

Coagulation analyzers—point of care, self-monitoring

The latest in POC and self-testing coag

Brendan Dabkowski

As coagulation testing moves closer to the point of care, makers of POC and self-monitoring coagulation testing systems have developed products that make it easier for their users—health care professionals and patient self-testers alike—to track and manage coagulation status.

“Since the end user is typically not laboratory trained, the POC coordinator expects the platform to have as few sources of error as possible,” says David Pearman, Helena Point of Care’s marketing manager of POC and hemostasis products. POC coordinators consider portability, connectivity, and pricing, too. Helena’s latest offering in this market is the Cascade POC system, which, along with its ease of use, features a broad test menu and smart card technology. The company plans to launch later this year a new version of the analyzer with an enhanced user interface and larger test menu.

Another company designing its POC coagulation analyzers with usability in mind is Roche Diagnostics, where Tim Huston, director of marketing, professional diagnostics – physician office laboratory, says the shift to anticoagulation testing at the physician’s office and in the patient’s home should continue to drive advances in the technology and services. Roche continues to offer its CoaguChek XS systems as well as the CoaguChek XS Plus system; the latter has received CLIA-waived status and provides users with new tools and connectivity options to help manage patients on warfarin therapy. The XS Plus can now hold up to 1,000 patient results. It also has a reduced blood-application sample size requirement of 8 µL (from 10 µL), which is available with all CoaguChek systems. Coming this summer is the CoaguChek XS Pro system, which is FDA-cleared and features bar-code scanning and the same data-management functionality as the XS Plus.

In addition to demanding increasingly portable devices that require smaller sample sizes with faster analysis, customers also want more “creature comforts,” says David Phillips, vice president of marketing for hemostasis/thrombosis at HemoSense/Inverness Medical. To this end, the company has added the INRatio 2 PC Connect to its INRatio 2 testing system. It’s a free software program that allows users to directly transfer patient test results from the analyzer to a PC.

Still available from International Technidyne is the Hemochron Signature Elite analyzer, a handheld whole blood microcoagulation system that features new compliance technology, says Noelle Meirose, product manager, hospital coagulation. The new technology improves safety, security, and compliance and integrates data management and connectivity.

CAPTODAY’s POC and self-monitoring coagulation analyzers product guide includes instruments from the aforementioned companies, as well as Abbott Point of Care, Instrumentation Laboratory, and Medtronic Cardiac Surgery.

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|--|---|---|
| Part 1 of 5 | | |
| Instrument name First year sold | i-STAT 1 2000 | Cascade POC 2008 |
| No. of units sold in U.S./Outside U.S. No. of units sold in 2009 • units sold to: Country where analyzer designed/Manufactured Is instrument POC or self-monitoring analyzer? | 8,000/4,000 — — U.S./U.S. POC | 150/50 — — U.S./U.S. POC and self-monitoring analyzer |
| Specimen type | fingerstick, venipuncture (whole blood, anticoagulated whole blood) | fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma) |
| Model type Dimensions in inches (H × W × D)/Weight Specimen volume needs | handheld/portable 9.25 × 3.03 × 2.85/18.34 oz accurate volume required (pipetted, fill line on cuvette) | 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 10.3 sec, high 87.5 sec; INR: low 0.9, high 8.0, ACT (kaolin), ACT (celite) | PT/INR, APTT, Celite ACT, low molecular weight heparin |
| Tests using other methodologies for which device has FDA-cleared applications | CHEM8+, BNP, CK-MB, troponin I, creatinine, urea nitrogen (BUN), glucose(Glu), chloride(Cl), sodium (Na), potassium (K), ionized calcium (iCa), hematocrit (Hct), hemoglobin (Hgb), pH, PCO ₂ , PO ₂ , TCO ₂ **, HCO ₃ , BE _{ecf} , SO ₂ , lactate, anion gap, ACT (Celite), ACT (Kaolin), PT/INR | — |
| FDA-cleared tests but not yet clinically released Tests submitted for 510(k) clearance Tests in development but not yet submitted for clearance | — — — | — — direct thrombin inhibitor, fibrinogen, heparin/protamine titration |
| Method of endpoint detection | electrogenic | photo-mechanical |
| Quality control methods • Electronic • Liquid • Lyophilized • Integrated QC with each analysis • Automatic lockout for QC failure • Other | yes no yes (plasma) yes yes lockout for QC failure is for failed electronic QC or per cartridge internal QC | yes no yes (plasma) no yes — |
| Time (in minutes) to perform control plus specimen test • PT: • PT & PTT: • ACT: | 3+ — 3+ | 2 5 5–12 |
| Data-management capability Includes QC System can automatically transfer data to information system • Patient data • QC data Interface supplied by instrument vendor | optional add-on yes yes yes yes (additional cost) | onboard yes yes yes yes (included) |
| 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 Lab can control analyzer remotely | yes package insert Sunquest, Cerner, Soft, McKesson, Meditech, GE, Siemens, VistA, others yes | no Web site — no |
| Real-time wireless linkage to LIS or HIS Positive identification system (e.g. bar code) for: • Patient specimen • Reagent | yes (infrared) yes no | yes yes yes |
| Onboard system for automatic error detection | yes, for sample (volume) | yes |
| Training provided with instrument purchase Approx. No. of training hours needed for: • Medical staff • Patient | yes (on site) 1 — | yes (on site) 30 minutes — |
| Patient self-testing program is available | no | no |
| Instrument list price Reagent rental or lease only 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 | call for pricing no varies call for pricing call for pricing call for pricing call for pricing moderate | \$3,590 yes variable \$2.50–\$3.24 variable \$2.25–\$3.50 variable \$2.25–\$3.50 nonwaived |
| Unique advantages (provided by the vendor) | broad testing menu; many data-management and interfacing options; easy to use | multiple tests, same device; eight-hour battery operation; low cost/test |

Coagulation analyzers—point of care, self-monitoring

| | 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 | HemoSense/Inverness Medical David Phillips 9975 Summers Ridge Rd. San Diego, CA 92121 877-441-7440 www.hemosense.com |
|--|--|---|---|
| Part 2 of 5 | | | |
| Instrument name First year sold | Actalyke XL 2002 | Actalyke Mini II 2004 | INRatio/INRatio2 PT INR Monitor 2003 (INRatio)/2008 (INRatio2) |
| No. of units sold in U.S./Outside U.S. No. of units sold in 2009 • units sold to: | 300+/200+ — operating room: 40; cardiac cath lab: 45; stat lab: 15; NICU: 15 | 150+/1,000+ — — | —/— — — |
| 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 and self-monitoring analyzer |
| Specimen type | venipuncture (whole blood) | venipuncture (whole blood) | fingerstick |
| Model type Dimensions in inches (H × W × D)/Weight Specimen volume needs | portable 5.6 × 10.7 × 10.3/15 lb accurate volume required (fill line on cuvette) | portable 6.25 × 6 × 5/6.3 lb accurate volume required (fill line on cuvette) | handheld/portable 5.9 × 2.9 × 1.8 in/9.3 oz with batteries accurate volume not necessary (drop) ~15 µL |
| Clotting-based tests for which device has FDA-cleared applications | activated clotting time (ACT)—whole blood, MAX-ACT; maximum factor XII activation ACT, celite, kaolin, glass | ACT—MAX-ACT, C-ACT, K-ACT, G-ACT | PT (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5) |
| Tests using other methodologies for which device has FDA-cleared applications | — | — | none |
| FDA-cleared tests but not yet clinically released | none | — | none |
| Tests submitted for 510(k) clearance | — | — | none |
| Tests in development but not yet submitted for clearance | APTT (whole blood), PT (whole blood), LMWH, heparin & protamine titration (AMK) | LMWH, APTT (whole blood), PT (whole blood), AMK | none |
| Method of endpoint detection | two-point electromechanical soft-clot detection principle | two-point electromechanical | electrochemical detection, change in impedance as sample clots |
| Quality control methods | | | |
| • Electronic | yes | yes | no (not required, built-in 2-level QC on each strip) |
| • Liquid | yes | yes | no (not required, built-in 2-level QC on each strip) |
| • Lyophilized | yes | yes | no |
| • Integrated QC with each analysis | no | no | yes |
| • Automatic lockout for QC failure | yes | no | yes |
| • Other | data management for entering heparin dose, L-J chart generation for all controls | — | — |
| Time (in minutes) to perform control plus specimen test | | | |
| • PT: | — | — | 1 |
| • PT & PTT: | — | — | — |
| • ACT: | 5 | 5 | — |
| Data-management capability | yes | no | optional add-on (CoagClinic from Standing Stone) |
| Includes QC | yes | no | yes |
| System can automatically transfer data to information system | | | |
| • Patient data | yes | — | yes |
| • QC data | yes | — | yes |
| Interface supplied by instrument vendor | interface specifications supplied, POCT1-A compliant | — | no |
| LOINC codes transmitted with results | no | no | — |
| How labs get LOINC codes for reagent kit | — | — | — |
| Commercially available systems for which interfaces are up and running in active user sites | — | — | CoagClinic from Standing Stone; PPM from QAS |
| Lab can control analyzer remotely | no | no | no |
| Real-time wireless linkage to LIS or HIS | yes | — | no |
| Positive identification system (e.g. bar code) for: | | | |
| • Patient specimen | yes | no | no |
| • Reagent | yes; all disposables have bar code for identification with use on any Actalyke model | no | no |
| Onboard system for automatic error detection | yes, stuck magnet, no tube; mechanical instrument parameters only; well rotation, temperature, and detection settings | yes, for stuck magnet, printer problems | yes, for sample (volume), reagent stability |
| Training provided with instrument purchase | yes (on site) | yes (on site) | yes (on site) |
| Approx. No. of training hours needed for: | | | |
| • Medical staff | 1–2 | 1 | 1 |
| • Patient | — | — | 1 |
| Patient self-testing program is available | no | no | yes |
| Instrument list price | \$3,805 | \$1,024 (battery only)—\$1,334 (with printer and battery) | \$1,595 professional; \$1,995 self-test |
| Reagent rental or lease only | purchase, lease, or reagent rental | purchase, lease, or reagent rental | no |
| Cost per sample for: | | | |
| • PT: Cost per sample for reagent rental | — | — | depends on volume |
| Cost per sample if device purchased | — | — | \$5.50 per strip professional; \$10 per self-test |
| • PTT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | — | — | — |
| • ACT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | \$0.74–\$1.76 | \$0.74–\$1.76 | — |
| CLIA '88 complexity rating | moderate | moderate | waived |
| Unique advantages (provided by the vendor) | two-point electromechanical soft-clot detection principle; MAX-ACT: maximum factor XII activation ACT test, 0.5-mL blood volume, linear up to 10 units of heparin, safer plastic tube construction, for use on Actalyke and Hemochron instruments; electronic clotting tube (ECT) that simulates and mimics actual blood clot formation for accurate ECT challenges; integrated printer; 3.5-in. diskette storage | two-point electromechanical soft-clot detection; magnetic detection device—electronic QC/ revolution; MAX-ACT tubes, 0.5-mL volume and linear to 6 U/mL; linear up to 6 U/mL of heparin; electronic clotting tube (ECT) available | onboard QC—two levels of quantitative controls with reportable results; simple three-step test process; human recombinant thromboplastin (ISI 1.0); individually wrapped test strips; nonrefrigerated test strips; one unmeasured drop; 12-month dating on test strips; 120-test memory, including QC values |

Coagulation analyzers—point of care, self-monitoring

| Part 3 of 5 | Instrumentation Laboratory Mike Wright mwright@ilww.com 180 Hartwell Rd. Bedford, MA 01730 781-861-4165 www.ilus.com | International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com | International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com |
|---|---|--|---|
| Instrument name | Gem PCL Plus | ProTime Microcoagulation System | Hemochron Signature Elite |
| First year sold | 2003 | ProTime Micro: 1995; ProTime 3: 2001; New ProTime: 2006 | 2005 |
| No. of units sold in U.S./Outside U.S. | >250/>250 | —/— | —/— |
| No. of units sold in 2009 | — | — | — |
| • units sold to: | — | — | — |
| Country where analyzer designed/Manufactured | U.S./U.S. | U.S./U.S. | U.S./U.S. |
| Is instrument POC or self-monitoring analyzer? | POC | POC | POC |
| Specimen type | fresh whole blood, citrated whole blood (fingerstick for PT only) | fingerstick | venipuncture, fingerstick, fresh whole blood, citrated blood |
| Model type | handheld/portable | handheld/portable | handheld/portable |
| Dimensions in inches (H × W × D)/Weight | 2.0 × 7.5 × 3.5/0.75 lb | 2.7 × 4.5 × 8.5/3 lb | 2 × 7.5 × 3.7/1.2 lb |
| Specimen volume needs | accurate volume not necessary (~50 µL), low sample volume error message if well not filled | small blood sample volume needed, ~25 µL | accurate volume not necessary, (low sample volume error message if well not filled) |
| Clotting-based tests for which device has FDA-cleared applications | PT and citrate PT (reportable range: 10–150 sec; INR: 0.8–12 sec), APTT (reportable range: 20–300 sec), ACT (reportable range: 65–1,005 sec), ACT–low range (reportable range: 67–400 sec) | PT (reportable range: low 10 sec, high 130 sec; INR: low 0.8, high 9.9) | PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR |
| Tests using other methodologies for which device has FDA-cleared applications | none | none | none |
| FDA-cleared tests but not yet clinically released | none | none | none |
| Tests submitted for 510(k) clearance | none | none | — |
| Tests in development but not yet submitted for clearance | none | — | — |
| Method of endpoint detection | mechanical endpoint clotting mechanism, monitored optically | mechanical clot detection | mechanical clot detection |
| Quality control methods | | | |
| • Electronic | yes | no (not required, onboard QC) | yes, internal automatic EQC |
| • Liquid | yes (simulated whole blood) | yes (available as an option but not required due to onboard controls) | yes (simulated whole blood) |
| • Lyophilized | no | no | yes (simulated whole blood) |
| • Integrated QC with each analysis | no | yes | no |
| • Automatic lockout for QC failure | yes | yes | yes |
| • Other | — | 2 levels of onboard QC integrated into each cuvette | operator lockout, certification lockout, audit trail, and patient identification lockout |
| Time (in minutes) to perform control plus specimen test | | | |
| • PT: | 2 | <5 | 2 |
| • PT & PTT: | 2 | — | 2 |
| • ACT: | 1–5 | — | 1–5 |
| Data-management capability | onboard (via Gem Premier 3000) | yes | onboard |
| Includes QC | yes | yes (onboard controls) | yes |
| System can automatically transfer data to information system | | | |
| • Patient data | yes | yes | yes |
| • QC data | yes | yes | yes |
| Interface supplied by instrument vendor | — | communication cable available | yes |
| LOINC codes transmitted with results | no | — | — |
| How labs get LOINC codes for reagent kit | — | — | — |
| Commercially available systems for which interfaces are up and running in active user sites | — | — | yes |
| Lab can control analyzer remotely | no | no | no |
| Real-time wireless linkage to LIS or HIS | no | no | no |
| Positive identification system (e.g. bar code) for: | | | |
| • Patient specimen | no | no | no |
| • Reagent | yes | yes | yes |
| Onboard system for automatic error detection | yes, for sample (volume), reagent, and instrument | yes, for sample (volume) and reagent/cuvette expiration date | yes, for sample (volume) and reagent/expiration date |
| Training provided with instrument purchase | yes (on site) | yes (on site) | yes (on site) |
| Approx. No. of training hours needed for: | | | |
| • Medical staff | 30 minutes | 1 | 1 |
| • Patient | — | 1.5 | — |
| Patient self-testing program is available | no | yes (training CD/Web-based training) | no |
| Instrument list price | \$5,329 (volume dependent) | \$1,749 professional, \$2,350 consumer | \$7,900 |
| Reagent rental or lease only | outright purchase, lease, reagent rental | yes | no |
| Cost per sample for: | | | |
| • PT: Cost per sample for reagent rental | varies with volume | volume dependent | — |
| Cost per sample if device purchased | varies with volume | volume dependent | — |
| • PTT: Cost per sample for reagent rental | varies with volume | — | — |
| Cost per sample if device purchased | varies with volume | — | — |
| • ACT: Cost per sample for reagent rental | varies with volume | — | — |
| Cost per sample if device purchased | varies with volume | — | — |
| CLIA '88 complexity rating | nonwaived | waived | moderate |
| Unique advantages (provided by the vendor) | utilized in conjunction with the Gem Premier 3000/3500 analyzer; consolidating blood gas/electrolytes/glucose/lactate/hematocrit/coagulation testing; comprehensive POC coagulation menu that allows for POC coagulation analysis throughout an institution; whole blood PT, citrate PT, APTT, ACT, and ACT-low range; patient safety features: automatic QC lockout, mandatory operator ID and patient ID options, database management (patient history query), fully automated sample measuring and mixing, inaccurate sample volume detection, automatic instrument and optical monitoring | two levels of integral reagent control automatically run with each patient; internal instrument checks verify optical, electrical, and mechanical functions—no further calibration required; sensitive thromboplastin reagent (ISI = 1.0), as recommended by AHA, CAP, and WHO; results in less than five minutes; 16-hour room-temperature open-pouch stability of cuvette; bar-coded cuvette—no coding necessary; accepts and stores patient ID/operator ID; automatically sends test results to printer, computer, LIS; onboard and external controls available | integrated bar-code scanner; new compliance technology; QC, PID, and OID; lockout and tracking; data-management storage and printing; optimal connectivity options; blood volume 15 µL; ease of use; Ethernet and RS232 ports |

Coagulation analyzers—point of care, self-monitoring

| Part 4 of 5 | International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com | International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com | Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com |
|--|--|--|--|
| Instrument name First year sold | Signature+ Signature+ introduced in 2002 | Hemochron Response 2000 | HMS Plus 1999 |
| No. of units sold in U.S./Outside U.S. No. of units sold in 2009 • 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, fingerstick, fresh whole blood, citrated blood | venipuncture (whole blood) |
| Model type | handheld/portable | handheld/portable | benchtop |
| Dimensions in inches (H × W × D)/Weight | 2 × 7.5 × 3.75/12 oz | 8.7 × 10.5 × 7.5/6.4 lb | 15.7 × 15 × 13/34 lb |
| Specimen volume needs | accurate volume not necessary (low sample volume error message if well not filled) | accurate volume required (fill line on tubes) | accurate volume required (automated dispensing) |
| Clotting-based tests for which device has FDA-cleared applications | PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR | ACT, (FTCA510, KACT, P214), HITT, TT, fib, HRT, KHRT, PRT, KPRT, PDAO, PDAOK, PT, APTT, PT citrated, APTT citrated | ACT, heparin dose response, heparin protamine titration |
| Tests using other methodologies for which device has FDA-cleared applications | none | none | none |
| FDA-cleared tests but not yet clinically released | none | none | — |
| Tests submitted for 510(k) clearance | — | none | — |
| Tests in development but not yet submitted for clearance | — | — | — |
| Method of endpoint detection | mechanical clot detection | mechanical clot detection | mechanical clot detection |
| Quality control methods | | | |
| • Electronic | yes | yes | yes |
| • Liquid | yes (simulated whole blood) | yes (simulated whole blood) | no |
| • Lyophilized | yes (simulated whole blood) | yes (simulated whole blood) | yes |
| • Integrated QC with each analysis | no | no | no |
| • Automatic lockout for QC failure | yes | yes | optional (user defined) |
| • Other | operator lockout | operator lockout | optional operator lockout |
| Time (in minutes) to perform control plus specimen test | | | |
| • PT: | 2 | 2 | — |
| • PT & PTT: | 2 | 2 | — |
| • ACT: | 1–5 | 1–5 | up to 12 (depending on patient sample) |
| Data-management capability | onboard | onboard | yes |
| Includes QC | yes | yes | yes |
| System can automatically transfer data to information system | | | |
| • Patient data | yes | yes | yes |
| • QC data | yes | yes | yes |
| Interface supplied by instrument vendor | yes | yes | no |
| LOINC codes transmitted with results | — | — | — |
| How labs get LOINC codes for reagent kit | — | — | Web site |
| Commercially available systems for which interfaces are up and running in active user sites | yes | yes | Telcor, RALS-Plus, Aegis POC in development |
| Lab can control analyzer remotely | no | no | no |
| Real-time wireless linkage to LIS or HIS | no | no | no |
| Positive identification system (e.g. bar code) for: | | | |
| • Patient specimen | no | no | yes |
| • Reagent | yes | yes | yes |
| Onboard system for automatic error detection | yes, for sample (volume) | yes, for sample (volume) and reagent/expiration date | yes |
| Training provided with instrument purchase | yes (on site) | yes (on site) | yes (on site) |
| Approx. No. of training hours needed for: | | | |
| • Medical staff | — | 1–2 | 6 |
| • Patient | — | — | — |
| Patient self-testing program is available | no | no | no |
| Instrument list price | \$5,280 | \$4,055 | \$26,000 |
| Reagent rental or lease only | no | no | rental and purchase available |
| Cost per sample for: | | | |
| • PT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | — | — | — |
| • PTT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | — | — | — |
| • ACT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | — | — | customer dependent, per contract |
| CLIA '88 complexity rating | moderate | moderate | moderate (nonwaived) |
| Unique advantages (provided by the vendor) | blood volume—15 µL; ease of use; data-management storage and printing; connectivity options; configurable QC and operator lockout | 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 |

Coagulation analyzers—point of care, self-monitoring

| Part 5 of 5 | Medtronic Cardiac Surgery 7611 Northland Drive North Minneapolis, MN 55428 800-328-3320 www.medtronic.com | Roche Diagnostics Courtney Sweeney courtney.sweeney@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-852-8766 www.poc.roche.com | Roche Diagnostics Courtney Sweeney courtney.sweeney@roche.com 9115 Hague Rd. Indianapolis, IN 46250 800-852-8766 www.poc.roche.com |
|--|--|--|---|
| Instrument name | ACT Plus | CoaguChek XS PT Test System | CoaguChek XS Plus PT Test System |
| First year sold | 2003 | 2006 (international)/2007 (U.S.) | 2007 |
| No. of units sold in U.S./Outside U.S. No. of units sold in 2009 • units sold to: | — — — | —/— — — | —/— — — |
| Country where analyzer designed/Manufactured Is instrument POC or self-monitoring analyzer? | U.S./U.S. POC | Germany/Germany POC and self-monitoring | Germany/Germany POC |
| Specimen type | venipuncture (whole blood) | fresh whole blood (venous or fingerstick capillary) | fresh whole blood (venous or fingerstick capillary) |
| Model type Dimensions in inches (H × W × D)/Weight Specimen volume needs | benchtop 11 × 8 × 13/11.5 lb accurate volume required (fill line on cuvette and optional easy fill accessory) | handheld/portable 5.43 × 3.07 × 1.10/4.48 oz 10 µL | handheld/portable 3.25 × 6.5 × 12.375/350 g 10 µL |
| Clotting-based tests for which device has FDA-cleared applications | ACT (high range, low range, recalcified, high range heparinase) | PT (reportable range: low 9.6 sec, high 96 sec; INR: low 0.8 sec, high 8.0 sec) | PT (reportable range: low 9.6 sec, high 96 sec; INR: low 0.8 sec, high 8.0 sec) |
| Tests using other methodologies for which device has FDA-cleared applications | none | none | none |
| FDA-cleared tests but not yet clinically released | — | none | none |
| Tests submitted for 510(k) clearance | — | none | none |
| Tests in development but not yet submitted for clearance | — | none | none |
| Method of endpoint detection | mechanical clot detection | amperometric detection | amperometric detection |
| Quality control methods | | | |
| • Electronic | yes | no (not required, onboard QC) | no (not required, onboard QC) |
| • Liquid | no | no | yes (available as an option but not required due to onboard controls) |
| • Lyophilized | yes | no | no |
| • Integrated QC with each analysis | no | yes | yes |
| • Automatic lockout for QC failure | optional (user defined) | no | yes |
| • Other | optional operator lockout | — | optional operator lockout |
| Time (in minutes) to perform control plus specimen test | | | |
| • PT: | — | <1 | <1 |
| • PT & PTT: | — | — | — |
| • ACT: | up to 12 (depends on patient sample) | — | — |
| Data-management capability | yes | no | yes |
| Includes QC | yes | no | yes |
| System can automatically transfer data to information system | | | |
| • Patient data | yes | no | yes |
| • QC data | yes | no | yes |
| Interface supplied by instrument vendor | no | with license | POCT1-A |
| LOINC codes transmitted with results | — | no | no |
| How labs get LOINC codes for reagent kit | Web site | — | — |
| Commercially available systems for which interfaces are up and running in active user sites | Telcor, RALS-Plus, Aegis POC in development | yes | 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 | yes | no | no |
| • Reagent | yes | 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 | 1.5 |
| • Patient | — | trainer dependent | — |
| Patient self-testing program is available | no | yes | no |
| Instrument list price | \$4,200 | varies by distributor | varies by distributor |
| Reagent rental or lease only | rental and purchase available | no | no |
| Cost per sample for: | | | |
| • PT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | — | — | — |
| • PTT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | — | — | — |
| • ACT: Cost per sample for reagent rental | — | — | — |
| Cost per sample if device purchased | customer dependent, per contract | — | — |
| CLIA '88 complexity rating | moderate (nonwaived) | CLIA waived | CLIA waived |
| Unique advantages (provided by the vendor) | data-management software application; duplicate test results; optional bar-code scanner; optional easy filling accessory | performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; 18-month strip shelf life, no refrigeration needed; top or side dosing; results in one minute or less | performs onboard quality control and determines patient results in a single test chamber; top or side dosing; results in one minute or less |