COAGULATION ANALYZERS— POINT OF CARE, SELF-MONITORING

Part 1 of 5 **See captodayonline.com/productguides for an interactive version of guide**	**Abbott Point of Care** **Joe Freels** joe.freels@apoc.abbott.com **400 College Rd. East** **Princeton, NJ 08540** **609-454-9000**	**Accriva Diagnostics** customerservice@accriva.com **6260 Sequence Drive** **San Diego, CA 92121** **858-263-2300** www.accriva.com	**Accriva Diagnostics** customerservice@accriva.com **6260 Sequence Drive** **San Diego, CA 92121** **858-263-2300** www.accriva.com
Instrument name	i-STAT 1	Hemochron Signature Elite	Hemochron Response
First year sold	2000	2005	2000
No. of units sold in U.S./Outside U.S.	—	—	—
No. of units sold in 2016	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	U.S./Canada	U.S./U.S.	U.S./U.S.
Is instrument POC or self-monitoring analyzer?	POC	POC	POC
Specimen type	fresh whole blood from arterial, venous, or skin puncture	venipuncture, fingerstick, fresh whole blood, citrated blood	venipuncture, fresh whole blood
Model type	handheld/portable	handheld/portable	portable
Dimensions in inches (H × W × D)/Weight	9.25 × 3.03 × 2.85/22.56 oz	2 × 7.5 × 3.7/1.2 lb	8.7 × 10.5 × 7.5/6.4 lb
Specimen volume needs	17 µL–95 µL	1–2 drops (low sample volume error message provided if well not filled)	0.4–2 mL (test dependent)
Clotting-based tests for which device has FDA-cleared applications	PT-INR, ACT kaolin, ACT celite	PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR	ACT (HRFTCA510, HRFTK-ACT, P214), HRT, KHRT, PRT, KPRT, PDAO, PDAOK
Tests using other methodologies for which device has FDA-cleared applications	chemistries/electrolytes (sodium, potassium, chloride, TCO2, anion gap, ionized calcium, glucose, urea nitrogen, creatinine, lactate); hematology (hematocrit, hemoglobin); blood gases (pH, PCO2, PO2, TCO2, HCO3, base excess, sO2); cardiac markers (cTnI, CK-MB, BNP), β-hCG	—	—
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	mechanical clot detection	mechanical clot detection
Quality control methods			
• Electronic	yes	yes (internal automatic EQC)	yes
• Liquid	yes	yes (simulated whole blood)	yes (simulated whole blood)
• Lyophilized	yes (plasma)	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	—	operator lockout, certification lockout, audit trail, and patient identification lockout	operator lockout
Time (in minutes) to perform control plus specimen test			
• PT	3+	2	—
• PT and PTT	—	2	—
• ACT	3+	>5	>8
Data-management capability	optional add-on	onboard	onboard
• 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	—	available via connectivity partners
Commercially available systems for which interfaces are up and running in active user sites	Sunquest, Cerner, Soft, McKesson, Meditech, GE, Siemens, Vista, others	Telcor QML, Alere RALS-Web 3, Aegis POC, Conworks UniPOC	Telcor QML, Alere RALS-Web 3, Aegis POC, Conworks UniPOC
LOINC codes transmitted with results	no	—	—
How labs get LOINC codes for reagent kit	package insert	—	—
Lab can control analyzer remotely	yes	no	no
Real-time wireless linkage to LIS or HIS	yes	yes, via connectivity partners	no
Positive identification system (e.g. barcode) for:			
• Patient specimen	yes	no	no
• Reagent	yes	yes	yes
Onboard system for automatic error detection	yes	yes, for sample (volume), reagent expiration date	yes, for sample (volume), reagent expiration date
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approximate number of training hours needed for:			
• Medical staff	1	1–2	1–2
• Patient	—	—	—
Patient self-testing program is available	no	—	—
Instrument list price	—	inquire	inquire
Reagent rental or lease only	no	purchase and usage agreement available (reagent rental)	purchase and usage agreement available (reagent rental)
Cost per sample:			
• PT: for reagent rental	—	volume dependent	—
if device purchased	—	—	—
• PTT: for reagent rental	—	—	—
if device purchased	—	volume dependent	—
• ACT: for reagent rental	—	—	volume dependent
if device purchased	—	volume dependent	—
CLIA '88 complexity rating	moderate	moderate	moderate
Distinguishing features (supplied by company)	broad testing menu; many data-management and interfacing options; easy to use; integrated wireless capability for real-time transmission to EMR	comprehensive microcoagulation test menu allows for standardization; integrated barcode scanner; compliance technology; QC, PID, and OID; lockout and tracking; data-management storage and printing; optimal connectivity options; 15 µL blood volume; Ethernet and RS232 ports; standardizes anticoagulation therapy monitoring across the continuum of care while enhancing compliance and patient safety and maximizing efficiencies	QC lockout; data-management storage; connectivity options; RxDx heparin/protamine dosing system

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 5 **See captodayonline.com/productguides for an interactive version of guide**	**CoaguSense** **Douglas Patterson** dpatterson@coagusense.com **48377 Fremont Blvd., Suite 113** **Fremont, CA 94538** **866-903-0890** www.coagusense.com	**Helena Laboratories Point of Care** **David Pearman** dpearman@helena.com **1530 Lindbergh Drive** **Beaumont, TX 77707** **800-231-5663** www.helena.com	**Helena Laboratories Point of Care** **David Pearman** dpearman@helena.com **1530 Lindbergh Drive** **Beaumont, TX 77707** **800-231-5663** www.helena.com
Instrument name	Coag-Sense PT/INR Monitoring System	Cascade Abrazo	Actalyke Mini II
First year sold	2010	2014 (EU/CE; 510(k) submitted to FDA)	2004
No. of units sold in U.S./Outside U.S.	—	—/200+	450+/5,000+
No. of units sold in 2016	—	—	—
• 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 and self-monitoring	POC	POC
Specimen type	fingerstick	fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma)	venipuncture (whole blood)
Model type	handheld/portable	handheld/portable	portable
Dimensions in inches (H × W × D)/Weight	3 × 6.5 × 5.75/1.2 lb (with 4 AA 1.5V alkaline batteries)	3.4 × 3.5 × 8.5/1.65 lb	4.8 × 6.1 × 6.3/5.3 lb
Specimen volume needs	accurate volume required (pipetted)	accurate volume not necessary (drop)	accurate volume required (fill line on cuvette)
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range—low: 7 seconds; high: 180 seconds; INR—low: 0.8 seconds; high: 8.0 seconds)	—	activated clotting time (whole blood), MAX-ACT, celite, kaolin, glass
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	—	PT-C, APTT, c-ACT, c-ACT-LR, direct thrombin inhibitors, LMWH, fibrinogen, heparin titration, protamine titration, direct oral anticoagulants (DOACs)	—
Method of endpoint detection	direct micromechanical clot detection, measures actual time required for clotting	optical/mechanical	two-point electromechanical soft-clot detection principle
Quality control methods			
• Electronic	—	yes	yes
• Liquid	yes	—	yes
• Lyophilized	yes	yes (plasma)	yes
• Integrated QC with each analysis	no	yes	no
• Automatic lockout for QC failure	no	yes (available feature)	no
• Other	—	—	—
Time (in minutes) to perform control plus specimen test			
• PT	<1	2	—
• PT and PTT	—	2–5	—
• ACT	—	variable per heparin concentration; calculated value faster than real time at therapeutic levels	5
Data-management capability	no	onboard, optional add-on	no
• Includes QC	—	yes	no
System can automatically transfer data to information system			
• Patient data	yes	yes	—
• QC data	yes	yes	—
Interface supplied by instrument vendor	yes	no	—
Commercially available systems for which interfaces are up and running in active user sites	Orchard Software	—	—
LOINC codes transmitted with results	no	no	no
How labs get LOINC codes for reagent kit	website, package insert, email query	—	—
Lab can control analyzer remotely	no	yes	no
Real-time wireless linkage to LIS or HIS	yes, optional	yes (radio frequency, infrared)	—
Positive identification system (e.g. barcode) for:			
• Patient specimen	yes, optional	yes	no
• Reagent	yes	yes (2-D barcode reader)	no
Onboard system for automatic error detection	yes, for sample (volume), reagent stability	yes, for sample (volume), reagent/cuvette expiration date	yes, for stuck magnet, printer problems
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approximate number of training hours needed for:			
• Medical staff	1	1	1
• Patient	1	—	—
Patient self-testing program is available	yes, available through IDTF	no	no
Instrument list price	$1,062.50	$5,995	$1,107–$1,442
Reagent rental or lease only	no	—	purchase, lease, or reagent rental
Cost per sample:			
• PT: for reagent rental	—	variable	—
if device purchased	<$4 per strip	variable	—
• PTT: for reagent rental	—	variable	—
if device purchased	—	variable	—
• ACT: for reagent rental	—	variable	—
if device purchased	—	variable	$0.74–$1.76
CLIA '88 complexity rating	CLIA waived	nonwaived	nonwaived
Distinguishing features (supplied by company)	directly detects clot formation; emulates WHO reference tilt-tube method using micromechanical means of clot detection; system not affected by low hemoglobin or hematocrit levels; %CVs of 2.5 percent; 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, nonrefrigerated, barcoded test strips with 24-month dating and ISI of 1.0	uses a card-based technology that affords a smaller reagent storage footprint; true smart-card type technology by using a 2-D barcode labeling system; incorporates enabling technology in an ergonomic package; running a test is user-friendly, requiring only three steps: scan the reagent card barcode, insert the reagent card, present the sample via hanging drop; digital device offers versatility and features unique to its class, such as a color touchscreen monitor and connectivity via USB configuration or wireless (such as Wi-Fi and Bluetooth)	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 5 **See captodayonline.com/productguides for an interactive version of guide**	**Helena Laboratories Point of Care** **David Pearman** dpearman@helena.com **1530 Lindbergh Drive** **Beaumont, TX 77707** **800-231-5663** www.helena.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	Actalyke XL	ACT Plus	HMS Plus
First year sold	2002	2003	1999
No. of units sold in U.S./Outside U.S.	300+/400+	—	—
No. of units sold in 2016	—	—	—
• 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 (whole blood)	venipuncture (whole blood)	venipuncture (whole blood)
Model type	portable	benchtop	benchtop
Dimensions in inches (H × W × D)/Weight	8 × 10.7 × 12/15 lb	11 × 8 × 13/11.5 lb	15.7 × 15 × 13/34 lb
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume required (fill line on cuvette and optional easy fill accessory)	accurate volume required (automated dispensing)
Clotting-based tests for which device has FDA-cleared applications	activated clotting time (whole blood), MAX-ACT, celite, kaolin, glass	ACT (high range, low range, recalcified, high-range heparinase)	ACT, heparin dose response, heparin protamine titration
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	two-point electromechanical soft-clot detection principle	mechanical clot detection	mechanical clot detection
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes	no	no
• Lyophilized	yes	yes	yes
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	yes	optional (user defined)	optional (user defined)
• Other	data management for entering heparin dose, L-J chart generation for all controls	optional operator lockout	optional operator lockout
Time (in minutes) to perform control plus specimen test			
• PT	—	—	—
• PT and PTT	—	—	—
• ACT	5	up to 12 (depending on patient sample)	up to 12 (depending on patient sample)
Data-management capability	yes	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	interface specifications supplied, POCT1-A compliant	no	no
Commercially available systems for which interfaces are up and running in active user sites	—	Telcor, Alere Informatics	Telcor, Alere Informatics
LOINC codes transmitted with results	no	—	—
How labs get LOINC codes for reagent kit	—	available from technical support	available from technical support
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	yes	no	no
Positive identification system (e.g. barcode) for:			
• Patient specimen	yes	yes	yes
• Reagent	yes (all disposables have barcode for identification with use on any Actalyke model)	yes	yes
Onboard system for automatic error detection	yes, for stuck magnet, no tube; mechanical instrument parameters only; well rotation, temperature, and detection settings	yes	yes
Training provided with instrument purchase	yes (on site)	yes (on site)	yes (on site)
Approximate number of training hours needed for:			
• Medical staff	1–2	1	6
• Patient	—	—	—
Patient self-testing program is available	no	no	no
Instrument list price	$4,114	$4,400	$29,000
Reagent rental or lease only	purchase, lease, or reagent rental	purchase and rental available	purchase and rental available
Cost per sample:			
• PT: for reagent rental	—	—	—
if device purchased	—	—	—
• PTT: for reagent rental	—	—	—
if device purchased	—	—	—
• ACT: for reagent rental	—	—	—
if device purchased	$0.74–$1.76	customer dependent, per contract	customer dependent, per contract
CLIA '88 complexity rating	moderate	moderate (nonwaived)	moderate (nonwaived)
Distinguishing features (supplied by company)	two-point electromechanical soft-clot detection principle; MAX-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 that simulates and mimics actual blood-clot formation for accurate ECT challenges; integrated printer; 3.5-inch diskette storage	data-management software application; duplicate test results; optional barcode scanner; optional easy filling accessory; ACT Plus Education Program CD	automated sample dispensing; constant temperature control; multiple testing capability; heparin dose response; heparin protamine titration; high-range ACT; optional barcode scanner; optional data-management software; HMS Plus Education Program CD

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COAGULATION ANALYZERS— POINT OF CARE, SELF-MONITORING

Part 4 of 5 **See captodayonline.com/productguides for an interactive version of guide**	**Roche Diagnostics** **Chris Grams** christopher.grams@roche.com **9115 Hague Rd.** **Indianapolis, IN 46250** **317-521-1829** coaguchek-usa.com	**Roche Diagnostics** **Chris Grams** christopher.grams@roche.com **9115 Hague Rd.** **Indianapolis, IN 46250** **317-521-1829** coaguchek-usa.com	**Roche Diagnostics** **Chris Grams** christopher.grams@roche.com **9115 Hague Rd.** **Indianapolis, IN 46250** **317-521-1829** coaguchek-usa.com
Instrument name	CoaguChek XS Pro PT Test System	CoaguChek XS Plus PT Test System	CoaguChek XS PT Test System
First year sold	2010	2007	2006 (international)/2007 (U.S.)
No. of units sold in U.S./Outside U.S.	—	—	—
No. of units sold in 2016	—	—	—
• units sold to:	—	—	—
Country where analyzer designed/Manufactured	Germany/Germany	Germany/Germany	Germany/Germany
Is instrument POC or self-monitoring analyzer?	POC	POC	POC and self-monitoring
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	9.09 × 3.89 × 1.65/12.35 oz	7.28 × 3.89 × 1.65/12.35 oz	5.43 × 3.07 × 1.10/4.48 oz
Specimen volume needs	8 µL	8 µL	8 µL
Clotting-based tests for which device has FDA-cleared applications	CoaguChek XS system monitors coagulation (blood-clotting) values (prothrombin time, PT, Quick value) with CoaguChek XS PT test strips	CoaguChek XS system monitors coagulation (blood-clotting) values (prothrombin time, PT, Quick value) with CoaguChek XS PT test strips	CoaguChek XS system monitors coagulation (blood-clotting) values (prothrombin time, PT, Quick value) with CoaguChek XS PT test strips
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	yes (available as an option but not required due to onboard controls)	yes (available as an option but not required due to onboard controls)	no
• Lyophilized	no	no	no
• Integrated QC with each analysis	yes	yes	yes
• Automatic lockout for QC failure	yes	yes	no
• 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	yes	yes	no
• Includes QC	yes	yes	no
System can automatically transfer data to information system			
• Patient data	yes	yes	no
• QC data	yes	yes	no
Interface supplied by instrument vendor	POCT1-A	POCT1-A	with license
Commercially available systems for which interfaces are up and running in active user sites	cobas IT 1000, Alere RALS-Plus, TELCOR QML	cobas IT 1000, Alere RALS-Plus, TELCOR QML	yes
LOINC codes transmitted with results	no	no	no
How labs get LOINC codes for reagent kit	—	—	—
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	no
Positive identification system (e.g. barcode) for:			
• Patient specimen	yes	no	no
• Reagent	yes	no	no
Onboard system for automatic error detection	yes	yes	yes
Training provided with instrument purchase	yes	yes	yes
Approximate number of training hours needed for:			
• Medical staff	1.5	1.5	1
• Patient	—	—	trainer dependent
Patient self-testing program is available	no	no	yes
Instrument list price	—	—	—
Reagent rental or lease only	no	no	no
Cost per sample:			
• PT: for reagent rental	—	—	—
if device purchased	—	—	—
• PTT: for reagent rental	—	—	—
if device purchased	—	—	—
• ACT: for reagent rental	—	—	—
if device purchased	—	—	—
CLIA '88 complexity rating	moderate	CLIA waived	CLIA waived
Distinguishing features (supplied by company)	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; top or side dosing; results in one minute or less; icon-driven color screen interface, memory of 2,000 patient and 500 optional liquid QC tests, ability to add comments with each patient and liquid quality control test; integrated barcode scanner able to scan operator and patient IDs	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; top or side dosing; results in one minute or less; icon-driven color screen interface, memory of 2,000 patient and 500 optional liquid QC 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; top or side dosing; results in one minute or less

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COAGULATION ANALYZERS— POINT OF CARE, SELF-MONITORING

Part 5 of 5 **See captodayonline.com/productguides for an interactive version of guide**	**Siemens Healthineers** **Maria Peluso-Lapsley** maria.peluso-lapsley@siemens-healthineers.com **2 Edgewater Drive** **Norwood, MA 02062** **781-269-3779** www.usa.siemens.com/xprecia
Instrument name	Xprecia Stride Coagulation Analyzer
First year sold	2015 (outside U.S.)
No. of units sold in U.S./Outside U.S.	—
No. of units sold in 2016	—
• units sold to:	—
Country where analyzer designed/Manufactured	Australia/Malaysia
Is instrument POC or self-monitoring analyzer?	POC
Specimen type	fingerstick
Model type	handheld/portable
Dimensions in inches (H × W × D)/Weight	6.7 × 2.8 × 1.6/10.6 oz (with batteries)
Specimen volume needs	accurate volume not necessary (drop, 6 µL)
Clotting-based tests for which device has FDA-cleared applications	PT (INR 0.8–4.5)
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	Electrochemical technology with amperometric (electric current) detection of thrombin activity
Quality control methods	
• Electronic	yes
• Liquid	yes
• Lyophilized	—
• Integrated QC with each analysis	—
• Automatic lockout for QC failure	yes
• Other	—
Time (in minutes) to perform control plus specimen test	
• PT	~1 minute (depending on clotting time)
• PT and PTT	—
• ACT	—
Data-management capability	Data-management software CD provided with analyzer for managing patient, QC results, transmitting to EMR/LIS/HIS, managing operators, and software upgrades
• Includes QC	yes
System can automatically transfer data to information system	
• Patient data	yes
• QC data	yes
Interface supplied by instrument vendor	yes
Commercially available systems for which interfaces are up and running in active user sites	—
LOINC codes transmitted with results	no
How labs get LOINC codes for reagent kit	5902-2 (www.loinc.org)
Lab can control analyzer remotely	no
Real-time wireless linkage to LIS or HIS	no
Positive identification system (e.g. barcode) for:	
• Patient specimen	yes
• Reagent	yes (integrated barcode scanner records strip and QC lot numbers with calibrated values; operator and patient IDs may be scanned or entered manually on the touchscreen)
Onboard system for automatic error detection	yes (detects test-strip degradation due to exposure to environmental conditions; electronic, signal, software, and memory integrity checks; performs various checks along the entire testing procedure to ensure process integrity)
Training provided with instrument purchase	—
Approximate number of training hours needed for:	
• Medical staff	on-screen tutorials with intuitive animation to facilitate operator training
• Patient	—
Patient self-testing program is available	—
Instrument list price	—
Reagent rental or lease only	—
Cost per sample:	
• PT: for reagent rental	—
if device purchased	—
• PTT: for reagent rental	—
if device purchased	—
• ACT: for reagent rental	—
if device purchased	—
CLIA '88 complexity rating	moderately complex
Distinguishing features (supplied by company)	• usability: touchscreen features include bright-color interface with step-by-step instructions; display shows clear, easy-to-read results; lot calibration is simple using integrated barcode scanner • safety: test-strip eject button; operator lockout feature; data transfer occurs seamlessly and securely via USB connection • accuracy: Xprecia PT/INR test strips and Siemens' central lab analyzers use same Dade Innovin reagent and liquid QC; barcode scanner offers fast, accurate patient and operator ID entry with optional manual entry on touchscreen

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