SURVEY OF INSTRUMENTS

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

Part 1 of 7	Abbott Laboratories Eric Perreault eric.perreault@abbott.com 4A Crosby Dr. Bedford, MA 01730-1402 781-276-4797	Abbott Laboratories Eric Perreault eric.perreault@abbott.com 4A Crosby Dr. Bedford, MA 01730-1402 781-276-4797
Instrument name	iStat	iStat 1
First year sold	1992	2000
No. of units sold in U.S./outside U.S.	25,000/—	3,000/2,500
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.
Specimen type	fingerstick, venipuncture (whole blood, anticoagulated whole blood)	fingerstick, venipuncture (whole blood, anticoagulated whole blood)
Model type	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/weight	8.25 x 2.52 x 2.05/18.34 oz	8.26 x 2.52 x 2.05/18.34 oz
Specimen volume needs	accurate volume required (fill line on cartridge)	accurate volume required (fill line on cuvette)
Clotting-based tests for which device has FDA-cleared applications	PT, ACT	PT, ACTc
Tests using other methodologies for which device has FDA-cleared applications	none	—
FDA-cleared tests but not yet clinically released	none	—
Tests submitted for 510(k) clearance	ACTk	—
Tests in development but not yet submitted for clearance	PTT	ACTk, PTT
How labs get LOINC codes for reagent kit	—	package insert
Method of endpoint detection	electrogenic	electrogenic
Quality control methods		
• Electronic	yes	yes
• Liquid	yes	yes
• Lyophilized	no	no
• Integrated QC with each analysis	yes	yes
• Automatic lockout for QC failure	yes	yes
• Other	n/a	—
Time (in minutes) to perform control plus specimen test		
• PT:	2 min	2 min
• PT & PTT:	—	—
• ACT:	2 min	2 min
Data management capability	onboard & optional add-on (SW mftr: iStat)	onboard & optional add-on (SW mftr: iStat)
Includes QC	yes (L-J plots)	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 (additional cost)
LOINC codes transmitted with results	—	yes
Commercially available systems for which interfaces are up and running in active user sites	Cerner, Sunquest, HBOC, Citation, Meditech, others	Cerner, Sunquest, HBOC, Citation, Meditech, others
Lab can control analyzer remotely	yes	yes
Real-time wireless linkage to LIS or HIS	yes (infrared)	yes
Positive identification system (e.g. bar code) for:		
• Patient specimen	yes	yes
• Reagent	yes	yes
Onboard system for automatic error detection	yes, for sample (volume)	yes, for sample (volume), reagent/cuvette expiration date
Training provided with instrument purchase	yes (on-site)	yes (on-site)
Approx. number of training hours needed for:		
• Medical staff	—	1 hr
• Patient	n/a	n/a
Patient self-testing program is available	no	no
Instrument list price	$7,900	$9,500
Reagent rental or lease only	no	no
Cost per sample for:		
• PT: Cost per sample for reagent rental	n/a	n/a
Cost per sample if device purchased	n/a	n/a
• PTT: Cost per sample for reagent rental	n/a	n/a
Cost per sample if device purchased	n/a	n/a
• ACT: Cost per sample for reagent rental	call for pricing	n/a
Cost per sample if device purchased	call for pricing	n/a
CLIA '88 complexity rating	moderate	moderate
Unique advantages	• handheld • QC lockout/operator lockout • bar-code scanner	• handheld portable device • QC lockout/operator lockout • menu: blood gas, chemistry, electrolytes, coagulation

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

Survey editor: Raymond D. Aller, MD

SURVEY OF INSTRUMENTS

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

Part 2 of 7	Bayer Diagnostics Jan Price jan.price.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6091 www.bayerdiag.com	Bayer Diagnostics Jan Price jan.price.b@bayer.com 511 Benedict Ave. Tarrytown, NY 10591 914-333-6091 www.bayerdiag.com	Beckman Coulter Inc. Primary Care Diagnostics Michael Coté mjcote@beckman.com 1050 Page Mill Rd. M/S P140 Palo Alto, CA 94303 650-845-3489 www.beckmancoulter.com/pcd
Instrument name	Rapidpoint Coag	Rapidpoint Accent	Icon PT; Icon PT Pro
First year sold	1995	2001	2003
No. of units sold in U.S./outside U.S.	—/—	n/a/n/a	—/—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Specimen type	fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma)	whole blood, anticoagulated whole blood (for OR use)	fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma)
Model type	handheld/portable	handheld/portable	handheld/portable (pocket size)
Dimensions in inches (H x W x D)/weight	3.9 x 6 x 10.5/4.25 lb	11.7 x 9.3 x 17/8.8 lb, 13 lb with coag analyzer	$1^{5}/_{16}$ x $2^{13}/_{16}$ x $5^{1}/_{4}$/5.9 oz (166 g)
Specimen volume needs	accurate volume not necessary (drop-35 µL); test tube citrated sample must be accurately drawn (9:1 blood to citrate)	accurate volume not necessary (drop-35 µL)	accurate volume not necessary (drop and tube), 15 µL sample drop/citrated collection
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 6 sec, high 150 sec; INR: low 0.8, high 4.0); PTT (reportable range: low 15 sec, high 300 sec); heparin management test (HMT) alternative to ACT (measures 1–10 units per mL of heparin)	heparin management test (HMT) alternative to ACT (measures 1–10 units per mL of hep.); heparin titration test (HTT); protamine response test (PRT)	PT (INR: low 0.7 to high 7.0)
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	low-range heparin management test	none	none
Tests submitted for 510(k) clearance	ecarin clotting time, enoxaparin	none	none
Tests in development but not yet submitted for clearance	none	none	none
How labs get LOINC codes for reagent kit	—	—	—
Method of endpoint detection	fibrin clot impedes movement of small metal particles in a flat test chamber	fibrin clot impedes movement of small metal particles in a flat test chamber	fluorescent thrombin substrate
Quality control methods			
• Electronic	yes	yes	yes
• Liquid	yes (plasma)	yes (plasma)	no
• Lyophilized	yes (plasma)	yes (plasma)	yes (plasma)
• Integrated QC with each analysis	no	no	no
• Automatic lockout for QC failure	yes	yes	yes (factory set)
• Other	analyzer can be programmed to prevent patient testing unless QC performed at specified intervals	analyzer can be programmed to prevent patient testing unless QC performed at specified intervals	n/a
Time (in minutes) to perform control plus specimen test			
• PT:	<5	n/a	8 (with electronic control both levels)
• PT & PTT:	<5	n/a	n/a
• ACT:	<5	n/a	n/a
Data management capability	onboard, optional add-on	onboard, optional add-on	onboard
Includes QC	yes	yes (L-J plots)	yes
System can automatically transfer data to information system			
• Patient data	yes	yes	no
• QC data	yes	yes	no
Interface supplied by instrument vendor	yes (additional cost, can be included in reagent rental and lease programs)	yes (additional cost, can be included in reagent rental and lease programs)	no
LOINC codes transmitted with results	—	—	—
Commercially available systems for which interfaces are up and running in active user sites	connects to LIS via Helix Interface for scripting, ASTM, HL7, RALS+ System, etc.	connects to LIS via Helix Interface, RALS+ System	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	yes	yes	yes
• Reagent	yes; each test card contains lot-specific information for reagents; instrument allows patient and operator IDs to be entered via alphanumeric keypad	yes; each test card contains lot-specific information for reagents; instrument allows patient and operator IDs to be entered via touchscreen	yes; system has several test modes that identify sample type (capillary, citrated whole blood, or plasma) as well as liquid or electronic controls
Onboard system for automatic error detection	yes, for reagent/card expiration date	yes, for reagent/card expiration date	yes, for sample (volume); system incorporates a number of error detection modes related to test sample processing and temp. monitors and indicating desicants to ensure proper test strip storage
Training provided with instrument purchase	yes (on-site)	yes (on-site)	yes (on-site)
Approx. number of training hours needed for:			
• Medical staff	1–2 hr	2–4 hr	1 hr
• Patient	n/a	n/a	n/a
Patient self-testing program is available	no	no	n/a
Instrument list price	$5,000	$14,000	$1,800 (2003 estimate)
Reagent rental or lease only	purchase or reagent rental	purchase or reagent rental	no
Cost per sample for:			
• PT: Cost per sample for reagent rental	varies based on volume of instruments and test cards	n/a	n/a
Cost per sample if device purchased	$3.50–$6.00	n/a	$3.50–$5.00
• PTT: Cost per sample for reagent rental	—	n/a	n/a
Cost per sample if device purchased	$3.50–$6.00	n/a	n/a
• ACT: Cost per sample for reagent rental	$3.50–$6.00	n/a	n/a
Cost per sample if device purchased	$3.50–$6.00	n/a	n/a
CLIA '88 complexity rating	moderate	moderate	CLIA waived, moderate
Unique advantages	• will analyze/monitor citrated or noncitrated samples • menu of PT, APTT, HMT (ACT) tests with expansion capability • Rapidlink Data Mgmt. system will allow connectivity to LIS/HIS; users can generate accession numbers for patient test results • patient & operator ID, restricted analyzer access, 1,000 result memory, QC lockout, QC range assignment • Rapidpoint Accent—total heparin management system	• brings patients into safe coagulation range sooner • reduces risk of post-op complications • improves decision-making speed and accuracy • ease-of-use (touchscreen)	• handheld/portable/pocket size • can use all 3 sample types: capillary, citrated whole blood, and plasma • Icon PT system control provides a Level 1 and Level 2 system check that meets the CLIA QC requirements efficiently and inexpensively • moving the unit during sample application or while test is running will not affect test results

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

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

Part 3 of 7	Helena Point of Care Jim Campbell pointofcare@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 800-231-5663 www.helena.com	Helena Point of Care Jim Campbell pointofcare@helena.com 1530 Lindbergh Dr. Beaumont, TX 77704 800-231-5663 www.helena.com	HemoSense Inc. Dale Clendon 600 Valley Way Milpitas, CA 95035 408-719-1393 www.hemosense.com
Instrument name	Actalyke XL	Actalyke Mini	INRatio
First year sold	2002	2001	cleared for professional use, 2002; FDA CLEARANCE PENDING for patient self-testing
No. of units sold in U.S./outside U.S.	25+/—	n/a/250+	n/a/n/a
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Specimen type	venipuncture (whole blood)	venipuncture (whole blood)	fingerstick
Model type	portable	benchtop	handheld/portable
Dimensions in inches (H x W x D)/weight	5.6 x 10.7 x 10.3/15 lb	6.25 x 6 x 4.75/5.3 lb	6.5 x 3 x 2 in/7 oz
Specimen volume needs	accurate volume required (fill line on cuvette)	accurate volume required (fill line on cuvette)	accurate volume not necessary (drop)
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
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	—	PT (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5)
Tests in development but not yet submitted for clearance	APTT (whole blood), PT (whole blood), heparin assay, protamine assay, therapeutic assessment kit (TAK), LMWH	LMWH, APTT (whole blood), PT (whole blood)	planned tests: APTT, ACT
How labs get LOINC codes for reagent kit	n/a	n/a	n/a
Method of endpoint detection	two-point electromechanical soft-clot detection principle	two-point electromechanical	change in impedance of the sample when clotting occurs
Quality control methods			
• Electronic	yes	yes	no (not required, built-in QC on patient strip)
• Liquid	yes (simulated whole blood)	yes (simulated whole blood)	no (not required, built-in QC on patient strip)
• Lyophilized	yes (simulated whole blood)	yes (simulated whole blood)	no
• Integrated QC with each analysis	no	no	yes (automatic self-check diagnosis)
• Automatic lockout for QC failure	yes	no	yes
• Other	data management for entering heparin dose, L-J chart generation for all controls	—	impedance check strip
Time (in minutes) to perform control plus specimen test			
• PT:	n/a	n/a	<2
• PT & PTT:	n/a	n/a	n/a
• ACT:	5	5	n/a
Data management capability	yes	no	onboard
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	n/a	—	yes (included in instrument price)
LOINC codes transmitted with results	no	no	—
Commercially available systems for which interfaces are up and running in active user sites	n/a	—	n/a
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	yes	—	planned
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 specimen placement	yes, for sample (volume), reagent stability
Training provided with instrument purchase	yes (on-site)	yes (on-site)	yes (on-site)
Approx. number of training hours needed for:			
• Medical staff	1–2 hr	1 hr	1 hr
• Patient	n/a	n/a	1 hr
Patient self-testing program is available	no	no	available when cleared
Instrument list price	$3,595	$1,049–$1,149 with printer	TBD
Reagent rental or lease only	no	no	no
Cost per sample for:			
• PT: Cost per sample for reagent rental	n/a	—	TBD
Cost per sample if device purchased	n/a	—	TBD
• PTT: Cost per sample for reagent rental	n/a	—	n/a
Cost per sample if device purchased	n/a	—	n/a
• ACT: Cost per sample for reagent rental	n/a	—	n/a
Cost per sample if device purchased	$0.74–$1.76	$0.74–$1.76	n/a
CLIA '88 complexity rating	moderate	not yet rated	not yet rated
Unique advantages	• two-point electromechanical "soft-clot" detection principle • MAX-ACT: maximum factor XII activation ACT test, 0.5 mL blood volume, linear up to 10 units of heparin, safer plastic tube construction, for use on Actalyke and Hemochron instruments • electronic clotting tube (EQC) that simulates and mimics actual blood clot formation for accurate EQC challenges • integrated printer • 3.5 in diskette storage	• two-point electromechanical "soft-clot" detection • magnetic detection device—electronic QC/revolution • MAX-ACT tubes, 0.5 mL volume & linear to 6 U/mL	• onboard QC—no external QC needed; therefore the best value for clinician and patient • fast total test of <2 min • very simple test procedure

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

SURVEY OF INSTRUMENTS

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

Part 4 of 7	Instrumentation Laboratory Todd Sheldon tsheldon@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4270 www.ilus.com	International Technidyne Corp. Bill Fitzgerald bfitzgerald@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com	International Technidyne Corp. George Halleck ghalleck@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com
Instrument name	Gem PCL (Portable Coagulation Laboratory)	Hemochron 401	ProTime Microcoagulation System/ProTime 3
First year sold	1998	1988	ProTime Micro: 1996; ProTime 3: 2001
No. of units sold in U.S./outside U.S.	150+/—	—/—	—/—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Specimen type	fingerstick, venipuncture (whole blood, anticoagulated whole blood)	venipuncture (whole blood, anticoagulated whole blood)	fingerstick
Model type	handheld/portable	portable	handheld/portable
Dimensions in inches (H x W x D)/weight	5.5 x 2 x 3.5/0.75 lb	12.5 x 18 x 23/1.7 kg	2.5 x 4.5 x 9/3 lb
Specimen volume needs	accurate volume not necessary (~50 µL), low sample volume error message if well not filled	accurate volume required (fill line on tube) 0.4–2.0 µL	accurate volume not required (fill line on sample cup) PT 5, 65 µL; PT 3, 25 µL
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 10 sec, high 150 sec; INR: low 0.8, high 12), PTT (reportable range: low 20 sec, high 300 sec), ACT (65–1005 sec), ACT–low range (67–400 sec)	PT (reportable range: low ~50 sec, high ~340 sec; INR: low 1, high 6), PT (citrated), APTT (reportable range: low 24 sec, high 120 sec plasma equiv.), ACT (FTCA5IO, KACT, P214), HiTT, TT, HNTT, Fib., HRT, KNRT, PRT, KPRT, PDAO, KPDAO, APTT (citrated)	PT (reportable range: low 10 sec., high 130 sec.; INR: low 0.8, high 9.9)
Tests using other methodologies for which device has FDA-cleared applications	none	none	none
FDA-cleared tests but not yet clinically released	none	none	none
Tests submitted for 510(k) clearance	none	none	none
Tests in development but not yet submitted for clearance	none	none	—
How labs get LOINC codes for reagent kit	n/a	—	—
Method of endpoint detection	mechanical endpoint clotting mechanism, monitored optically	mechanical clot detection	optical detection of clot
Quality control methods			
• Electronic	yes	yes	no (not required, onboard QC)
• Liquid	yes (simulated whole blood)	yes (simulated whole blood)	yes (available as an option but not required due to onboard controls)
• Lyophilized	yes	yes (simulated whole blood)	no
• Integrated QC with each analysis	no	no	yes
• Automatic lockout for QC failure	no	no	yes
• Other	n/a	n/a	2 levels of onboard QC integrated into each cuvette
Time (in minutes) to perform control plus specimen test			
• PT:	2	2	6
• PT & PTT:	2	2	n/a
• ACT:	1–5	1–5	n/a
Data management capability	onboard (via Gem Premier 3000)	no	yes
Includes QC	yes	no	yes
System can automatically transfer data to information system			
• Patient data	yes	no	no
• QC data	yes	no	no
Interface supplied by instrument vendor	yes to Gem Premier 3000	n/a	n/a
LOINC codes transmitted with results	no	—	—
Commercially available systems for which interfaces are up and running in active user sites	n/a	n/a	n/a
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	no	yes
Onboard system for automatic error detection	yes, for sample (volume), reagent/cuvette expiration date, and instrument	yes (instrument-related)	yes, for sample (volume) and reagent/cuvette expiration date
Training provided with instrument purchase	yes (on-site)	yes (on-site)	yes (on-site)
Approx. number of training hours needed for:			
• Medical staff	0.5 hr	1 hr	1 hr
• Patient	n/a	n/a	1.5 hr
Patient self-testing program is available	no	no	yes (programmed instruction/video)
Instrument list price	$3,670 (volume dependent)	$3,500	$1,500 professional, $2,000 patient
Reagent rental or lease only	outright purchase, lease, reagent rental	no	no
Cost per sample for:			
• PT: Cost per sample for reagent rental	varies with volume	n/a	n/a
Cost per sample if device purchased	varies with volume	$2.95	$5 for professional/$10 for consumer
• PTT: Cost per sample for reagent rental	varies with volume	n/a	n/a
Cost per sample if device purchased	varies with volume	$2.85	n/a
• ACT: Cost per sample for reagent rental	varies with volume	n/a	n/a
Cost per sample if device purchased	varies with volume	$1.34–$1.43	n/a
CLIA '88 complexity rating	moderate	moderate	waived
Unique advantages	• Gem PCL is a component of the Gem Premier 3100; the only system that provides analysis of blood gases, hematocrit, electrolytes, metabolites, and coagulation • comprehensive POC coagulation menu that allows for POC coagulation analysis throughout an institution; whole blood PT, APTT, ACT, and ACT–low range • onboard data management	• gold standard • ease-of-use • consistent, accurate results	• onboard quality controls, which eliminates need for separate liquid controls • one cuvette needed per patient, which includes the upper and lower control levels as well as patient test • recombinant human thromboplastin reagent, with ISI=1.0, as recommended by AHA, CAP, WHO • 30-day room temperature storage of cuvettes

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

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

Part 5 of 7	International Technidyne Corp. Bill Fitzgerald bfitzgerald@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com	International Technidyne Corp. Bill Fitzgerald bfitzgerald@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com	LifeScan Inc., a Johnson & Johnson company Customer Service customerservice@lifescan.com 1000 Gibraltar Drive Milpitas, CA 95035 877-520-8608 www.lifescan.com
Instrument name	Hemochron Jr.—Signature/Signature+	Hemochron Response	Harmony INR Monitoring System (for patient self-testing and INR monitoring in professional settings)
First year sold	1998; Signature+ introduced in 2002	2000	2002
No. of units sold in U.S./outside U.S.	—/—	—/—	—/—
Country where analyzer designed/manufactured	U.S./U.S.	U.S./U.S.	U.S./U.S.
Specimen type	fingerstick, venipuncture (whole blood)	venipuncture (whole blood, anticoagulated whole blood)	fingerstick, venipuncture (whole blood)
Model type	handheld/portable	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/weight	2 x 7.5 x 3.75/12 oz	8.7 x 10.5 x 7.5/6.4 lb	7.9 x 3.3 x 2.2/12.9 oz
Specimen volume needs	accurate volume not necessary (drop)	accurate volume required (fill line on tubes)	accurate volume not necessary (drop)
Clotting-based tests for which device has FDA-cleared applications	PT (reportable range: low 11.4 sec., high 129 sec.; INR: low 0.8, high 12.0), PT (citrated), PTT (reportable range: low 20 sec, high 400 sec plasma equiv.), APTT (citrated), ACT low-range, ACT+	PT (reportable range: low 50 sec, high 340 sec; INR: low 1, high 6), PT (citrated), PTT (reportable range: low 24 sec, high 120 sec), APTT (citrated), ACT, (FTCA510, KACT, P214), HiTT, TT, HNTT, Fib., HRT, KHRT, PRT, KPRT, PDAO, KPDAO	PT (INR: low, 0.8; high, 8.0)
Tests using other methodologies for which device has FDA-cleared applications	none	none	—
FDA-cleared tests but not yet clinically released	none	none	PT
Tests submitted for 510(k) clearance	none	none	—
Tests in development but not yet submitted for clearance	—	—	—
How labs get LOINC codes for reagent kit	—	—	—
Method of endpoint detection	optical detection of clot	mechanical clot detection	direct optical detection of clot
Quality control methods			
• Electronic	yes	yes	no (not required, onboard QC integrated into test strip)
• Liquid	yes (simulated whole blood)	yes (simulated whole blood)	no (not required, onboard QC integrated into test strip)
• Lyophilized	yes (simulated whole blood)	yes (simulated whole blood)	no
• Integrated QC with each analysis	no	no	yes
• Automatic lockout for QC failure	Signature, no; Signature+, yes	yes	yes
• Other	Signature+, operator lockout	operator lockout	two levels of onboard QC integrated into test strip
Time (in minutes) to perform control plus specimen test			
• PT:	2	2	2
• PT & PTT:	2	2	n/a
• ACT:	1–5	1–5	n/a
Data management capability	onboard	onboard	—
Includes QC	yes (QC Data Management)	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	—	—	—
Commercially available systems for which interfaces are up and running in active user sites	yes	yes	—
Lab can control analyzer remotely	no	no	no
Real-time wireless linkage to LIS or HIS	no	no	—
Positive identification system (e.g. bar code) for:			
• Patient specimen	no	no	no
• Reagent	yes	yes	no
Onboard system for automatic error detection	yes, for sample (volume)	yes, for sample volume and reagent/expiration date	yes, for sample (volume)
Training provided with instrument purchase	yes (on-site)	yes (on-site)	yes
Approx. number of training hours needed for:			
• Medical staff	1 hr	1–2 hr	—
• Patient	n/a	n/a	—
Patient self-testing program is available	no	no	yes, instructor-led and interactive computerized performace-based training programs will be available; includes hands-on patient training to ensure patient can successfully perform self-tests
Instrument list price	Signature, $3,750; Signature+, $5,000	$3,975	$1,500 for patient self-testing
Reagent rental or lease only	no	no	—
Cost per sample for:			
• PT: Cost per sample for reagent rental	n/a	n/a	—
Cost per sample if device purchased	$3.31	$2.10	$21 for patient self-testing
• PTT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	$3.50	$2.10	n/a
• ACT: Cost per sample for reagent rental	n/a	n/a	n/a
Cost per sample if device purchased	$2.58	$0.86–$1.84	n/a
CLIA '88 complexity rating	moderate	moderate	CLIA '88 waived
Unique advantages	• blood volume—15 µL • ease-of-use • data management storing/printing • connectivity options • configurable lockout for Signature+	• gold standard for ACT • QC lockout • data storage and management • connectivity options	• recombinant human thromboplastin reagent equivalent to WHO standard—ISI range 1.0–1.3 • onboard QC eliminates need for separate test strips and control solutions—only one sample needed for a controlled INR result • room temperature storage of test strips enables ease of use for patient testing anytime, anywhere

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

SURVEY OF INSTRUMENTS

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

Part 6 of 7	Medtronic Cardiac Surgery 7601 Northland Dr. N. Minneapolis, MN 55428 763-391-9288 www.medtronic.com	Medtronic Cardiac Surgery 7601 Northland Dr. N. Minneapolis, MN 55428 763-391-9288 www.medtronic.com
Instrument name	**ACT II**	**HMS Plus**
First year sold	**1994**	**1999**
No. of units sold in U.S./outside U.S.	**—/—**	**—/—**
Country where analyzer designed/manufactured	**U.S./U.S.**	**U.S./U.S.**
Specimen type	**venipuncture**	**venipuncture**
Model type	**benchtop**	**benchtop**
Dimensions in inches (H x W x D)/weight	**6.5 x 6.5 x 9.5/8 lb**	**15.7 x 15 x 13/34 lb**
Specimen volume needs	**0.2 to 0.4 cc/test, fill to line**	**accurate volume required (automated dispensing)**
Clotting-based tests for which device has FDA-cleared applications	**PT, PTT, ACT, heparinase test**	**ACT, heparin dose response, heparin protamine titration, platelet function**
Tests using other methodologies for which device has FDA-cleared applications	**none**	**none**
FDA-cleared tests but not yet clinically released	**—**	**—**
Tests submitted for 510(k) clearance	**—**	**—**
Tests in development but not yet submitted for clearance	**—**	**ATIII**
How labs get LOINC codes for reagent kit	**Web site**	**Web site**
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	**no**	**optional (user defined)**
• Other	**n/a**	**n/a**
Time (in minutes) to perform control plus specimen test		
• PT:	**5–6**	**n/a**
• PT & PTT:	**6–12**	**n/a**
• ACT:	**up to 12 (depending on patient sample)**	**up to 12 (depending 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	**yes**	**no**
LOINC codes transmitted with results	**yes, through user-definable tables**	**yes, through user-definable tables**
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	**no**	**no**
Onboard system for automatic error detection	**yes**	**yes**
Training provided with instrument purchase	**yes (on-site)**	**yes (on-site)**
Approx. number of training hours needed for:		
• Medical staff	**2 hr**	**6 hr**
• Patient	**n/a**	**n/a**
Patient self-testing program is available	**no**	**no**
Instrument list price	**$2,900**	**$26,000**
Reagent rental or lease only	**yes**	**yes**
Cost per sample for:		
• PT: Cost per sample for reagent rental	**—**	**—**
Cost per sample if device purchased	**—**	**—**
• PTT: Cost per sample for reagent rental	**customer-dependent, per contract**	**customer-dependent, per contract**
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	**• automated mixing of reagent and sample** **• constant temperature control** **• complete QC program**	**• automated sample dispensing** **• constant temperature control** **• multiple testing capability** **• HDR: heparin dose response** **• HPT: heparin protamine titration** **• high-range ACT** ***** ***version 3.0 software available Sept. 2002*** **†** ***site up and running Sept. 2002***

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

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

Part 7 of 7	Roche Diagnostics Corp. Point of Care 9115 Hague Rd., Bldg. H Indianapolis, IN 46250 800-852-8766 www.roche.com	Roche Diagnostics Corp. Point of Care 9115 Hague Rd., Bldg. H Indianapolis, IN 46250 800-852-8766 www.roche.com
Instrument name	CoaguChek Pro DM System	CoaguChek S System for Prothrombin Time Testing (Professional Use)
First year sold	1999	2001
No. of units sold in U.S./outside U.S.	—/—	10,000/52,000
Country where analyzer designed/manufactured	Germany/Germany	Germany/Germany
Specimen type	fresh whole blood (venous, arterial, or fingerstick capillary)	capillary, venous, whole blood
Model type	handheld/portable	handheld/portable
Dimensions in inches (H x W x D)/weight	8.1 x 4.5 x 2/1.5 lb	1.8 x 4.9 x 6.8/1.0 lb
Specimen volume needs	accurate volume not necessary (drop), minimum of approx. 25 µL to 45 µL	accurate volume not necessary (drop), minimum 10 µL
Clotting-based tests for which device has FDA-cleared applications	ACT, APTT, PT	PT (reportable range: low 9.6 sec, high 33.9 sec; INR: low 0.6, high 8.0)
Tests using other methodologies for which device has FDA-cleared applications	none	none
FDA-cleared tests but not yet clinically released	none	none
Tests submitted for 510(k) clearance	none	none
Tests in development but not yet submitted for clearance	none	none
How labs get LOINC codes for reagent kit	n/a	n/a
Method of endpoint detection	laser photometry detects change in blood flow when clot forms	iron particles mixed with the sample move in magnetic fields; reflectance photometry detects change in particle movement with clot formation
Quality control methods		
• Electronic	yes	yes
• Liquid	yes	yes
• Lyophilized	yes (simulated whole blood)	no
• Integrated QC with each analysis	no	no
• Automatic lockout for QC failure	yes	no
• Other	password protected QC lockouts by time of day, shift, or QC level	n/a
Time (in minutes) to perform control plus specimen test		
• PT:	within 4	1 min for either test or QC result; QC not required with every sample
• PT & PTT:	within 5 each	n/a
• ACT:	within 6	n/a
Data management capability	onboard	no
Includes QC	yes (L-J plots and QC results report)	no
System can automatically transfer data to information system		
• Patient data	yes	no
• QC data	yes	no
Interface supplied by instrument vendor	yes (via additional DataCare software)	no
LOINC codes transmitted with results	n/a	n/a
Commercially available systems for which interfaces are up and running in active user sites	AccuChek HDM 3.2.1	n/a
Lab can control analyzer remotely	no	no
Real-time wireless linkage to LIS or HIS	no	no
Positive identification system (e.g. bar code) for:		
• Patient specimen	yes, patient and operator IDs can be entered by bar-code reader	no
• Reagent	yes, reagent type and expiration date contained on each test cartridge; lot-specific code key contains calibration data and expiration date	no
Onboard system for automatic error detection	yes, for sample (volume), reagent expiration date, and internal monitor operation	yes, for sample (volume) and reagent/cuvette expiration date
Training provided with instrument purchase	yes (on-site)	yes (on-site)
Approx. number of training hours needed for:		
• Medical staff	1.5 hr	1 hr
• Patient	n/a	n/a
Patient self-testing program is available	no	no
Instrument list price	$3,795	$1,295
Reagent rental or lease only	contact Roche Diagnostics sales	contact Roche Diagnostics sales
Cost per sample for:		
• PT: Cost per sample for reagent rental	usage dependent	contact Roche Diagnostics sales
Cost per sample if device purchased	usage dependent	$6.00
• PTT: Cost per sample for reagent rental	usage dependent	n/a
Cost per sample if device purchased	usage dependent	n/a
• ACT: Cost per sample for reagent rental	usage dependent	n/a
Cost per sample if device purchased	usage dependent	n/a
CLIA '88 complexity rating	moderate	CLIA waived for professional use
Unique advantages	• user-defined QC lockout, new lot lockout, and operator lockout options • can establish mandatory entry of operator IDs, patient IDs, and comment codes • monitor can interface with AccuCheck HDM 3.2.1 data management software and with hospital LIS via RALS-Plus or DataCare software • 11 different types of reports can be directly printed from monitor	• fast: patient results in as little as 30 sec • small sample: 10 µL from fingerstick • alliance partnerships with Bristol Myers Squibb and Standing Stone for patient management software

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