

Coagulation analyzers (point of care, self-monitoring)

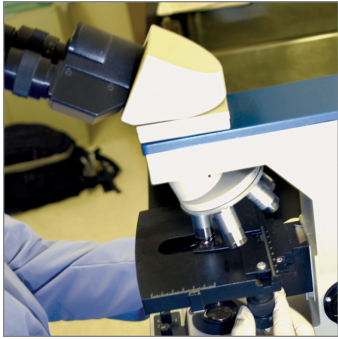
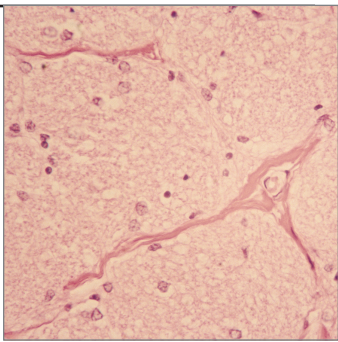
Part 1 of 5

Abbott Point of Care
 Michael A. Saperstein michael.saperstein@i-stat.com
 Marketing Communications
 104 Windsor Center Drive
 East Windsor, NJ 08520
 609-469-0342

Abbott Point of Care
 Michael A. Saperstein michael.saperstein@i-stat.com
 Marketing Communications
 104 Windsor Center Drive
 East Windsor, NJ 08520
 609-469-0342

See accompanying article on page 14

| Instrument name | i-STAT 1 | i-STAT |
|---|---|---|
| First year sold | 2000 | 1992 |
| No. of units sold in U.S./Outside U.S. | 4,000/2,900 | — |
| No. of units sold in 2006 | — | — |
| • units sold to: | — | — |
| Country where analyzer designed/Manufactured | U.S./U.S. | U.S./U.S. |
| Is instrument POC or self-monitoring analyzer? | POC | POC |
| 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 | 9.25 x 3.03 x 2.85/18.34 oz | 8.25 x 2.52 x 2.05/18.34 oz |
| Specimen volume needs | accurate volume required (fill line on cuvette) | accurate volume required (fill line on cartridge) |
| Clotting-based tests for which device has FDA-cleared applications | PT/INR, Celite ACT, Kaolin ACT, CK-MB, BNP | PT/INR, Celite ACT, Kaolin ACT |
| Tests using other methodologies for which device has FDA-cleared applications | blood gases, electrolytes, chemistry, immunoassay (troponin), chem 8+ | blood gases, electrolytes, chemistry |
| FDA-cleared tests but not yet clinically released | — | none |
| Tests submitted for 510(k) clearance | — | — |
| Tests in development but not yet submitted for clearance | — | APTT |
| Method of endpoint detection | electrogenic | electrogenic |
| Quality control methods | | |
| • Electronic | yes | yes |
| • Liquid | yes | yes |
| • Lyophilized | yes | yes |
| • 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 mfr: i-STAT) | onboard & optional add-on (SW mfr: i-STAT) |
| Includes QC | yes | yes (L-J plots) |
| System can automatically transfer data to information system | yes | yes |
| • 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 | — |
| How labs get LOINC codes for reagent kit | package insert | — |
| Commercially available systems for which interfaces are up and running in active user sites | Cerner, Misys, McKesson, Citation, Meditech, others | Cerner, Misys, McKesson, Citation, Meditech, others |
| Lab can control analyzer remotely | yes | yes |
| Real-time wireless linkage to LIS or HIS | yes (infrared) | yes (infrared) |
| 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), reagent/cartridge error | yes, for sample (volume), reagent/cartridge error |
| Training provided with instrument purchase | yes (on site) | yes (on site) |
| Approx. No. 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 | \$6,000 | \$5,000 |
| Reagent rental or lease only | yes | yes |
| 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 | call for pricing |
| Cost per sample if device purchased | call for pricing | call for pricing |
| CLIA '88 complexity rating | moderate | moderate |
| Unique advantages (provided by the vendor) | <ul style="list-style-type: none"> • handheld portable device • QC lockout/operator lockout • menu: blood gas, chemistry, electrolytes, coagulation, immunoassay • bar-code scanner • downloader/recharger | <ul style="list-style-type: none"> • handheld • QC lockout/operator lockout |



Experience the CAP difference

- Established fields of anatomic and clinical pathology
- New technologies
- Laboratory management

To fill your Pathology, Laboratory Medicine or Laboratory Management positions, advertise in CAP TODAY classifieds for the best results. Call

1-800-983-7737

Coagulation analyzers (point of care, self-monitoring)

| | | | |
|---|--|--|---|
| Part 2 of 5 | <p>Helena Point of Care Jim Campbell pointofcare@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com</p> | <p>Helena Point of Care Jim Campbell pointofcare@helena.com 1530 Lindbergh Drive Beaumont, TX 77704 800-231-5663 www.helena.com</p> | <p>HemoSense Inc. David Phillips 651 River Oaks Parkway San Jose, CA 95134 408-719-1393 www.hemosense.com</p> |
| <i>See accompanying article on page 14</i> | | | |
| Instrument name | Actalyke XL | Actalyke Mini II | INRatio PT/INR |
| First year sold | 2002 | 2004 | 2003 |
| No. of units sold in U.S./Outside U.S. No. of units sold in 2006 • units sold to: | 200+/100+ — operating room-40; cardiac cath lab-45; stat lab-15; NICU-15 | 75+/650+ — — | n/a/n/a — — |
| Country where analyzer designed/Manufactured Is instrument POC or self-monitoring analyzer? Specimen type | U.S./U.S. POC venipuncture (whole blood) | U.S./U.S. POC venipuncture (whole blood) | U.S./U.S. POC and self-monitoring analyzer fingertick |
| Model type | portable | portable | 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 5/6.3 lb | 6.125 x 3 x 2.2 in/8.1 oz |
| Specimen volume needs | accurate volume required (fill line on cuvette) | accurate volume required (fill line on cuvette) | accurate volume not necessary (drop) ~15 µL |
| Clotting-based tests for which device has FDA-cleared applications | activated clotting time (ACT)—whole blood, MAX-ACT: maximum factor XII activation ACT, celite, kaolin, glass | ACT—MAX-ACT, C-ACT, K-ACT, G-ACT | PT (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5) |
| Tests using other methodologies for which device has FDA-cleared applications | — | — | none |
| FDA-cleared tests but not yet clinically released | none | — | none |
| Tests submitted for 510(k) clearance | — | — | none |
| Tests in development but not yet submitted for clearance | APTT (whole blood), PT (whole blood), LMWH, heparin & protamine titration (AMK) | LMWH, APTT (whole blood), PT (whole blood), AMK | none |
| Method of endpoint detection | two-point electromechanical soft-clot detection principle | two-point electromechanical | electrochemical detection, change in impedance as sample clots |
| Quality control methods | | | |
| • Electronic | yes | yes | no (not required, built-in 2-level QC on each strip) |
| • Liquid | yes (simulated whole blood) | yes (simulated whole blood) | no (not required, built-in 2-level QC on each strip) |
| • Lyophilized | yes (simulated whole blood) | yes (simulated whole blood) | 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: | n/a | n/a | <2 |
| • PT & PTT: | n/a | n/a | — |
| • 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 | n/a | n/a | n/a |
| Commercially available systems for which interfaces are up and running in active user sites | n/a | — | 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 hr | 1 hr | 1 hr |
| • Patient | n/a | n/a | 1 hr |
| Patient self-testing program is available | no | no | yes |
| Instrument list price | \$3,695 | \$1,205–\$1,375 (battery only)—\$1,249 (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 | n/a | — | depends on volume |
| Cost per sample if device purchased | n/a | — | \$5.50 per strip professional; \$10 per self-test |
| • 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 | moderate | waived |
| Unique advantages (provided by the vendor) | <ul style="list-style-type: none"> 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-inch diskette storage | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> onboard QC—2 levels of quantitative controls with reportable results simple 3-step test process human recombinant thromboplastin (ISI 1.0) non-refrigerated test strips one unmeasured drop 12-month dating on test strips room temperature storage of test strips 60 patient memory including QC values |

Coagulation analyzers (point of care, self-monitoring)

| Part 3 of 5 | | Instrumentation Laboratory Elizabeth Walsh ewalsh@ilww.com 101 Hartwell Ave. Lexington, MA 02421 781-861-4165 www.ilus.com | International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com | International Technidyne Corp. customerservice@itcmed.com 8 Olsen Ave. Edison, NJ 08820 732-548-5700 www.itcmed.com |
|--|---|--|--|---|
| <i>See accompanying article on page 14</i> | | | | |
| Instrument name | Gem PCL Plus (Portable Coagulation Laboratory) | ProTime Microcoagulation System | HEMOCHRON Jr.—Signature/Signature+ 1998; Signature+ introduced in 2002 | |
| First year sold | 2003 | ProTime Micro: 1995; ProTime 3: 2001; New ProTime: 2006 | | |
| No. of units sold in U.S./Outside U.S. | —/— | —/— | —/— | |
| No. of units sold in 2006 | — | — | — | |
| • 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) | fingerstick | venipuncture, fingerstick, fresh whole blood, citrated blood | |
| Model type | handheld/portable | handheld/portable | handheld/portable | |
| Dimensions in inches (H x W x D)/Weight | 5.5 x 2 x 3.5/0.75 lb | 2.7 x 4.5 x 8.5/3 lb | 2 x 7.5 x 3.75/12 oz | |
| Specimen volume needs | accurate volume not necessary (~50 µL), low sample volume error message if well not filled | small blood sample volume needed, ~25 µL | accurate volume needed (fill line in cuvette sample well) | |
| Clotting-based tests for which device has FDA-cleared applications | PT and citrate PT (reportable range: 10–150 sec; INR: 0.8–12), APTT (reportable range: 20–300 sec), ACT (65–1,005 sec), ACT–low range (67–400 sec) | PT (reportable range: low 10 sec, high 130 sec; INR: low 0.8, high 9.9) | PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR | |
| Tests using other methodologies for which device has FDA-cleared applications | none | none | none | |
| FDA-cleared tests but not yet clinically released | none | none | none | |
| Tests submitted for 510(k) clearance | none | none | — | |
| Tests in development but not yet submitted for clearance | none | — | — | |
| Method of endpoint detection | mechanical endpoint clotting mechanism, monitored optically | mechanical clot detection | optical detection of clot | |
| Quality control methods | | | | |
| • Electronic | yes | no (not required, onboard QC) | yes | |
| • Liquid | yes (simulated whole blood) | yes (available as an option but not required due to onboard controls) | yes (simulated whole blood) | |
| • Lyophilized | yes | no | yes (simulated whole blood) | |
| • Integrated QC with each analysis | no | yes | no | |
| • Automatic lockout for QC failure | yes | yes | Signature, no; Signature+, yes | |
| • Other | n/a | 2 levels of onboard QC integrated into each cuvette | operator lockout | |
| Time (in minutes) to perform control plus specimen test | | | | |
| • PT: | 2 | <5 | 2 | |
| • PT & PTT: | 2 | n/a | 2 | |
| • ACT: | 1–5 | n/a | 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 | n/a | communication cable available | yes | |
| LOINC codes transmitted with results | no | — | — | |
| How labs get LOINC codes for reagent kit | n/a | — | — | |
| Commercially available systems for which interfaces are up and running in active user sites | n/a | n/a | yes | |
| Lab can control analyzer remotely | no | no | no | |
| Real-time wireless linkage to LIS or HIS | no | no | no | |
| Positive identification system (e.g. bar code) for: | | | | |
| • Patient specimen | no | no | no | |
| • Reagent | yes | yes | yes | |
| Onboard system for automatic error detection | yes, for sample (volume), reagent, and instrument | yes, for sample (volume) and reagent/cuvette expiration date | yes, for sample (volume) | |
| Training provided with instrument purchase | | | | |
| Approx. No. of training hours needed for: | | | | |
| • Medical staff | yes (on site) | yes (on site) | yes (on site) | |
| • Patient | 0.5 hr | 1 hr | 1 hr | |
| Patient self-testing program is available | n/a | 1.5 hr | n/a | |
| Instrument list price | no | yes (training CD/Web-based training) | no | |
| Reagent rental or lease only | \$5,329 (volume dependent) | \$1,749 professional, \$2,350 consumer | Signature, \$3,825; Signature+, \$5,100 | |
| Cost per sample for: | outright purchase, lease, reagent rental | yes | no | |
| • PT: Cost per sample for reagent rental | varies with volume | volume dependent | n/a | |
| Cost per sample if device purchased | varies with volume | volume dependent | — | |
| • PTT: Cost per sample for reagent rental | varies with volume | n/a | n/a | |
| Cost per sample if device purchased | varies with volume | 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 | n/a | — | |
| CLIA '88 complexity rating | non-waived | waived | moderate | |
| Unique advantages (provided by the vendor) | <ul style="list-style-type: none"> • Gem PCL Plus can be used in conjunction with the Gem Premier 3000; consolidating BG/lytes/glu/lac/Hct testing • comprehensive POC coagulation menu that allows for POC coagulation analysis throughout an institution; whole blood PT, citrate PT, APTT, ACT, and ACT-low range • onboard data management • mandatory operator ID and patient ID options | <ul style="list-style-type: none"> • 2 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 5 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 • both onboard and external controls available | <ul style="list-style-type: none"> • blood volume—15 µL • ease of use • data management storage and printing • connectivity options • configurable QC and operator lockout for Signature+ | |

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 |
| <i>See accompanying article on page 14</i> | | | |
| Instrument name | HEMOCHRON Response | HEMOCHRON Signature Elite | HMS Plus |
| First year sold | 2000 | 2005 | 1999 |
| No. of units sold in U.S./Outside U.S. | —/— | —/— | —/— |
| No. of units sold in 2006 | — | — | 85 |
| • 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, 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 x W x D)/Weight | 8.7 x 10.5 x 7.5/6.4 lb | 2 x 7.5 x 3.7/1.2 lb | 15.7 x 15 x 13/34 lb |
| Specimen volume needs | accurate volume required (fill line on tubes) | accurate volume needed (fill line in cuvette sample well) | accurate volume required (automated dispensing) |
| Clotting-based tests for which device has FDA-cleared applications | ACT, (FTCA510, KACT, P214), HITT, TT, fib, HRT, KHRT, PRT, KPRT, PDAO, PDAOK, PT, APTT, PT citrated, APTT citrated | PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR | ACT, heparin dose response, heparin protamine titration |
| Tests using other methodologies for which device has FDA-cleared applications | none | none | none |
| FDA-cleared tests but not yet clinically released | none | none | — |
| Tests submitted for 510(k) clearance | none | — | — |
| Tests in development but not yet submitted for clearance | — | — | — |
| Method of endpoint detection | mechanical clot detection | optical detection of clot | mechanical clot detection |
| Quality control methods | | | |
| • Electronic | yes | yes | yes |
| • Liquid | yes (simulated whole blood) | yes (simulated whole blood) | no |
| • Lyophilized | yes (simulated whole blood) | yes (simulated whole blood) | yes |
| • Integrated QC with each analysis | no | no | no |
| • Automatic lockout for QC failure | yes | yes | optional (user defined) |
| • Other | operator lockout | operator lockout | — |
| Time (in minutes) to perform control plus specimen test | | | |
| • PT: | 2 | 2 | n/a |
| • PT & PTT: | 2 | 2 | n/a |
| • ACT: | 1–5 | 1–5 | up to 12 (depending on patient sample) |
| Data management capability | onboard | onboard | yes |
| Includes QC | yes | yes | yes |
| System can automatically transfer data to information system | | | |
| • Patient data | yes | yes | yes |
| • QC data | yes | yes | yes |
| Interface supplied by instrument vendor | yes | yes | no |
| LOINC codes transmitted with results | — | — | — |
| How labs get LOINC codes for reagent kit | — | — | Web site |
| Commercially available systems for which interfaces are up and running in active user sites | yes | yes | Telcor, RALS Plus in development |
| Lab can control analyzer remotely | no | no | no |
| Real-time wireless linkage to LIS or HIS | no | no | no |
| Positive identification system (e.g. bar code) for: | | | |
| • Patient specimen | no | no | yes |
| • Reagent | yes | yes | yes |
| Onboard system for automatic error detection | yes, for sample (volume) and reagent/expiration date | yes, for sample (volume) and reagent/expiration date | yes |
| Training provided with instrument purchase | yes (on site) | yes (on site) | yes (on site) |
| Approx. No. of training hours needed for: | | | |
| • Medical staff | 1–2 hr | 1 hr | 6 hr |
| • Patient | n/a | n/a | n/a |
| Patient self-testing program is available | no | no | no |
| Instrument list price | \$4,055 | \$7,900 | \$26,000 |
| Reagent rental or lease only | no | no | rental and purchase available |
| Cost per sample for: | | | |
| • PT: Cost per sample for reagent rental | n/a | n/a | — |
| Cost per sample if device purchased | — | — | — |
| • PTT: Cost per sample for reagent rental | n/a | n/a | — |
| Cost per sample if device purchased | — | — | — |
| • ACT: Cost per sample for reagent rental | n/a | n/a | — |
| Cost per sample if device purchased | — | — | — |
| CLIA '88 complexity rating | moderate | moderate | customer dependent, per contract moderate (non-waived) |
| Unique advantages (provided by the vendor) | <ul style="list-style-type: none"> • QC lockout • data storage and management • connectivity options • RxDx heparin/protamine dosing system | <ul style="list-style-type: none"> • new compliance technology • QC lockout • data management storage and printing • connectivity options • blood volume—15 µL • ease of use • configurable QC and operator lockout | <ul style="list-style-type: none"> • 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 Roche Sales 9115 Hague Rd. Indianapolis, IN 46250 800-852-8766 www.roche-diagnostics.com | Roche Diagnostics Roche Sales 9115 Hague Rd. Indianapolis, IN 46250 800-852-8766 www.roche-diagnostics.com |
|---|--|---|---|
| <i>See accompanying article on page 14</i> | | | |
| Instrument name | ACT Plus | CoaguChek XS PT Test System | CoaguChek S System for Prothrombin Time Testing (professional use) |
| First year sold | 2003 | 2006 (international)/2007 (U.S.) | 2001 |
| No. of units sold in U.S./Outside U.S. | —/— | —/— | 30,000/100,000 |
| No. of units sold in 2006 | 415 | — | — |
| • units sold to: | — | — | — |
| Country where analyzer designed/Manufactured | U.S./U.S. | Germany/Germany | Germany/Germany |
| Is instrument POC or self-monitoring analyzer? | POC | POC and self-monitoring | POC |
| Specimen type | venipuncture (whole blood) | fresh whole blood (venous or fingerstick capillary) | fresh whole blood (venous or fingerstick capillary) |
| Model type | benchtop | handheld/portable | handheld/portable |
| Dimensions in inches (H x W x D)/Weight | 11 x 8 x 13/11.5 lb | 5.43 x 3.07 x 1.10/4.48 oz | 1.8 x 4.9 x 6.8/1.0 lb |
| Specimen volume needs | accurate volume required (fill line on cuvette and optional easy fill accessory) | accurate volume not necessary (drop), minimum 10 µL | accurate volume not necessary (drop), minimum 10 µL |
| Clotting-based tests for which device has FDA-cleared applications | ACT (high range, low range, recalcified, high range heparinase) | PT (reportable range: low 9.6 sec, high 96 sec; INR: low 0.8, high 8.0) | PT (reportable range: low 9.6 sec, high 33.9 sec; INR: low 0.6, high 8.0) |
| Tests using other methodologies for which device has FDA-cleared applications | none | none | none |
| FDA-cleared tests but not yet clinically released | — | none | none |
| Tests submitted for 510(k) clearance | — | CoaguChek XS Plus System (professional use only) | none |
| Tests in development but not yet submitted for clearance | — | none | none |
| Method of endpoint detection | mechanical clot detection | amperometric detection | 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 | no | yes |
| • Liquid | no | no | yes |
| • Lyophilized | yes | no | no |
| • Integrated QC with each analysis | no | yes | no |
| • Automatic lockout for QC failure | optional (user defined) | no | no |
| • Other | — | n/a | n/a |
| Time (in minutes) to perform control plus specimen test | | | |
| • PT: | — | < 1 minute | 1 min for either test or QC result; QC not required with every sample |
| • PT & PTT: | — | n/a | n/a |
| • ACT: | up to 12 min (depends on patient sample) | n/a | n/a |
| Data management capability | yes | no | yes, external software programs |
| Includes QC | yes | no | no |
| System can automatically transfer data to information system | | | |
| • Patient data | yes | no | yes |
| • QC data | yes | no | yes |
| Interface supplied by instrument vendor | no | — | software vendor |
| LOINC codes transmitted with results | — | no | n/a |
| How labs get LOINC codes for reagent kit | Web site | n/a | n/a |
| Commercially available systems for which interfaces are up and running in active user sites | Telcor, RALS Plus in development | — | Coag Clinic from Standing Stone Inc. |
| Lab can control analyzer remotely | no | no | no |
| Real-time wireless linkage to LIS or HIS | no | no | no |
| Positive identification system (e.g. bar code) for: | | | |
| • Patient specimen | yes | no | no |
| • Reagent | yes | no | no |
| Onboard system for automatic error detection | yes | yes, for sample (volume), meter performance, proper strip chemistry/strip mishandling | yes, for sample (volume) and reagent/cuvette 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 | 1 hr | — | 1 hr |
| • Patient | n/a | — | n/a |
| Patient self-testing program is available | no | yes | no |
| Instrument list price | \$4,200 | varies by distributor | \$1,149 |
| Reagent rental or lease only | rental and purchase available | — | contact Roche Diagnostics sales |
| Cost per sample for: | | | |
| • PT: Cost per sample for reagent rental | — | — | contact Roche Diagnostics sales |
| Cost per sample if device purchased | — | — | \$5 |
| • PTT: Cost per sample for reagent rental | — | — | n/a |
| Cost per sample if device purchased | — | — | n/a |
| • ACT: Cost per sample for reagent rental | — | — | n/a |
| Cost per sample if device purchased | customer dependent, per contract | — | n/a |
| CLIA '88 complexity rating | moderate (non-waived) | CLIA waived | CLIA waived for professional use |
| Unique advantages (provided by the vendor) | <ul style="list-style-type: none"> • data management software application • duplicate test results • optional bar-code scanner • optional easy filling accessory | <ul style="list-style-type: none"> • only system to perform onboard quality control and to determine 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 | <ul style="list-style-type: none"> • fast test time—results in 1 minute • small sample: 10 µL from fingerstick • automatic calibration and system checks for consistent reliability • simple one-button operation makes training easy |