For POC coag, direct clot-detection technology, new quality features, Ensemble software

While portability, connectivity, and ease of use continue to be the chief demands for point-of-care coagulation test system users, says Dave Pearman, global marketing manager for hemostasis/POC divisions, Helena Point of Care, the market is "starting to see some fibrillation of its own as pharmaceutical manufacturers start to crank out esoteric anticoagulants."

This is one reason, he says, that Helena will soon release its Abrazo analyzer, a next-generation version of the company's Cascade POC coagulation system that can host "numerous assay targets on one box." Pearman calls the technology on which Abrazo is based "an evolution of the Cardiovascular Diagnostics/PharmaNetics/Bayer Rapidpoint coagulation technology that today resides in a box that is 65 percent smaller," and notes that the new platform has a color touchscreen, USB and Bluetooth connectivity, and a built-in bar-code reader. "What is unique about Abrazo is that it represents an enterprise-type platform, but the test menu would strictly consist of hemostasis assays," Pearman says. The platform's initial test menu will consist of PT, APTT, ACT, and ACT-LR, followed later by direct thrombin inhibitor assay, low-molecular-weight heparin, fibrinogen, and heparin/protamine titration. Helena in November submitted the Abrazo platform to the FDA for 510(k) clearance. "Customers are as excited as we are for the FDA to give us the nod," Pearman says.

Helena's Actalyke XL, Actalyke Mini II, and Cascade POC analyzers are profiled in the following pages (Abrazo is not), along with those from ITC, Abbott, Alere, Instrumentation Laboratory, Medtronic Cardiac Surgery, Roche Diagnostics, and CoaguSense.

CoaguSense, which in December 2010 launched its Coag-Sense PT/INR monitoring system, is new to the CAP TODAY point-of-care coagulation analyzers product guide. The portable meter, which was previously distributed by Abbott, is equipped with direct clot-detection technology by which clots are lifted from the reaction well, "similar in principle to the research gold-standard Fibrometer," says Doug Patterson, the company's CEO. The technology allows for samples with hematocrits as low as 15 percent, as well as plasma controls, to be read accurately. The system's new 3.85-version software now provides printing capabilities.

The latest from Abbott Point of Care is the i-Stat 1 wireless system, which received FDA 510(k) clearance in February 2011, says Sara Scibal, global product manager, acute care. The i-Stat 1 wireless, a handheld version of the company's i-Stat 1 POC testing device, enables users to perform testing and transmit results to an electronic medical record directly from a patient's bedside. This month advanced quality features have been added to help improve compliance, oversight, and control, she says. The new features include liquid quality control pass/fail determination, which simplifies the liquid QC process (electronic value assignment sheets are now downloaded and transferred to the handheld upon docking); liquid QC scheduling and lockout, which ensure that QC is completed successfully and on schedule or otherwise prevent further patient testing; customizable reportable ranges, which allow the laboratory to set upper and lower limits of the measurement range for each i-Stat analyte; and positive patient identification, which enables the system to display patient name, birth date, and gender.

The Joint Commission's national patient safety goals have increased demand for data-management capabilities, patient bar-code identifiers, and methods and tools to improve anticoagulation therapy management, notes Beth O'Connell, director of marketing, ITC. To this end, says O'Connell, ITC will soon introduce its Ensemble point-of-care software, which provides a single, common data-management and configuration platform to connect the company's POC coagulation analyzers as well as CO-oximetry and blood gas instruments. The software provides customers with Web capability, connects with all ITC devices, and has common interfaces with laboratory information systems, she adds.

Remaining available and featured in this month's product guide is ITC's Hemochron Signature Elite analyzer, which has a test menu consisting of ACT, ACT-LR, PT, APTT, citrated PT, and citrated APTT. For CLIA-waived PT testing and patient self-testing there's the ProTime Microcoagulation system, which is designed to safely monitor the clotting activity in blood in patients on warfarin anticoagulant therapy. ProTime also stores patient and/or operator identification numbers and automatically sends results.

The companies that market these and other instruments provided the data displayed on pages 20–30. Readers interested in a particular product should confirm it has the stated features and capabilities.

—Brendan Dabkowski, associate editor

Part 1 of 6 *See* captodayonline.com/productguides *for an interactive version of guide*	Abbott Point of Care Joe Freels joe.freels@apoc.abbott.com 400 College Road East Princeton, NJ 08540 609-454-9000
Instrument name	i-STAT 1
First year sold	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./Canada
Is instrument POC or self-monitoring analyzer?	POC
Specimen type	fresh whole blood from arterial, venous, or skin puncture
Model type	handheld/portable
Dimensions in inches (H × W × D)/Weight	9.25 × 3.03 × 2.85/22.56 oz
Specimen volume needs	17 µL–95 µL
Clotting-based tests for which device has FDA-cleared applications	PT/INR, ACT kaolin, ACT celite
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
Quality control methods	
• Electronic	yes
• Liquid	yes
• Lyophilized	yes (plasma)
• Integrated QC with each analysis	yes
• Automatic lockout for QC failure	yes
• Other	—
Time (in minutes) to perform control plus specimen test	
• PT	3+
• PT and PTT	—
• ACT	3+
Data-management capability	optional add-on
Includes QC	yes
System can automatically transfer data to information system	
• Patient data	yes
• QC data	yes
Interface supplied by instrument vendor	yes
LOINC codes transmitted with results	no
How labs get LOINC codes for reagent kit	package insert
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
Real-time wireless linkage to LIS or HIS	yes
Positive identification system (e.g., bar code) for:	
• Patient specimen	yes
• Reagent	yes
Onboard system for automatic error detection	yes
Training provided with instrument purchase	yes (on site)
Approx. No. of training hours needed for:	
• Medical staff	1
• Patient	—
Patient self-testing program is available	no
Instrument list price	—
Reagent rental or lease only	no
Cost per sample for:	
• PT: Cost per sample for reagent rental	variable
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
Unique advantages (provided by the vendor)	broad testing menu; many data-management and interfacing options; easy to use; integrated wireless capability for real-time transmission to EMR

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Coagulation analyzers—point of care, self-monitoring

Part 2 of 6 *See* captodayonline.com/productguides *for an interactive version of guide*	**Alere** **Dennis Dalangin** **9975 Summers Ridge Road** **San Diego, CA 92121** **877-441-7440** www.alere.com	**CoaguSense** **Douglas Patterson** dpatterson@coagusense.com **48377 Fremont Boulevard, Suite 113** **Fremont, CA 94538** **866-903-0890** www.coagusense.com	**Helena Point of Care** **David Pearman** dpearman@helena.com **1530 Lindbergh Dr.** **Beaumont, TX 77707** **800-231-5663** www.helena.com
Instrument name **First year sold**	**INRatio/INRatio2 PT INR Monitor** **2003 (INRatio)/2008 (INRatio2)**	**Coag-Sense PT/INR Monitoring System** **2010**	**Cascade POC** **2008**
No. of units sold in U.S./Outside U.S. **No. of units sold in 2010** **• units sold to:**	**—** **—** **—**	**—** **—** **—**	**300+/200+** **—** **—**
Country where analyzer designed/Manufactured **Is instrument POC or self-monitoring analyzer?**	**U.S./U.S.** **POC and self-monitoring analyzer**	**U.S./U.S.** **POC and self-monitoring**	**U.S./U.S.** **POC and self-monitoring**
Specimen type	**fingerstick**	**fingerstick**	**fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma)**
Model type **Dimensions in inches (H × W × D)/Weight** **Specimen volume needs**	**handheld/portable** **5.9 × 2.9 × 1.8/9.3 oz with batteries** **accurate volume not necessary (drop) ~15 µL**	**handheld/portable** **3 × 6.5 × 5.75/1.2 lb (with 4 AA 1.5V alkaline batteries)** **accurate volume required (pipetted)**	**handheld/portable** **3.9 × 6 × 10.5/4.25 lb** **accurate volume required (pipetted)**
Clotting-based tests for which device has FDA-cleared applications	**PT (reportable range: low 7 seconds, high 75 seconds; INR: low 0.7, high 7.5)**	**PT (reportable range: low 7 seconds, high 180 seconds; INR: low 0.8, high 8.0)**	**PT/INR, APTT, Celite ACT, low-molecular–weight heparin**
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**
Method of endpoint detection	**electrochemical detection, change in impedance as sample clots**	**direct micro-mechanical clot detection, measures actual time required for clotting**	**photo-mechanical**
Quality control methods			
• Electronic	**no (not required, built-in two-level QC on each strip)**	**—**	**yes**
• Liquid	**no (not required, built-in two-level QC on each strip)**	**yes**	**no**
• Lyophilized	**no**	**yes**	**yes (plasma)**
• Integrated QC with each analysis	**yes**	**no**	**no**
• Automatic lockout for QC failure	**yes**	**no**	**yes**
• Other	**—**	**—**	**—**
Time (in minutes) to perform control plus specimen test			
• PT	**1**	**<1**	**2**
• PT and PTT	**—**	**—**	**5**
• ACT	**—**	**—**	**5–12**
Data-management capability	**yes**	**no**	**onboard**
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**	**yes**	**yes (included)**
LOINC codes transmitted with results	**—**	**no**	**no**
How labs get LOINC codes for reagent kit	**—**	**Web site, package insert, e-mail query**	**Web site**
Commercially available systems for which interfaces are up and running in active user sites	**CoagClinic and PPM from Alere**	**Orchard Software**	**—**
Lab can control analyzer remotely	**no**	**no**	**no**
Real-time wireless linkage to LIS or HIS	**no**	**no**	**yes**
Positive identification system (e.g., bar code) for:			
• Patient specimen	**no**	**no**	**yes**
• Reagent	**no**	**yes**	**yes**
Onboard system for automatic error detection	**yes, for sample (volume), reagent stability**	**yes, for sample (volume), reagent stability**	**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**	**30 minutes**
• Patient	**1**	**1**	**—**
Patient self-testing program is available	**yes**	**yes, available through IDTF**	**no**
Instrument list price	**$1,595 professional; $1,995 self-test**	**$1,062.50**	**$3,590**
Reagent rental or lease only	**no**	**no**	**yes**
Cost per sample for:			
• PT: Cost per sample for reagent rental	**volume-dependent**	**—**	**variable**
Cost per sample if device purchased	**—**	**<$5 per strip**	**$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**
CLIA '88 complexity rating	**CLIA-waived**	**CLIA-waived**	**nonwaived**
Unique advantages (provided by the vendor)	**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)**	**directly detects clot formation; emulates WHO reference tilt-tube method using micro-mechanical means of clot detection; system not affected by low hemoglobin or hematocrit levels; %CVs of 2.5%; runs true plasma controls with the actual thromboplastin and plasma of known INR; two levels of controls included with each box of strips; individually wrapped, non-refrigerated, bar-coded test strips with 24-month dating and ISI of 1.0**	**multiple tests, same device; eight-hour battery operation; low cost per test**

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.

Coagulation analyzers—point of care, self-monitoring

Part 3 of 6 *See* captodayonline.com/productguides *for an interactive version of guide*	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	Instrumentation Laboratory **Mike Wright** mwright@ilww.com 180 Hartwell Road Bedford, MA 01730 781-861-4165 www.ilus.com
Instrument name	Actalyke XL	Actalyke Mini II	GEM PCL Plus
First year sold	2002	2004	2003
No. of units sold in U.S./Outside U.S.	300+/300+	200+/1,700+	>250/>250
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	POC	POC
Specimen type	venipuncture (whole blood)	venipuncture (whole blood)	fresh whole blood, citrated whole blood (fingerstick for PT only)
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	2.0 × 7.5 × 3.5/0.75 lb
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume required (fill line on cuvette)	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	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 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)
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	APTT (whole blood), PT (whole blood), LMWH, heparin, and protamine titration (AMK)	LMWH, APTT (whole blood), PT (whole blood), AMK	—
Method of endpoint detection	two-point electromechanical soft-clot detection principle	two-point electromechanical	mechanical endpoint clotting mechanism, monitored optically
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes	yes	yes (simulated whole blood)
• Lyophilized	yes	yes	no
• Integrated QC with each analysis	no	no	no
• 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 and PTT	—	—	2
• ACT	5	5	1–5
Data-management capability	yes	no	onboard (via GEM Premier 3000)
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	—	—
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	—	—	—
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	yes
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, 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	1–2	1	30 minutes
• Patient	—	—	—
Patient self-testing program is available	no	no	no
Instrument list price	$3,805	$1,024 (battery only)–$1,334 (with printer and battery)	$5,329 (volume-dependent)
Reagent rental or lease only	purchase, lease, or reagent rental	purchase, lease, or reagent rental	outright purchase, lease, reagent rental
Cost per sample for:			
• PT: Cost per sample for reagent rental	—	—	volume-dependent
Cost per sample if device purchased	—	—	volume-dependent
• PTT: Cost per sample for reagent rental	—	—	volume-dependent
Cost per sample if device purchased	—	—	volume-dependent
• ACT: Cost per sample for reagent rental	—	—	volume-dependent
Cost per sample if device purchased	$0.74–$1.76	$0.74–$1.76	volume-dependent
CLIA '88 complexity rating	moderate	moderate	nonwaived
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 available	used in conjunction with the GEM Premier 3000/3500 analyzer; independently interfaces with HIS/LIS; consolidates 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

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

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Coagulation analyzers—point of care, self-monitoring

Part 4 of 6 *See* captodayonline.com/productguides *for an interactive version of guide*	**ITC** customerservice@itcmed.com **8 Olsen Avenue** **Edison, NJ 08820** **732-548-5700** www.itcmed.com	**ITC** customerservice@itcmed.com **8 Olsen Avenue** **Edison, NJ 08820** **732-548-5700** www.itcmed.com	**ITC** customerservice@itcmed.com **8 Olsen Avenue** **Edison, NJ 08820** **732-548-5700** www.itcmed.com
Instrument name	**ProTime Microcoagulation System**	**Hemochron Signature Elite**	**Hemochron Signature+**
First year sold	**ProTime Micro: 1995; ProTime 3: 2001; New ProTime: 2006**	**2005**	**2002**
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**	**POC**
Specimen type	**fingerstick**	**venipuncture, fingerstick, fresh whole blood, citrated blood**	**venipuncture, fingerstick, fresh whole blood, citrated blood**
Model type	**handheld/portable**	**handheld/portable**	**handheld/portable**
Dimensions in inches (H × W × D)/Weight	**2.7 × 4.5 × 8.5/3 lb**	**2 × 7.5 × 3.7/1.2 lb**	**2 × 7.5 × 3.75/12 oz**
Specimen volume needs	**small blood sample volume needed, ~25 µL**	**accurate volume not necessary (low sample volume error message if well not filled)**	**accurate volume not necessary (low sample volume error message if well not filled)**
Clotting-based tests for which device has FDA-cleared applications	**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**	**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 clot detection**	**mechanical clot detection**	**mechanical clot detection**
Quality control methods			
• Electronic	**no (not required, onboard QC)**	**yes, internal automatic EQC**	**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**	**yes**	**yes**
• Other	**two levels of onboard QC integrated into each cuvette**	**operator lockout, certification lockout, audit trail, and patient identification lockout**	**operator lockout**
Time (in minutes) to perform control plus specimen test			
• PT	**<5**	**2**	**2**
• PT and PTT	—	**2**	**2**
• ACT	—	**1–5**	**1–5**
Data-management capability	**yes**	**onboard**	**onboard**
Includes QC	**yes (onboard controls)**	**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	**communication cable available**	**available via connectivity partners**	**available via connectivity partners**
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**	**no**
Real-time wireless linkage to LIS or HIS	**no**	**yes, via connectivity partners**	**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) and reagent/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	**1**	**1**	—
• Patient	**1.5**	—	—
Patient self-testing program is available	**yes (training CD/Web-based training)**	—	—
Instrument list price	**$1,749 professional, $2,350 consumer**	**$7,900**	**$5,280**
Reagent rental or lease only	**yes**	**purchase and rental available**	**purchase and rental available**
Cost per sample for:			
• PT: Cost per sample for reagent rental	**volume-dependent**	**volume-dependent**	**volume-dependent**
Cost per sample if device purchased	**volume-dependent**	—	—
• PTT: Cost per sample for reagent rental	—	**volume-dependent**	**volume-dependent**
Cost per sample if device purchased	—	**volume-dependent**	—
• ACT: Cost per sample for reagent rental	—	—	**volume-dependent**
Cost per sample if device purchased	—	**volume-dependent**	—
CLIA '88 complexity rating	**waived**	**moderate**	**moderate**
Unique advantages (provided by the vendor)	**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**	**comprehensive microcoagulation test menu allows for standardization; 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**	**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**

Note: a dash in lieu of an answer means company did not answer question or question is not applicable

Coagulation analyzers—point of care, self-monitoring

Part 5 of 6 *See* captodayonline.com/productguides *for an interactive version of guide*	**ITC** customerservice@itcmed.com **8 Olsen Avenue** **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	**Medtronic Cardiac Surgery** **7611 Northland Drive North** **Minneapolis, MN 55428** **800-328-3320** www.medtronic.com
Instrument name **First year sold**	**Hemochron Response** **2000**	**HMS Plus** **1999**	**ACT Plus** **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 Is instrument POC or self-monitoring analyzer?	U.S./U.S. POC	U.S./U.S. POC	U.S./U.S. POC
Specimen type	venipuncture, fingerstick, fresh whole blood, citrated blood	venipuncture (whole blood)	venipuncture (whole blood)
Model type Dimensions in inches (H × W × D)/Weight Specimen volume needs	handheld/portable 8.7 × 10.5 × 7.5/6.4 lb accurate volume required (fill line on tubes)	benchtop 15.7 × 15 × 13/34 lb accurate volume required (automated dispensing)	benchtop 11 × 8 × 13/11.5 lb accurate volume required (fill line on cuvette and optional easy fill accessory)
Clotting-based tests for which device has FDA-cleared applications	ACT, (FTCA510, KACT, P214), HITT, TT, HRT, KHRT, PRT, KPRT, PDAO, PDAOK, PT, APTT, PT citrated, APTT citrated	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	mechanical clot detection
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes (simulated whole blood)	no	no
• Lyophilized	yes (simulated whole blood)	yes	yes
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	yes	optional (user defined)	optional (user defined)
• Other	operator lockout	optional operator lockout	optional operator lockout
Time (in minutes) to perform control plus specimen test			
• PT	2	—	—
• PT and PTT	2	—	—
• ACT	1–5	up to 12 (depending on patient sample)	up to 12 (depends on patient sample)
Data-management capability	onboard	yes	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	available via connectivity partners	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	yes	Telcor, RALS-Plus, Aegis POC	Telcor, RALS-Plus, Aegis POC
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	yes	yes
• Reagent	yes	yes	yes
Onboard system for automatic error detection	yes, for sample (volume) and reagent/expiration date	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	1–2	6	1
• Patient	—	—	—
Patient self-testing program is available	—	no	no
Instrument list price	$4,620	$26,000	$4,200
Reagent rental or lease only	purchase and rental available	rental and purchase available	rental and purchase available
Cost per sample for:			
• PT: Cost per sample for reagent rental	volume-dependent	—	—
Cost per sample if device purchased	—	—	—
• PTT: Cost per sample for reagent rental	volume-dependent	—	—
Cost per sample if device purchased	—	—	—
• ACT: Cost per sample for reagent rental	volume-dependent	—	—
Cost per sample if device purchased	—	customer-dependent, per contract	customer-dependent, per contract
CLIA '88 complexity rating	moderate	moderate (nonwaived)	moderate (nonwaived)
Unique advantages (provided by the vendor)	QC lockout; data-management storage; 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; 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

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.

Coagulation analyzers—point of care, self-monitoring

Part 6 of 6 *See* captodayonline.com/productguides *for an interactive version of guide*	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, high 8.0)**	**PT (reportable range: low 9.6 seconds, high 96 seconds; INR: low 0.8, high 8.0)**	**PT (reportable range: low 9.6 seconds, high 96 seconds; INR: low 0.8, high 8.0)**
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