas. OPEN TO ALL CAP MEMBERS. Funding is provided by Olympus America.

INFORMATICS TRAVEL STIPENDS:

■ **CAP Foundation Conference Travel Stipends for Informatics** (APIII) for CAP Junior Members and other qualified applicants provide funding for recipients to attend the fall National Conference on Advancing Practice, Instruction and Innovation through Informatics (APIII).

■ **CAP Foundation Conference Travel Stipends for Informatics** (CHC) for CAP Junior Members provide funding for recipients to attend the fall Cerner Health Conference. Funding is provided by Cerner Corporation.

How Do I Apply?

For more information on how to apply and application guidelines for a CAP Foundation grant, visit **http://foundation.cap.org**, email **CAPFdn @cap.org**, or call **800-323-4040 ext. 7324**. An application must be completed in its entirety and postmarked by the date of the application deadline to be considered.

Grant Eligibility Requirements

■ Pathology residents and those doing fellowships are eligible to apply for the all Conference Travel Grants for Informatics, Informatics Scholarship, Telepathology Grant, Futurescape Conference Grants. CAP Junior Membership is required and available at no charge.

▼ All pathologists (residents, practicing, and emeritus) are eligible to apply for Humanitarian Grants. CAP Membership is required.

Coagulation analyzers—point of care, self-monitoring

Part 1 of 5	Abbott Point of Care Dan Molloy marketing@i-stat.com Marketing Communications 104 Windsor Center Drive East Windsor, NJ 08520 800-366-8020	Helena Point of Care Joe Golias helena@helena.com 1530 Lindbergh Dr. Beaumont, TX 77707 800-231-5663 www.helena.com
Instrument name	i-STAT 1	Cascade POC
First year sold	2000	2008
No. of units sold in U.S./Outside U.S.	8,000/4,000	20 (as of April 2008 release)
No. of units sold in 2007	—	—
• 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 and self-monitoring analyzer
Specimen type	finger-stick, venipuncture (whole blood, anticoagulated whole blood)	finger-stick, venipuncture (whole blood, anticoagulated whole blood, plasma)
Model type	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	9.25 × 3.03 × 2.85/18.34 oz	3.9 × 6 × 10.5/4.25 lb
Specimen volume needs	accurate volume required (pipetted, fill line on cuvette)	accurate volume required (pipetted)
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 10.3 sec, high 87.5 sec; INR: low 0.9, high 8.0)	PT/INR, PTT, Celite ACT, low molecular weight heparin
Tests using other methodologies for which device has FDA-cleared applications	CHEM8+, BNP, CK-MB, troponin I, creatinine, urea nitrogen (BUN), glucose(Glu), chloride(Cl), sodium (Na), potassium (K), ionized calcium (iCa), hematocrit (Hct), hemoglobin (Hgb), pH, PCO2, PO2, TCO2**, HCO3, BEecf, SO2, lactate, anion gap, ACT (Celite), ACT (Kaolin), PT/INR	—
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
Method of endpoint detection	electrogenic	photo-mechanical
Quality control methods		
• Electronic	yes	yes
• Liquid	no	no
• Lyophilized	yes (plasma)	yes (plasma)
• Integrated QC with each analysis	yes	no
• Automatic lockout for QC failure	yes	yes
• Other	lockout for QC failure is for failed electronic QC or per cartridge internal QC	—
Time (in minutes) to perform control plus specimen test		
• PT:	2	2
• PT & PTT:	—	5
• ACT:	2+	5–12
Data-management capability	optional add-on	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 (additional cost)	yes (included)
LOINC codes transmitted with results	yes	no
How labs get LOINC codes for reagent kit	package insert	Web site
Commercially available systems for which interfaces are up and running in active user sites	Sunquest, Cerner, Soft, McKesson, Meditech, GE, Siemens, VistA, others	—
Lab can control analyzer remotely	yes	no
Real-time wireless linkage to LIS or HIS	yes (infrared)	no
Positive identification system (e.g. bar code) for:		
• Patient specimen	yes	yes
• Reagent	no	yes
Onboard system for automatic error detection	yes, for sample (volume)	yes
Training provided with instrument purchase	yes (on site)	yes (on site)
Approx. No. of training hours needed for:		
• Medical staff	1	30 min
• Patient	—	—
Patient self-testing program is available	no	no
Instrument list price	$7,140	$3,590
Reagent rental or lease only	no	yes
Cost per sample for:		
• PT: Cost per sample for reagent rental	varies	variable
Cost per sample if device purchased	call for pricing	$2.50–$3.24
• PTT: Cost per sample for reagent rental	call for pricing	variable
Cost per sample if device purchased	call for pricing	$2.25–$3.50
• ACT: Cost per sample for reagent rental	call for pricing	variable
Cost per sample if device purchased	call for pricing	$2.25–$3.50
CLIA '88 complexity rating	moderate	nonwaived
Unique advantages (provided by the vendor)	• broad testing menu • many data-management and interfacing options • easy to use	• multiple tests, same device • eight-hour battery operation • low cost/test

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

Survey editor: Raymond Aller, MD

Coagulation analyzers—point of care, self-monitoring

Part 2 of 5	Helena Point of Care Joe Golias pointofcare@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Point of Care Joe Golias pointofcare@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com	HemoSense Inc. David Phillips 651 River Oaks Parkway San Jose, CA 95134 408-719-1393 www.hemosense.com
Instrument name	Actalyke XL	Actalyke Mini II	INRatio PT/INR
First year sold	2002	2004	2003
No. of units sold in U.S./Outside U.S.	300+/200+	100+/800+	—/—
No. of units sold in 2007	—	—	—
• 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 and self-monitoring analyzer
Specimen type	venipuncture (whole blood)	venipuncture (whole blood)	finger-stick
Model type	portable	portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	5.6 × 10.7 × 10.3/15 lb	6.25 × 6 × 5/6.3 lb	6.125 × 3 × 2.2 in/8.1 oz
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume required (fill line on cuvette)	accurate volume not necessary (drop) ~15 µL
Clotting-based tests for which device has FDA-cleared applications	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	PT (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5)
Tests using other methodologies for which device has FDA-cleared applications	—	—	none
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 (whole blood), PT (whole blood), LMWH, heparin & protamine titration (AMK)	LMWH, APTT (whole blood), PT (whole blood), AMK	none
Method of endpoint detection	two-point electromechanical soft-clot detection principle	two-point electromechanical	electrochemical detection, change in impedance as sample clots
Quality control methods			
• Electronic	yes	yes	no (not required, built-in 2-level QC on each strip)
• Liquid	yes	yes	no (not required, built-in 2-level QC on each strip)
• Lyophilized	yes	yes	no
• Integrated QC with each analysis	no	no	yes
• Automatic lockout for QC failure	yes	no	yes
• 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 & PTT:	—	—	—
• ACT:	5	5	—
Data-management capability	yes	no	optional add-on (CoagClinic from Standing Stone)
Includes QC	yes	no	yes
System can automatically transfer data to information system			
• Patient data	yes	—	yes
• QC data	yes	—	yes
Interface supplied by instrument vendor	interface specifications supplied, POCT1-A compliant	—	no
LOINC codes transmitted with results	no	no	—
How labs get LOINC codes for reagent kit	—	—	—
Commercially available systems for which interfaces are up and running in active user sites	—	—	CoagClinic from Standing Stone; PPM from QAS
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	yes	—	no
Positive identification system (e.g. bar code) for:			
• Patient specimen	yes	no	no
• Reagent	yes; all disposables have bar code for identification with use on any Actalyke model	no	no
Onboard system for automatic error detection	yes, stuck magnet, no tube; mechanical instrument parameters only; well rotation, temperature, and detection settings	yes, for stuck magnet, printer problems	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	1–2	1	1
• Patient	—	—	1
Patient self-testing program is available	no	no	yes
Instrument list price	$3,805	$1,024 (battery only)–$1,334 (with printer and battery)	$1,595 professional; $1,995 self-test
Reagent rental or lease only	purchase, lease, or reagent rental	purchase, lease, or reagent rental	no
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	—	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	$0.74–$1.76	$0.74–$1.76	—
CLIA '88 complexity rating	moderate	moderate	waived
Unique advantages (provided by the vendor)	• 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-inch 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 (ECT) available	• onboard QC—two levels of quantitative controls with reportable results • simple three-step test process • human recombinant thromboplastin (ISI 1.0) • individually wrapped test strips • non-refrigerated test strips • one unmeasured drop • 12-month dating on test strips • room-temperature storage of test strips • 60 patient memory, including QC values

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

Coagulation analyzers—point of care, self-monitoring

Part 3 of 5	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	International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com
Instrument name	Gem PCL Plus (Portable Coagulation Laboratory)	ProTime Microcoagulation System	Hemochron Jr.—Signature+
First year sold	2003	ProTime Micro: 1995; ProTime 3: 2001; New ProTime: 2006	1998; Signature+ introduced in 2002
No. of units sold in U.S./Outside U.S.	—/—	—/—	—/—
No. of units sold in 2007	—	—	—
• 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 (finger-stick for PT)	finger-stick	venipuncture, finger-stick, fresh whole blood, citrated blood
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	5.5 × 2 × 3.5/0.75 lb	2.7 × 4.5 × 8.5/3 lb	2 × 7.5 × 3.75/12 oz
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 needed (fill line in cuvette sample well)
Clotting-based tests for which device has FDA-cleared applications	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)	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	none	—
Tests in development but not yet submitted for clearance	none	—	—
Method of endpoint detection	mechanical endpoint clotting mechanism, monitored optically	mechanical clot detection	optical detection of clot
Quality control methods			
• Electronic	yes	no (not required, onboard QC)	yes
• Liquid	yes (simulated whole blood)	yes (available as an option but not required due to onboard controls)	yes (simulated whole blood)
• Lyophilized	yes	no	yes (simulated whole blood)
• Integrated QC with each analysis	no	yes	no
• Automatic lockout for QC failure	yes	yes	Signature, no; Signature+, yes
• Other	—	2 levels of onboard QC integrated into each cuvette	operator lockout
Time (in minutes) to perform control plus specimen test			
• PT:	2	<5	2
• PT & 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)
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approx. No. of training hours needed for:			
• Medical staff	30 min	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	Signature+, $5,280
Reagent rental or lease only	outright purchase, lease, reagent rental	yes	no
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)	• 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 five minutes • 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	• blood volume—15 µL • ease of use • data-management storage and printing • connectivity options • configurable QC and operator lockout for Signature+

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

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	Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com
Instrument name	Hemochron Response	Hemochron Signature Elite	HMS Plus
First year sold	2000	2005	1999
No. of units sold in U.S./Outside U.S.	—/—	—/—	—/—
No. of units sold in 2007	—	—	—
• 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, finger-stick, fresh whole blood, citrated blood	venipuncture, finger-stick, fresh whole blood, citrated blood	venipuncture (whole blood)
Model type	handheld/portable	handheld/portable	benchtop
Dimensions in inches (H × W × D)/Weight	8.7 × 10.5 × 7.5/6.4 lb	2 × 7.5 × 3.7/1.2 lb	15.7 × 15 × 13/34 lb
Specimen volume needs	accurate volume required (fill line on tubes)	accurate volume needed (fill line in cuvette sample well)	accurate volume required (automated dispensing)
Clotting-based tests for which device has FDA-cleared applications	ACT, (FTCA510, KACT, P214), HITT, TT, fib, HRT, KHRT, PRT, KPRT, PDAO, PDAOK, PT, APTT, PT citrated, APTT citrated	PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR	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	—	—
Tests in development but not yet submitted for clearance	—	—	—
Method of endpoint detection	mechanical clot detection	optical detection of clot	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	yes	yes	optional (user defined)
• Other	operator lockout	operator lockout	optional operator lockout
Time (in minutes) to perform control plus specimen test			
• PT:	2	2	—
• PT & PTT:	2	2	—
• 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	Telcor, RALS Plus in development, Aegis POC in development
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) and reagent/expiration date	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	1–2	1	6
• Patient	—	—	—
Patient self-testing program is available	no	no	no
Instrument list price	$4,055	$7,900	$26,000
Reagent rental or lease only	no	no	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
CLIA '88 complexity rating	moderate	moderate	moderate (nonwaived)
Unique advantages (provided by the vendor)	• QC lockout • data-management storage • 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	• 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

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	Roche Diagnostics Roche Sales 9115 Hague Rd. Indianapolis, IN 46250 800-852-8766 www.roche-diagnostics.com	Roche Diagnostics Kevin A. Sanford Kevin.sanford@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-852-8766 www.poc.roche.com
Instrument name	ACT Plus	CoaguChek XS PT Test System	CoaguChek XS Plus
First year sold	2003	2006 (international)/2007 (U.S.)	2007
No. of units sold in U.S./Outside U.S.	—	—/—	—/—
No. of units sold in 2007	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./U.S.	Germany/Germany	Germany/Germany
Is instrument POC or self-monitoring analyzer?	POC	POC and self-monitoring	POC
Specimen type	venipuncture (whole blood)	fresh whole blood (venous or finger-stick capillary)	finger-stick, venipuncture (anticoagulated whole blood)
Model type	benchtop	handheld/portable	handheld/portable
Dimensions in inches (H × W × D)/Weight	11 × 8 × 13/11.5 lb	5.43 × 3.07 × 1.10/4.48 oz	3.25 × 6.5 × 12.375/350 g
Specimen volume needs	accurate volume required (fill line on cuvette and optional easy fill accessory)	accurate volume not necessary (drop), minimum 10 µL	accurate volume not necessary (drop), 10 µL
Clotting-based tests for which device has FDA-cleared applications	ACT (high range, low range, recalcified, high range heparinase)	PT (reportable range: low 9.6 sec, high 96 sec; INR: low 0.8, high 8.0)	PT (reportable range: low 9.6 sec, high 96 sec; INR: low 0.8, 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	—	CoaguChek XS Plus System (professional use only)	prothrombin time testing
Tests in development but not yet submitted for clearance	—	none	none
Method of endpoint detection	mechanical clot detection	amperometric detection	amperometric detection
Quality control methods			
• Electronic	yes	no	yes
• Liquid	no	no	yes (simulated whole blood)
• Lyophilized	yes	no	no
• Integrated QC with each analysis	no	yes	yes
• Automatic lockout for QC failure	optional (user defined)	no	yes
• Other	optional operator lockout	—	—
Time (in minutes) to perform control plus specimen test			
• PT:	—	<1	<1
• PT & PTT:	—	PT	PT
• ACT:	up to 12 (depends on patient sample)	no	no
Data-management capability	yes	no	optional add-on
Includes QC	yes	no	no
System can automatically transfer data to information system			
• Patient data	yes	no	no
• QC data	yes	no	no
Interface supplied by instrument vendor	no	no	no
LOINC codes transmitted with results	—	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	Telcor, RALS Plus in development, Aegis POC in development	Standing Stone CoagClinic	RALS Plus pending
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	no	no
• Reagent	yes	no	no
Onboard system for automatic error detection	yes	yes, for sample (volume), meter performance, proper strip chemistry/strip mishandling	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	1.5
• Patient	—	trainer dependent	—
Patient self-testing program is available	no	yes	no
Instrument list price	$4,200	varies by distributor	varies by distributor
Reagent rental or lease only	rental and purchase available	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	customer dependent, per contract	—	—
CLIA '88 complexity rating	moderate (nonwaived)	CLIA waived	CLIA waiver pending
Unique advantages (provided by the vendor)	• data-management software application • duplicate test results • optional bar-code scanner • optional easy filling accessory	• 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	• performs onboard quality control and determines patient results in a single test chamber (data on file at Roche Diagnostics) • heparin insensitivity • top or side dosing

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