

| Part 1 of 7 | Bio/Data Corp. Robert F. Wheaton III rob.wheaton@biodatacorp.com Horsham, PA 215-441-4000 or 800-257-3282 www.biodatacorp.com | Chrono-log Corp. Kathy Jacobs jacobs@chronolog.com Havertown, PA 610-853-1130 or 800-247-6665 www.chronolog.com | Chrono-log Corp. Kathy Jacobs jacobs@chronolog.com Havertown, PA 610-853-1130 or 800-247-6665 www.chronolog.com |
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| See captodayonline.com/productguides for an interactive version of guide | | | |
| Instrument name/First year sold | Platelet Aggregation Profiler PAP 8E/2005 | Optical Aggregation Systems Models 490 4+, 490 4+4/2017 | Whole Blood Optical Lumi-Aggregation System 700-2, 700-4/2006 |
| Number of units installed in U.S./Outside U.S. | 401/267 | — | 160/205 |
| Number of contracts signed between 1/1/18 and 11/15/18 | — | — | — |
| Country where analyzer designed/Manufactured | U.S./U.S. | U.S./U.S. | U.S./U.S. |
| Operational type | batch, random access | batch, random access | batch, random access |
| Reagent type | open reagent system (liquid, lyophilized, reconstituted manually) | open reagent system (lyophilized, reconstituted manually) | open reagent system, assay kits, reference plasmas, controls (lyophilized, reconstituted manually) |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | whole blood, spun plasma |
| Sample handling system | electronic pipette with presets and memory | manual | manual |
| Model type | benchtop | benchtop | benchtop |
| Dimensions (H x W x D)/Weight/Instrument footprint | 21.5 x 27.5 x 21.7 in./40 lbs./4 sq. ft. | for each 4-channel module: 8.5 x 14 x 15 in./19.3 lbs./1.5 sq. ft. | 8.5 x 14 x 18 in./40 lbs./M700-2: 1.75 sq. ft.; M700-4: 3.5 sq. ft. |
| FDA-cleared clotting-based tests | — | — | — |
| FDA-cleared chromogenic tests | — | — | — |
| FDA-cleared immunologic tests | ristocetin cofactor assay, RIPA, agglutination; open system for other Ab-Ag tests | — | — |
| Other FDA-cleared tests | platelet activation: spontaneous platelet aggregation, sticky platelet syndrome, compound and vehicle tests; platelet aggregation: PRP, PPP, PFP washed platelet samples, multiple agonists and RUO agents, WBC aggregation | LTA aggregation, ristocetin cofactor assay | platelet-dense granule secretion, whole blood impedance aggregation, LTA aggregation, ristocetin cofactor assay |
| User-defined tests in clinical use | >99 active | LTA aggregation, ristocetin cofactor assay | platelet-dense granule secretion, whole blood impedance aggregation, LTA aggregation with all standard reagents, ristocetin cofactor assay |
| Tests submitted for 510(k) clearance | — | — | — |
| Tests in development but not yet submitted | proprietary | — | — |
| Methodologies supported | turbidimetric, immunologic (agglutination) | turbidimetric; LTA aggreg., ristocetin cofactor assay | turbidimetric, platelet-dense granule secretion, whole blood impedance aggreg., LTA aggreg., ristocetin cofactor assay |
| Operator must load sep. reagent pack per specimen/Test run | no/no | no/no | no/— |
| Number of different measured assays onboard simultaneously | 99 | 4-8 | 2-4 |
| Number of different assays programmed and calib. at one time | 99 | 4-8 | 4-8 |
| Number of user-definable (open) channels | 8 | 4-8 | 2-4 |
| Of those defined, number active simultaneously | 8 | 4-8 | 2-4 |
| Factor assays require manual manipulation or dilutions | yes (von Willebrand factor activity) | — | yes |
| Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard | 2, with inserts for various sizes/varies/no | —/—/no | no/—/no |
| Multiple reagent configurations supported | yes | yes | yes |
| Reagents, consumables loaded without interrupting testing | yes | yes | yes |
| Same capabilities when third-party reagent used | no | yes | no |
| Maximum time same lot number of reagents can be used | 1 year, extended periods may be available for projects | 12-30 months | 12-30 months |
| Walkaway capacity: Number of specimens/Number of tests | 8/9 | 4-8/4-8 | 2-4/4-8 |
| Minimum sample volume aspirated precisely at one time | 25 µL | 250 µL | — |
| Standard specimen volume required to run PT or PTT/ Factor VIII activity | — | — | 225 µL PRP-lumi aggregation 450 µL; 450 µL whole blood-lumi aggregation 450 µL/25 µL ristocetin cofactor 50 µL |
| Disposables used/Price of each | siliconized microtubes: 100 @ \$36.25; plastic-coated microstir bars: 50 @ \$21; pipette tips: 960 @ \$48; MagneTubes: 50 @ \$50 | cuvettes: 144 @ \$45; stir bars: 144 @ \$35; pipette tips: \$85, \$67, and \$73 | cuvettes: 144 @ \$34; stir bars: 144 @ \$30; impedance probes: 25 @ \$130; pipette tips: 1,000 @ \$73, \$55, and \$60 |
| Supports direct-from-track sampling | no | no | no |
| Primary tube sampling supported/Pierces caps on primary tubes | no/no | no/no | no/no |
| Sample/Reagent barcode reading capability | yes/yes | no/no | no/no |
| Onboard test automatic inventory | no | no | no |
| Measures No. of tests remaining/Short sample detection | no/no | no/no | no/no |
| Clot detection as preanalytical variable in plasma sample | no | no | no |
| Auto. detects adequate reagents for aspiration and analysis | no | no | no |
| Hemolysis/Turbidity detection-quantitation | yes/yes | no/— | no/no |
| Dilution of patient samples onboard | no | no | no |
| Automatic rerun capability/Auto reflex testing capability | no/no | yes/no | yes/no |
| Lag time during which hypercoagulable sample not detected | — | — | — |
| Read time extended for prolonged clotting times | — | yes | yes |
| User can set different-than-standard: | | | |
| • Reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| • No. and sources of reagent | yes | yes | yes |
| • Incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Autocalib. or autocalib. alert/Multipoint calib. supported | yes/yes | yes/yes | yes/— |
| Auto shutdown/Auto startup programmable | yes/no | no/no | no/no |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | — | — | — |
| • PT, PTT | — | — | — |
| • Fibrinogen | — | — | — |
| • Factor VIII activity assay | — | — | — |
| Time delay from ordering stat to aspiration of sample | — | — | — |
| Automatic transfer of QC results to LIS | no | no | no |
| Data-management capability | onboard (includes QC: L-J plots, Westgard multirules for low-volume tests); optional add-on (\$275, Bio/Data) | onboard | onboard |
| Interface supplied by instrument vendor | — | yes | yes |
| Interfaces in active user sites for: | — | — | — |
| Bidirectional interface capability | no | no | no |
| Results transferred to LIS as soon as test time complete | no | no | no |
| LOINC codes transmitted with all results | no | no | no |
| How labs get LOINC codes for reagent kits | email query | email query | — |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system | no | no | no |
| Modem servicing | no | no | no |
| Time required for maintenance by lab personnel | weekly: 15 minutes; monthly: 30 minutes | 30 minutes when optical calibration required | 30 minutes when optical calibration required |
| Onboard maintenance records | no | yes | yes |
| Training provided with purchase | 1.5 days on site; at vendor offices on special request | — | 1.5 days on site |
| Approximate number of training hours needed per tech | 4-6 | — | 8 |
| List price | \$21,990 | M490 4+: \$11,800; M490 4+4: \$20,700 | M700-2: \$19,500; M700-4: \$32,000 |
| Annual service contract cost (24/7)/Warranty with purchase | \$2,050 (during business hours)/2 yrs., includes in-lab PC service | M490 4+: \$1,804; M490 4+4: \$3,008 for 3 years/1 year | M700-2: \$1,804; M700-4: \$3,008 for 3 years/1 year |
| Distinguishing features (supplied by company) | patented electro-optical circuitry sensitive to microaggregates and compromised samples; no moving parts in analyzer; 2-year warranty, incl. 2-year in-lab service on PC so patient data never leave the lab; TeleCheck calibration verification service performed in lab with telephone guidance | continuously monitors temperature and stirring with warning messages; optical calibration by laboratory personnel; Windows-based software provides customized color-coding options | tests platelet aggregation; measures ATP release in 4 samples simultaneously using whole blood, PRP, washed, or gel-filtered platelets; continuously monitors temp. and stirring speed; optical calibration by lab personnel; dedicated software packages calculate amplitude, slope, lag time, and more |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> | | | |

| Part 2 of 7 | Diagnostica Stago Nichole Howard nichole.howard@us.stago.com Parsippany, NJ 800-222-2624 www.stago-us.com | Diagnostica Stago Nichole Howard nichole.howard@us.stago.com Parsippany, NJ 800-222-2624 www.stago-us.com | Diagnostica Stago Barry Ray barry.ray@us.stago.com Parsippany, NJ 800-222-2624 www.stago-us.com |
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| See captodayonline.com/productguides for an interactive version of guide | | | |
| Instrument name/First year sold | STA Compact Max/2013 | STA Satellite/2010 | STA-R Max/2015 |
| Number of units installed in U.S./Outside U.S. | ~1,300/~5,200 | ~550/~1,300 | ~220/2,000 |
| Number of contracts signed between 1/1/18 and 11/15/18 | — | — | — |
| Country where analyzer designed/Manufactured | France/France | France/France | France/France |
| Operational type | continuous random access | random access | continuous random access |
| Reagent type | open reagent system | open reagent system | open reagent system, complete line of routine and specialty assays |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Sample handling system | continuous load sample drawer | carousel | rack with continuous specimen access |
| Model type | benchtop | benchtop | floor standing |
| Dimensions (H × W × D)/Weight/Instrument footprint | 27.75 × 38.18 × 28.73 in./309 lbs./7 sq. ft. | 27.4 × 21.1 × 25.5 in./72 lbs./4 sq. ft. | 49.2 × 50.3 × 32.2 in./564 lbs./26.8 sq. ft. |
| FDA-cleared clotting-based tests | PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT (screen and confirm) | PT, APTT, fibrinogen | PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT (screen and confirm) |
| FDA-cleared chromogenic tests | heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin | heparin (UFH and LMWH), AT | heparin (UFH and LMWH), protein C, AT, plasminogen, antiplasmin |
| FDA-cleared immunologic tests | D-dimer, VWF, total and free protein S, AT antigen | D-dimer | D-dimer, VWF, total and free protein S, AT antigen |
| Other FDA-cleared tests | — | — | — |
| User-defined tests in clinical use | — | — | APCR, other clotting chromogenic and immunological tests with user-defined applications |
| Tests submitted for 510(k) clearance | — | — | — |
| Tests in development but not yet submitted | — | — | — |
| Methodologies supported | exclusive mechanical clot detection, chromogenic, immunologic | exclusive mechanical clot detection, chromogenic, immunologic | exclusive mechanical clot detection, chromogenic, immunologic |
| Operator must load sep. reagent pack per specimen/Test run | no/no | no/no | no/no |
| Number of different measured assays onboard simultaneously | 80 | 80 | 200 |
| Number of different assays programmed and calib. at one time | 80 | 80 | 200 |
| Number of user-definable (open) channels | 80 | 80 | 200 |
| Of those defined, number active simultaneously | 80 | 80 | 200 |
| Factor assays require manual manipulation or dilutions | no | — | no |
| Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard | 45/varies/yes (15°–19°C) | 16/varies/yes (15°–19°C) | 70/varies/yes (15°–19°C) |
| Multiple reagent configurations supported | yes | yes | yes |
| Reagents, consumables loaded without interrupting testing | consumables: yes; reagents: no | consumables: yes; reagents: no | consumables: yes; reagents: no |
| Same capabilities when third-party reagent used | yes | yes | yes |
| Maximum time same lot number of reagents can be used | 18 months | 18 months | 18 months |
| Walkaway capacity: Number of specimens/Number of tests | 96/12 | 20/12 per specimen | 215/32 |
| Minimum sample volume aspirated precisely at one time | 5 µL | 5 µL | 5 µL |
| Standard specimen volume required to run PT or PTT/ Factor VIII activity | 50 µL/5 µL | 50 µL/— | 50 µL/5 µL |
| Disposables used/Price of each | cuvettes, cleaner solution/varies | cuvettes, cleaner solution/varies | cuvettes, cleaner solution/varies |
| Supports direct-from-track sampling | no | no | yes (Beckman Coulter, Siemens, Roche, Abbott, Ortho, Labotix, Inpeco) |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/yes | yes/no | yes/yes |
| Sample/Reagent barcode reading capability | yes/yes | yes/yes | yes/yes |
| Onboard test automatic inventory | yes | yes | yes |
| Measures No. of tests remaining/Short sample detection | no/yes | no/yes | no/yes |
| Clot detection as preanalytical variable in plasma sample | no | no | no |
| Auto. detects adequate reagents for aspiration and analysis | yes | yes | yes |
| Hemolysis/Turbidity detection-quantitation | no (not necessary)/no (not necessary) | no (not necessary)/no (not necessary) | no/no (not necessary for mechanical detection technology) |
| Dilution of patient samples onboard | yes | yes | yes |
| Automatic rerun capability/Auto reflex testing capability | yes/yes | yes/no | yes/yes |
| Lag time during which hypercoagulable sample not detected | no | no | no |
| Read time extended for prolonged clotting times | yes | yes | yes (selectable on menus) |
| User can set different-than-standard: | | | |
| • Reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| • No. and sources of reagent | yes | yes | yes |
| • Incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Autocalib. or autocalib. alert/Multipoint calib. supported | yes/yes | yes/yes | yes/yes |
| Auto shutdown/Auto startup programmable | no (not necessary)/no (not necessary) | no (not necessary)/no (not necessary) | no (not necessary)/no (not necessary) |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | <6 minutes/~150 specimens | <6 minutes/~50 specimens | <6 minutes/~300 specimens |
| • PT, PTT | <6 minutes/~100 specimens | <6 minutes/~40 specimens | <6 minutes/~200 specimens |
| • Fibrinogen | <6 minutes/~100 specimens | <6 minutes/~40 specimens | <6 minutes/~180 specimens |
| • Factor VIII activity assay | <6 minutes/~50 specimens | — | <6 minutes/~180 specimens |
| Time delay from ordering stat to aspiration of sample | <15 seconds | <15 seconds | <15 seconds |
| Automatic transfer of QC results to LIS | yes | yes | yes |
| Data-management capability | onboard (includes QC: L-J plots, Westgard rules) | onboard (includes QC: L-J plots) | onboard (includes QC: L-J plots, Westgard rules) |
| Interface supplied by instrument vendor | no | no | no |
| Interfaces in active user sites for: | all major LIS vendors | all major LIS vendors | all major LIS vendors |
| Bidirectional interface capability | yes (broadcast download, host query) | yes (host query) | yes (broadcast download, host query) |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| LOINC codes transmitted with all results | yes | no | yes |
| How labs get LOINC codes for reagent kits | — | — | — |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system | no | no | yes (Beckman Coulter, Siemens, Roche, Abbott, Ortho, Labotix, Inpeco) |
| Modem servicing | yes | no | yes |
| Time required for maintenance by lab personnel | weekly: <15 minutes; monthly: <15 minutes | weekly: <15 minutes; monthly: <15 minutes | weekly: <15 minutes; monthly: <15 minutes |
| Onboard maintenance records | yes | yes | yes |
| Training provided with purchase | 3.5 days at Stago headquarters | 2.5 days at Stago headquarters | 3.5 days at Stago headquarters |
| Approximate number of training hours needed per tech | 24 | 12 | 24 |
| List price | \$150,000 | \$55,000 | \$241,000 |
| Annual service contract cost (24/7)/Warranty with purchase | —/1 year | —/1 year | —/1 year |
| Distinguishing features (supplied by company) | viscosity-based, mechanical clot detection; integrated STA Coag Expert (enhanced software) delivers full autoverification, repeat/reflex testing, expert rules to simplify complex factor assays and LA tests, comprehensive patient/QC management; online, customizable Quality Control peer program; standardized with all STA analyzers | viscosity-based, mechanical clot detection; integrated STA Coag Expert (enhanced software) delivers full autoverification, repeat/reflex testing, expert rules to simplify complex factor assays and LA tests, comprehensive patient/QC management; online, customizable Quality Control peer program; standardized with all STA analyzers | viscosity-based, mechanical clot detection; integrated STA Coag Expert (enhanced software) delivers full autoverification, repeat/reflex testing, expert rules to simplify complex factor assays and LA tests, comprehensive patient/QC management; online, customizable Quality Control peer program; standardized with all STA analyzers |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> | | | |

| Part 3 of 7 | Diagnostica Stago Nichole Howard nichole.howard@us.stago.com Parsippany, NJ 800-222-2624 www.stago-us.com | Helena Laboratories David Pearman dpearman@helena.com Beaumont, TX 409-842-3714 ext. 265 www.helena.com | Helena Laboratories David Pearman dpearman@helena.com Beaumont, TX 409-842-3714 ext. 265 www.helena.com |
|--|--|---|---|
| Instrument name/First year sold | StArt Hemostasis Analyzer/1998 | AggRAM/2005 | Cascade M-4/1992 |
| Number of units installed in U.S./Outside U.S. | ~750/>9,000 | 100+/500+ | 200+/-40 |
| Number of contracts signed between 1/1/18 and 11/15/18 | — | 8 | 5 |
| Country where analyzer designed/Manufactured | France/France | U.S./U.S. | U.S./U.S. |
| Operational type | batch | batch, random access | random access |
| Reagent type | open reagent system | open reagent system | open reagent system |
| Operates on whole blood or spun plasma | spun plasma | spun plasma, platelet rich plasma | spun plasma |
| Sample handling system | manual | manual | manual |
| Model type | benchtop | benchtop | benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 4.7 × 16.1 × 16.5 in./12.5 lbs./1.8 sq. ft. | 6 × 10 × 17 in./15 lbs./— | 8 × 15 × 13 in./25 lbs./1.4 sq. ft. |
| FDA-cleared clotting-based tests | PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRW (screen and confirm) | — | PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII |
| FDA-cleared chromogenic tests | — | — | — |
| FDA-cleared immunologic tests | — | — | — |
| Other FDA-cleared tests | — | ristocetin cofactor and platelet aggregation | — |
| User-defined tests in clinical use | — | ristocetin cofactor, platelet aggregation (ADP, EPI, COL, ristocetin, arachidonic acid) | PT, APTT, fibrinogen, TCT, factor assays II, V, VII–XII |
| Tests submitted for 510(k) clearance | — | — | — |
| Tests in development but not yet submitted | — | lumi, chromogenics, HIT | DRWVT |
| Methodologies supported | exclusive mechanical clot detection | ristocetin cofactor, platelet aggregation | clot detection, optical; turbidimetric |
| Operator must load sep. reagent pack per specimen/Test run | no/no | no/no | no/no |
| Number of different measured assays onboard simultaneously | 1 | 4–8 | 4 |
| Number of different assays programmed and calib. at one time | 20 | 4–8 | 4 |
| Number of user-definable (open) channels | 4 | 12 | 4 |
| Of those defined, number active simultaneously | 1 | 4–8 | 2 |
| Factor assays require manual manipulation or dilutions | yes | yes | yes |
| Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard | 2/varies/no | —/—/no | 0/—/no |
| Multiple reagent configurations supported | yes | no | no |
| Reagents, consumables loaded without interrupting testing | no | no | no |
| Same capabilities when third-party reagent used | yes | — | yes |
| Maximum time same lot number of reagents can be used | 18 months | 12 months | 12 months |
| Walkaway capacity: Number of specimens/Number of tests | — (semiautomated)/— | — | — |
| Minimum sample volume aspirated precisely at one time | — | — | manual, 50 µL |
| Standard specimen volume required to run PT or PTT/ Factor VIII activity | 50 µL/50 µL | platelet aggregation: 225 µL PRP; ristocetin cofactor: 50 µL/ platelet aggregation: 225 µL PRP; ristocetin cofactor: 50 µL | 100 µL, minimum 50 µL/100 µL (diluted), minimum 50 µL (diluted) |
| Disposables used/Price of each | cuvettes, balls/varies | cuvettes: 200 @ \$55.65; pipette tips: 1,000 @ \$82; stir bars: 30 @ \$62.25 | cuvettes: 500 @ \$54; pipette tips: 1,000 @ \$82 |
| Supports direct-from-track sampling | no | no | no |
| Primary tube sampling supported/Pierces caps on primary tubes | no/— | no/— | no/— |
| Sample/Reagent barcode reading capability | no/no | no/no | no/no |
| Onboard test automatic inventory | no | no | no |
| Measures No. of tests remaining/Short sample detection | no/— | no/no | no/no |
| Clot detection as preanalytical variable in plasma sample | no | — | — |
| Auto. detects adequate reagents for aspiration and analysis | no | no | no |
| Hemolysis/Turbidity detection-quantitation | no/no (not necessary) | no/no | no/no |
| Dilution of patient samples onboard | no | no | no |
| Automatic rerun capability/Auto reflex testing capability | no/— | no/no | no/no |
| Lag time during which hypercoagulable sample not detected | yes (selectable on menus) | — | yes (PT: 4 seconds; PTT: 14 seconds) |
| Read time extended for prolonged clotting times | — | — | yes (selectable on menus) |
| User can set different-than-standard: | | | |
| • Reagent volumes/Sample volumes | yes/— | yes/yes | yes/yes |
| • No. and sources of reagent | yes | yes | yes |
| • Incubation times/Reading times | no/yes | yes/yes | yes/yes |
| Autocalib. or autocalib. alert/Multipoint calib. supported | — | no/yes | no/yes |
| Auto shutdown/Auto startup programmable | — | no/no | no/no |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | <6 minutes/up to 120 specimens | — | 3 minutes/140 specimens |
| • PT, PTT | — | — | 7 minutes/80 specimens |
| • Fibrinogen | <6 minutes/up to 120 specimens | — | 3 minutes/160 specimens |
| • Factor VIII activity assay | <6 minutes/up to 60 specimens | — | 7 minutes/80 specimens |
| Time delay from ordering stat to aspiration of sample | — | — | — |
| Automatic transfer of QC results to LIS | no | yes | yes |
| Data-management capability | no | onboard (includes QC: L-J plots, Westgard multirules) | no |
| Interface supplied by instrument vendor | no | no | no |
| Interfaces in active user sites for: | — | — | — |
| Bidirectional interface capability | no (unidirectional only) | no | no |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| LOINC codes transmitted with all results | no | no | no |
| How labs get LOINC codes for reagent kits | — | — | — |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system | no | no | no |
| Modem servicing | no | — | no |
| Time required for maintenance by lab personnel | weekly: <5 minutes; monthly: <5 minutes | daily: 15 minutes; weekly: 15 minutes; monthly: 1 hour | daily: 10 minutes; weekly: 10 minutes; monthly: 30 minutes |
| Onboard maintenance records | no | yes | no |
| Training provided with purchase | 1 day on site | 2 days on site | 1 day on site |
| Approximate number of training hours needed per tech | 1 | 4–8 | 2 |
| List price | \$12,000 | \$15,744 | \$10,115 |
| Annual service contract cost (24/7)/Warranty with purchase | —/1 year | \$1,984/1 year | \$1,291/1 year |
| Distinguishing features (supplied by company) | viscosity-based detection system; ideal for low-volume testing or backup for optical system; programmable and preprogrammed assays with curve storage plus 4 independently timed measurement wells | specialized coagulation instrument intended for platelet aggregation and ristocetin cofactor | 4-channel manual analyzer, QC program onboard, singles or duplicates |

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

| Part 4 of 7 | Instrumentation Laboratory Venita Shirley vshirley@ilww.com Bedford, MA 800-955-9525 www.instrumentationlaboratory.com | Instrumentation Laboratory Venita Shirley vshirley@ilww.com Bedford, MA 800-955-9525 www.instrumentationlaboratory.com | Instrumentation Laboratory Venita Shirley vshirley@ilww.com Bedford, MA 800-955-9525 www.instrumentationlaboratory.com |
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| See captodayonline.com/productguides for an interactive version of guide | | | |
| Instrument name/First year sold | ACL TOP 750 Series/2016 | ACL TOP 550 CTS/2016 | ACL TOP 350/300 CTS/2012 |
| Number of units installed in U.S./Outside U.S. | 4,000+/8,000+ (all ACL models combined) | 4,000+/8,000+ (all ACL models combined) | 4,000+/8,000+ (all ACL models combined) |
| Number of contracts signed between 1/1/18 and 11/15/18 | — | — | — |
| Country where analyzer designed/Manufactured | U.S./U.S. | U.S./U.S. | U.S./U.S. |
| Operational type | continuous random access | continuous random access | continuous random access |
| Reagent type | open reagent system | open reagent system | open reagent system |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Sample handling system | racks, continuous loading of primary tubes | racks, continuous loading of primary tubes | racks, continuous loading of primary tubes |
| Model type | benchtop | benchtop | benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 29 × 60 × 35 in./331 lbs./21 sq. ft. | 29 × 43 × 35 in./312 lbs./14 sq. ft. | 29 × 32 × 33 in./200 lbs./8 sq. ft. |
| FDA-cleared clotting-based tests | PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVT), APCR-V, proteins C and S, FVIII (with VWF) | PT, APTT, fibrinogen, TT, factors, lupus (SCT and DRVT), APCR-V, proteins C and S, FVIII (with VWF) | PT, APTT, fibrinogen, TT, factors, FVIII (with VWF) |
| FDA-cleared chromogenic tests | anti-Xa, protein C, AT, plasminogen, plasmin inhibitor | anti-Xa, protein C, AT, plasminogen, plasmin inhibitor | anti-Xa, AT |
| FDA-cleared immunologic tests | D-Dimer, D-Dimer HS, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine, heparin-induced thrombocytopenia | D-Dimer, D-Dimer HS, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine, heparin-induced thrombocytopenia | Domain 1, D-Dimer, D-Dimer HS, heparin-induced thrombocytopenia |
| Other FDA-cleared tests | — | — | — |
| User-defined tests in clinical use | — | — | — |
| Tests submitted for 510(k) clearance | — | — | — |
| Tests in development but not yet submitted | VWF (RCo), direct oral anticoagulants (dabigatran, rivaroxaban, apixaban) | VWF (RCo), direct oral anticoagulants (dabigatran, rivaroxaban, apixaban) | VWF (RCo), direct oral anticoagulants (dabigatran, rivaroxaban, apixaban) |
| Methodologies supported | LED optical detection: clotting, chromogenic, and immunologic | LED optical detection: clotting, chromogenic, and immunologic | LED optical detection: clotting, chromogenic, and immunologic |
| Operator must load sep. reagent pack per specimen/Test run | no/no | no/no | no/no |
| Number of different measured assays onboard simultaneously | 500 | 500 | 500 |
| Number of different assays programmed and calib. at one time | 500 | 500 | 500 |
| Number of user-definable (open) channels | 250 | 250 | 250 |
| Of those defined, number active simultaneously | 30 | 30 | 30 |
| Factor assays require manual manipulation or dilutions | no | no | no |
| Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard | 60/varies/yes | 40/varies/yes | 24/varies/yes |
| Multiple reagent configurations supported | yes | yes | yes |
| Reagents, consumables loaded without interrupting testing | yes | yes | yes |
| Same capabilities when third-party reagent used | yes | yes | yes |
| Maximum time same lot number of reagents can be used | 18 months | 18 months | 18 months |
| Walkaway capacity: Number of specimens/Number of tests | 120/800 | 80/800 | 40/800 |
| Minimum sample volume aspirated precisely at one time | 4 µL | 4 µL | 4 µL |
| Standard specimen volume required to run PT or PTT/ Factor VIII activity | 50 µL/25 µL | 50 µL/25 µL | 50 µL/— |
| Disposables used/Price of each | cuvettes/varies | cuvettes/varies | cuvettes/varies |
| Supports direct-from-track sampling | yes (model available) | no | no |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/yes (optional) | yes/yes | yes/yes |
| Sample/Reagent barcode reading capability | yes/yes | yes/yes | yes/yes |
| Onboard test automatic inventory | yes | yes | yes |
| Measures No. of tests remaining/Short sample detection | yes/yes | yes/yes | yes/yes |
| Clot detection as preanalytical variable in plasma sample | optional | optional | optional |
| Auto. detects adequate reagents for aspiration and analysis | yes | yes | yes |
| Hemolysis/Turbidity detection-quantitation | optional/optional | optional/optional | optional/optional |
| Dilution of patient samples onboard | yes | yes | yes |
| Automatic rerun capability/Auto reflex testing capability | yes/yes | yes/yes | yes/yes |
| Lag time during which hypercoagulable sample not detected | no | no | no |
| Read time extended for prolonged clotting times | yes | yes | yes |
| User can set different-than-standard: | | | |
| • Reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| • No. and sources of reagent | yes | yes | yes |
| • Incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Autocalib. or autocalib. alert/Multipoint calib. supported | yes/yes | yes/yes | yes/yes |
| Auto shutdown/Auto startup programmable | not needed/not needed | not needed/not needed | not needed/not needed |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | <3 minutes/360 specimens | <3 minutes/240 specimens | <3 minutes/110 specimens |
| • PT, PTT | <6 minutes/165 specimens | <6 minutes/90 specimens | <6 minutes/55 specimens |
| • Fibrinogen | <3 minutes/108 specimens | <3 minutes/78 specimens | <6 minutes/60 specimens |
| • Factor VIII activity assay | 8 minutes/100 specimens | 8 minutes/77 specimens | <11 minutes/38 specimens |
| Time delay from ordering stat to aspiration of sample | 0 seconds | 0 seconds | 0 seconds |
| Automatic transfer of QC results to LIS | yes | yes | yes |
| Data-management capability | yes | yes | yes |
| Interface supplied by instrument vendor | no | no | no |
| Interfaces in active user sites for: | most major vendors | most major vendors | most major vendors |
| Bidirectional interface capability | yes (broadcast download and host query) | yes (broadcast download and host query) | yes (broadcast download and host query) |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| LOINC codes transmitted with all results | no | no | no |
| How labs get LOINC codes for reagent kits | — | — | — |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system | yes | no | no |
| Modem servicing | in development | in development | in development |
| Time required for maintenance by lab personnel | daily: <10 minutes; weekly: 10 minutes; monthly: none | daily: <10 minutes; weekly: 10 minutes; monthly: none | daily: <10 minutes; weekly: 10 minutes; monthly: none |
| Onboard maintenance records | yes | yes | yes |
| Training provided with purchase | 4 days at vendor offices | 4 days at vendor offices | 4 days at vendor offices |
| Approximate number of training hours needed per tech | 24–40 | 24–40 | 24–40 |
| List price | — | — | — |
| Annual service contract cost (24/7)/Warranty with purchase | —/1 year | —/1 year | —/1 year |
| Distinguishing features (supplied by company) | complete standardization solution; on-demand HIT testing; detects underfilled samples; 671-nm LED detection minimizes interferences from HIL, samples with HIL levels exceeding assay threshold are flagged; complete HemosIL assay menu, including D-Dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH | complete standardization solution; on-demand HIT testing; detects underfilled samples; 671-nm LED detection minimizes interferences from HIL, samples with HIL levels exceeding assay threshold are flagged; complete HemosIL assay menu, including D-Dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH | complete standardization solution; on-demand HIT testing; detects underfilled samples; 671-nm LED detection minimizes interferences from HIL, samples with HIL levels exceeding assay threshold are flagged; complete HemosIL assay menu, including D-Dimer HS with VTE exclusion; HemosIL plasma sets for validation of INR test system; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> | | | |

| Part 5 of 7 | Instrumentation Laboratory Venita Shirley vshirley@ilwww.com Bedford, MA 800-955-9525 www.instrumentationlaboratory.com | Instrumentation Laboratory Venita Shirley vshirley@ilwww.com Bedford, MA 800-955-9525 www.instrumentationlaboratory.com | LABiTec GmbH Matthias Schramm matthias.schramm@labitec.de Ahrensburg, Germany 011-49-4102-47950 www.labitec.com |
|--|--|---|--|
| See captodayonline.com/productguides for an interactive version of guide | | | |
| Instrument name/First year sold | ACL ELITE Series/2006 | ACL AcuStar/2010 | CoaLAB 1000/2009 |
| Number of units installed in U.S./Outside U.S. | 4,000+/8,000+ (all ACL models combined) | 4,000+/8,000+ (all ACL models combined) | —/>500 |
| Number of contracts signed between 1/1/18 and 11/15/18 | — | — | — |
| Country where analyzer designed/Manufactured | U.S./U.S. | U.S./U.S. | Germany/Germany |
| Operational type | modified random access | random access | batch, random access |
| Reagent type | open reagent system | multiuse reagent cartridges (liquid) | open reagent system (reconstituted manually) |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Sample handling system | tray, primary tubes | rack | two fixed racks of 11 samples each plus 3 stat |
| Model type | benchtop | benchtop | benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 24 × 37 × 24 in./139 lbs./6 sq. ft. | 21 × 34 × 24 in./170 lbs./15 sq. ft. | 30.7 × 22.9 × 19.6 in./55.1 lbs./— |
| FDA-cleared clotting-based tests | PT, APTT, fibrinogen, TT, factors | — | — |
| FDA-cleared chromogenic tests | anti-Xa | — | — |
| FDA-cleared immunologic tests | D-Dimer, VWF (Act. and Ag.), free protein S, factor XIII Ag., homocysteine | Domain 1, HIT IgG, anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM | — |
| Other FDA-cleared tests | — | — | — |
| User-defined tests in clinical use | — | — | — |
| Tests submitted for 510(k) clearance | — | — | — |
| Tests in development but not yet submitted | — | VWF (RCo), VWF (Ag.), HIT total ab, ADAMTS13 | — |
| Methodologies supported | clot detection, LED optical (nephelometric), chromogenic, immunologic | immunologic (chemiluminescent) | LED optical, turbidimetric for clot detection, immunologic, chromogenic, and aggregation tests |
| Operator must load sep. reagent pack per specimen/Test run | no/no | no/no | no/no |
| Number of different measured assays onboard simultaneously | 22 | 20 | 15 maximum |
| Number of different assays programmed and calib. at one time | 300 | 20 | 50 |
| Number of user-definable (open) channels | 100 | 0 | 2 |
| Of those defined, number active simultaneously | 20 | — | 2 |
| Factor assays require manual manipulation or dilutions | no | — | no |
| Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard | 22/varies/yes | 20/varies/yes (4°C) | 15/200 maximum/no |
| Multiple reagent configurations supported | yes | no | yes |
| Reagents, consumables loaded without interrupting testing | yes | no | no |
| Same capabilities when third-party reagent used | yes | no | yes |
| Maximum time same lot number of reagents can be used | 18 months | — | 1 year |
| Walkaway capacity: Number of specimens/Number of tests | 40/260 | 30/280 | 25 maximum/>10 |
| Minimum sample volume aspirated precisely at one time | 5 µL | — | 2 µL |
| Standard specimen volume required to run PT or PTT/ Factor VIII activity | 60 µL/18 µL | — | PT: 100 µL reagent, 50 µL sample; APTT: 50 µL reagent, 50 µL sample, 50 µL CAC12/50 µL APTT, 50 µL deficient plasma, 50 µL sample, 50 µL CAC12 |
| Disposables used/Price of each | cuvettes/varies | cuvettes/varies | cuvette ring (32 single cuvettes per ring), sample cups/— |
| Supports direct-from-track sampling | no | no | no |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/no | yes/no | yes (1.7–4 mL)/no |
| Sample/Reagent barcode reading capability | yes/yes | yes/yes | yes/no |
| Onboard test automatic inventory | yes | yes | yes |
| Measures No. of tests remaining/Short sample detection | yes/yes | yes/yes | yes/yes |
| Clot detection as preanalytical variable in plasma sample | no | yes | yes |
| Auto. detects adequate reagents for aspiration and analysis | yes | yes | yes |
| Hemolysis/Turbidity detection-quantitation | no/no | no/no | no/yes |
| Dilution of patient samples onboard | yes | yes | yes |
| Automatic rerun capability/Auto reflex testing capability | yes/yes | yes/yes | yes/no |
| Lag time during which hypercoagulable sample not detected | yes (PT and PTT: 3 seconds) | — | yes (PT: <10 seconds; PTT: <20 seconds) |
| Read time extended for prolonged clotting times | yes | — | yes |
| User can set different-than-standard: | | | |
| • Reagent volumes/Sample volumes | yes/yes | no/no | yes/yes |
| • No. and sources of reagent | yes | no | yes |
| • Incubation times/Reading times | yes/yes | no/no | yes/yes |
| Autocalib. or autocalib. alert/Multipoint calib. supported | no/yes | yes/yes | yes/yes |
| Auto shutdown/Auto startup programmable | not needed/not needed | not needed/not needed | no/no |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | 4 minutes/175 specimens | — | <2 minutes/120 specimens |
| • PT, PTT | 8 minutes/270 specimens | — | <5 minutes/71 specimens |
| • Fibrinogen | 4 minutes/175 specimens | — | <5 minutes/50 specimens |
| • Factor VIII activity assay | 8 minutes/125 specimens | — | depends on assay |
| Time delay from ordering stat to aspiration of sample | 15 seconds | <1 minute | 3 minutes |
| Automatic transfer of QC results to LIS | yes | yes | yes |
| Data-management capability | yes | onboard (includes QC: L-J plots and Westgard multirules) | onboard (includes QC: L-J plots and Westgard multirules) |
| Interface supplied by instrument vendor | no | no | yes (included) |
| Interfaces in active user sites for: | most major vendors | — | via LAN, Windows OS, Linux OS |
| Bidirectional interface capability | yes (broadcast download and host query) | yes (host query) | yes (host query) |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| LOINC codes transmitted with all results | no | no | no |
| How labs get LOINC codes for reagent kits | — | — | — |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system | no | no | no |
| Modem servicing | no | no | no |
| Time required for maintenance by lab personnel | daily: <5 minutes; weekly: 10 minutes; monthly: 5 minutes | daily: 5 minutes; weekly: 5 minutes | per shift: <1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: calibration 15 minutes |
| Onboard maintenance records | yes | no | no |
| Training provided with purchase | 4 days at vendor offices | — | 3 days at vendor offices, on site on request |
| Approximate number of training hours needed per tech | 24 | 6 on site | — |
| List price | — | — | — |
| Annual service contract cost (24/7)/Warranty with purchase | various options available/1 year | — | —/1 year |
| Distinguishing features (supplied by company) | test menu featuring D-Dimer; barcoded reagent management; ACL family harmonization; HemosIL INR plasma sets for INR test system validation or calibration, or both; HemosIL liquid anti-Xa with universal calibration curve for UFH and LMWH | easy to use; uses sensitive chemiluminescent technology; throughput of 60 tests per hour (<30 minutes to first test result); reagent cartridges stable up to 12 weeks onboard; reagents are precalibrated; replaces the need to run manual, time-consuming ELISA assays | standalone device, requires no additional PC monitor to control, onboard software, only external printer; flexible and extendable by software add-ons; different wavelength available; optimized for small to mid-size labs; special hemostasis of diagnostic assays |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> | | | |

| Part 6 of 7 | LABiTec GmbH Matthias Schramm matthias.schramm@labitec.de Ahrensburg, Germany 011-49-4102-47950 www.labitec.com | Siemens Healthineers Jason Lam jason.lam@siemens-healthineers.com Tarrytown, NY https://usa.healthcare.siemens.com/hemostasis | Siemens Healthineers Jason Lam jason.lam@siemens-healthineers.com Tarrytown, NY https://usa.healthcare.siemens.com/hemostasis |
|--|---|--|--|
| Instrument name/First year sold | CoaData 2004 and 4004/— | Sysmex CS-2500 System/2016 | Sysmex CS-5100 System/2016 |
| Number of units installed in U.S./Outside U.S. | —/>>500 | >500/>2,000 | 75/1,000 |
| Number of contracts signed between 1/1/18 and 11/15/18 | — | — | — |
| Country where analyzer designed/Manufactured | Germany/Germany | Japan/Japan | Japan/Japan |
| Operational type | discrete | continuous random access | continuous random access |
| Reagent type | open reagent system | open reagent system (liquid, lyophilized, reconstituted manually) | open reagent system (liquid, lyophilized, reconstituted manually) |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Sample handling system | semiautomated manual pipette, auto start | continuous loading capped and uncapped 10-tube position primary sample rack × 5 | continuous loading capped and uncapped 10-tube position primary sample rack × 10 |
| Model type | benchtop | benchtop | floor standing |
| Dimensions (H × W × D)/Weight/Instrument footprint | 3.54 × 10.24 × 12.99 in./8.6 lbs./2 sq. ft. | 27 × 30.6 × 35.2 in./242.5 lbs./7.5 sq. ft. | 50.4 × 40.6 × 45.3 in./612.9 lbs./12.8 sq. ft. |
| FDA-cleared clotting-based tests | — | PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI, XII, protein C, lupus, factor V Leiden, TT, batroxobin time | PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI, XII, protein C, lupus, factor V Leiden, TT, batroxobin time |
| FDA-cleared chromogenic tests | — | Innovance Antithrombin, protein C, Innovance Heparin | Innovance Antithrombin, protein C, Innovance Heparin |
| FDA-cleared immunologic tests | — | Innovance D-Dimer, Innovance free protein S antigen, factor VIII, chromogenic, plasminogen | Innovance D-Dimer, Innovance free protein S antigen, factor VIII chromogenic, plasminogen |
| Other FDA-cleared tests | — | — | — |
| User-defined tests in clinical use | — | — | — |
| Tests submitted for 510(k) clearance | — | — | — |
| Tests in development but not yet submitted | — | von Willebrand factor, a2-antiplasmin | von Willebrand factor, a2-antiplasmin |
| Methodologies supported | LED photometer (2 wavelengths per channel) incl. mixing; supports coagulation, chromogenic, and immunologic assays | clot detection, optical; turbidimetric; clot detection, simultaneous multiwavelength scanning and PSI checks; chromogenic; immunologic | clot detection, optical; turbidimetric; clot detection, simultaneous multiwavelength scanning and PSI checks; chromogenic; immunologic |
| Operator must load sep. reagent pack per specimen/Test run | no/no | no/no | no/no |
| Number of different measured assays onboard simultaneously | 1 | 60 | 60 |
| Number of different assays programmed and calib. at one time | 15 | 60 | 60 |
| Number of user-definable (open) channels | 8 | 80,000 | 80,000 |
| Of those defined, number active simultaneously | 1 | 60 | 60 |
| Factor assays require manual manipulation or dilutions | yes | no | no |
| Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard | 4/reagent manufacturer defined/no | 40/up to 200/yes (10°C ± 2°C) | 40/up to 200/yes (10°C ± 2°C) |
| Multiple reagent configurations supported | yes | yes | yes |
| Reagents, consumables loaded without interrupting testing | yes | yes | yes |
| Same capabilities when third-party reagent used | yes | yes | yes |
| Maximum time same lot number of reagents can be used | reagent manufacturer defined | 1 year | 1 year |
| Walkaway capacity: Number of specimens/Number of tests | 16/18 incubational positions | 50/up to 500 | 100/up to 1,000 |
| Minimum sample volume aspirated precisely at one time | 50 µL (150 µL total volume) | 5 µL | 5 µL |
| Standard specimen volume required to run PT or PTT/ Factor VIII activity | 50 µL/— | 50 µL/— | 50 µL/— |
| Disposables used/Price of each | micro single cuvette, printer paper/— | reaction tubes, CA clean I and II/— | reaction tubes, CA clean I and II/— |
| Supports direct-from-track sampling | no | no | yes (Siemens Aptio Automation) |
| Primary tube sampling supported/Pierces caps on primary tubes | no/no | yes (1–4.5 mL)/yes | yes (1–4.5 mL)/yes |
| Sample/Reagent barcode reading capability | optional/no | yes/yes | yes/yes |
| Onboard test automatic inventory | no | yes | yes |
| Measures No. of tests remaining/Short sample detection | no/no | yes/yes | yes/yes |
| Clot detection as preanalytical variable in plasma sample | no | yes | yes |
| Auto. detects adequate reagents for aspiration and analysis | no | yes | yes |
| Hemolysis/Turbidity detection-quantitation | no/no | yes/yes | yes/yes |
| Dilution of patient samples onboard | no | yes | yes |
| Automatic rerun capability/Auto reflex testing capability | no/no | yes/yes | yes/yes |
| Lag time during which hypercoagulable sample not detected | no | yes (PT: 7 seconds; PTT: 15 seconds) | yes (PT: 7 seconds; PTT: 15 seconds) |
| Read time extended for prolonged clotting times | yes (selectable on menus) | yes (selectable on menus) | yes (selectable on menus) |
| User can set different-than-standard: | | | |
| • Reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| • No. and sources of reagent | yes | yes | yes |
| • Incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Autocalib. or autocalib. alert/Multipoint calib. supported | no/yes | yes/yes | yes/yes |
| Auto shutdown/Auto startup programmable | no/no | no/no | no/no |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | — | 6.5 minutes/180 results | 6.5 minutes/400 results |
| • PT, PTT | — | 6.5 minutes/180 results | 6.5 minutes/400 results |
| • Fibrinogen | — | 6.5 minutes/— | 6.5 minutes/— |
| • Factor VIII activity assay | — | — | — |
| Time delay from ordering stat to aspiration of sample | — | 1 minute | 1 minute |
| Automatic transfer of QC results to LIS | no | yes | yes |
| Data-management capability | no | onboard (includes QC: L-J plots and Westgard multirules) | onboard (includes QC: L-J plots and Westgard multirules) |
| Interface supplied by instrument vendor | no | no | no |
| Interfaces in active user sites for: | — | most major vendors | most major vendors |
| Bidirectional interface capability | no | yes (broadcast download and host query) | yes (broadcast download and host query) |
| Results transferred to LIS as soon as test time complete | yes (unidirectional interface) | yes | yes |
| LOINC codes transmitted with all results | no | no | no |
| How labs get LOINC codes for reagent kits | — | — | — |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system | no | no | no |
| Modem servicing | no | no | no |
| Time required for maintenance by lab personnel | per shift: <1 minute (cleaning housing); daily: <1 minute (cleaning housing); weekly: <5 minutes (cleaning housing and incubating block) | daily: <6 minutes; weekly: 1 minute; monthly: <1 minute | daily: <6 minutes; weekly: 1 minute; monthly: <1 minute |
| Onboard maintenance records | no | yes | yes |
| Training provided with purchase | 1 day, on request | 3 days at vendor offices; varies on site | 3 days at vendor offices; varies on site |
| Approximate number of training hours needed per tech | 4 | 6 | 6 |
| List price | — | \$155,000 | \$205,000 |
| Annual service contract cost (24/7)/Warranty with purchase | —/1 year | —/1 year | —/1 year |
| Distinguishing features (supplied by company) | price-competitive 2-channel (CoaData 2004) and 4-channel (CoaData 4004) new generation; photometer optics provide 2 wavelengths on each measuring channel including mechanical stirring (HIL optimized); low maintenance and repair costs | confidence: simultaneous multiwavelength detection and PSI technology designed to ensure high-quality first-run results; operational efficiency: user-friendly software on Windows 7 and tilted reagent vials for maximum efficiency; consistency: for multisite patient monitoring, with sample result traceability for in-depth audit capabilities | confidence: simultaneous multiwavelength detection and PSI technology designed to ensure high-quality first-run results; operational efficiency: user-friendly software on Windows 7, tilted reagent vials and point-in-space automation ready; consistency: for multisite patient monitoring, with sample result traceability for in-depth audit capabilities |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> | | | |

| Part 7 of 7 | Siemens Healthineers Jason Lam jason.lam@siemens-healthineers.com Tarrytown, NY https://usa.healthcare.siemens.com/hemostasis | Siemens Healthineers Jason Lam jason.lam@siemens-healthineers.com Tarrytown, NY https://usa.healthcare.siemens.com/hemostasis | Siemens Healthineers Jason Lam jason.lam@siemens-healthineers.com Tarrytown, NY https://usa.healthcare.siemens.com/hemostasis |
|--|--|--|---|
| Instrument name/First year sold | Sysmex CA-600 Systems/2012 | BFT II/1999 | BCS XP/2006 |
| Number of units installed in U.S./Outside U.S. | >2,500/>5,000 | — | — |
| Number of contracts signed between 1/1/18 and 11/15/18 | — | — | — |
| Country where analyzer designed/Manufactured | Japan/Japan | Germany/Germany | Germany/Germany |
| Operational type | continuous random access | batch | batch, continuous random access |
| Reagent type | open reagent system (reconstituted manually) | open reagent system (reconstituted manually) | open reagent system (liquid, lyophilized, reconstituted manually), optimized for Siemens instruments |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Sample handling system | 10-tube position sample rack | manual | 10-tube position sample rack |
| Model type | benchtop | benchtop | benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 22.5 × 19.5 × 19.5 in./~94.6 lbs./~3.05 sq. ft. | 3.9 × 7.9 × 11.8 in./8.4 lbs./0.65 sq. ft. | 37 × 49 × 25 in./330 lbs./8.5 sq. ft. |
| FDA-cleared clotting-based tests | PT, APTT, fibrinogen, TT, reptilase time, protein C clot, factor assays | PT, APTT, fibrinogen | PT, APTT, fibrinogen, TT, reptilase time, factor assays, DRVVT (screen and confirm), factor V Leiden, protein C clot, protein S activity |
| FDA-cleared chromogenic tests | Innovance AT, Berichrom AT, protein C chromo, heparin | — | Innovance AT, Innovance free protein S antigen, Berichrom AT, plasminogen, factor VIII chromo, alpha-2 antiplasmin, protein C chromo, heparin |
| FDA-cleared immunologic tests | Innovance D-Dimer | — | Innovance D-Dimer |
| Other FDA-cleared tests | — | — | BC WWF-ristocetin cofactor assay (agglutination of fixed platelets) |
| User-defined tests in clinical use | — | — | — |
| Tests submitted for 510(k) clearance | — | — | — |
| Tests in development but not yet submitted | — | — | ETP (for research use only) |
| Methodologies supported | clot detection, optical; turbidimetric, chromogenic, immunologic | turbidensitometric | clot detection, optical (xenon flasher lamp); chromogenic, immunologic |
| Operator must load sep. reagent pack per specimen/Test run | no/no | no/no | no/no |
| Number of different measured assays onboard simultaneously | 5 | 1 | >100 tests, samples |
| Number of different assays programmed and calib. at one time | 7 | 3 | 99 |
| Number of user-definable (open) channels | 7 | — | 7,999 |
| Of those defined, number active simultaneously | 5 | 1 | >100 |
| Factor assays require manual manipulation or dilutions | no | — | no |
| Number of reagent containers onboard at once/Tests per container/Reagents refrigerated onboard | 11/up to 200/yes (15°C) | 4/up to 200/no | 90/up to 200/yes (<15°C) |
| Multiple reagent configurations supported | yes | yes | yes |
| Reagents, consumables loaded without interrupting testing | yes | yes | yes |
| Same capabilities when third-party reagent used | yes | yes | yes |
| Maximum time same lot number of reagents can be used | 12 months | 12 months | 1 year |
| Walkaway capacity: Number of specimens/Number of tests | 10/50 | 1/1 | 100 samples/400 cuvettes |
| Minimum sample volume aspirated precisely at one time | 5 µL | 50 µL | 3 µL |
| Standard specimen volume required to run PT or PTT/ Factor VIII activity | 50 µL/5 µL | 50 µL/— | 50 µL/20 µL, minimum 100 µL (includes dead volume); 50 µL, minimum 100 µL |
| Disposables used/Price of each | reaction tubes, CA clean I, CA clean II, thermal paper/varies with volume | cuvettes, printer paper/varies with volume | cuvette rotors, washing solution, terralin disinfectant, BC validation kit/varies with volume |
| Supports direct-from-track sampling | no | no | no |
| Primary tube sampling supported/Pierces caps on primary tubes | yes (2.7–5.0 mL)/no | no/no | yes (all up to 100 mm long, ext. diameter 11–16 mm)/no |
| Sample/Reagent barcode reading capability | yes/no | no/no | yes/yes |
| Onboard test automatic inventory | yes | no | yes |
| Measures No. of tests remaining/Short sample detection | yes/yes | no/no | yes/yes |
| Clot detection as preanalytical variable in plasma sample | no | no | no |
| Auto. detects adequate reagents for aspiration and analysis | yes | no | yes |
| Hemolysis/Turbidity detection-quantitation | no/yes | no/no | yes/no |
| Dilution of patient samples onboard | yes | no | yes |
| Automatic rerun capability/Auto reflex testing capability | no/no | no/no | yes/yes |
| Lag time during which hypercoagulable sample not detected | yes (PT: <7 seconds; PTT: <15 seconds) | yes (PT: 5 seconds; APTT: 15 seconds) | yes (7 seconds for PT and APTT) |
| Read time extended for prolonged clotting times | yes (selectable on menus) | no | yes |
| User can set different-than-standard: | | | |
| • Reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| • No. and sources of reagent | yes | yes | yes |
| • Incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Autocalib. or autocalib. alert/Multipoint calib. supported | no/yes | yes/yes | yes/yes |
| Auto shutdown/Auto startup programmable | no/no | no/no | no/no |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | 7 minutes/60 results | 1 minute/— (manual) | <5 minutes/~380 results (including abnormal) |
| • PT, PTT | 8 minutes/48 results | <5 minutes/— (manual) | <5 minutes/~325 results (including abnormal) |
| • Fibrinogen | 7 minutes/60 results | <1 minute/— (manual) | <5 minutes (if curve available)/~315 results |
| • Factor VIII activity assay | — | — | <5 minutes (if curve available)/~280 results |
| Time delay from ordering stat to aspiration of sample | 2 minutes | — | varies by test in progress, ~>5 minutes |
| Automatic transfer of QC results to LIS | yes | no | yes |
| Data-management capability | onboard (includes QC: L-J plots) | no | onboard (includes QC: L-J plots) |
| Interface supplied by instrument vendor | no | — | no |
| Interfaces in active user sites for: | all major LIS vendors | — | all major LIS vendors |
| Bidirectional interface capability | yes (host query) | no | yes (host query) |
| Results transferred to LIS as soon as test time complete | yes | no | yes |
| LOINC codes transmitted with all results | no | no | no |
| How labs get LOINC codes for reagent kits | upon request | upon request | — |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system | no | no | no |
| Modem servicing | no | no | yes |
| Time required for maintenance by lab personnel | daily: <10 minutes; quarterly: <5 minutes | daily: 1 minute | daily: <5 minutes; weekly: <10 minutes; monthly: 15 minutes |
| Onboard maintenance records | no | no | yes |
| Training provided with purchase | 2 days on site, personalized education plan online training course | quick reference guide | 3 days at vendor offices for 2 key operators, personalized education plan online training course |
| Approximate number of training hours needed per tech | 2 | 2 | 8 on site |
| List price | CA-620: \$42,000; CA-660: \$55,000 | \$8,685 | \$171,921 |
| Annual service contract cost (24/7)/Warranty with purchase | — | — | — |
| Distinguishing features (supplied by company) | maximizes counter space with compact footprint in low-volume labs; increases uptime and reduces service expenses; two models to meet individual laboratory needs: CA-620 system for routine clotting-based testing, CA-660 system for clotting, chromogenic, and immunologic testing needs | 2-channel micro reagent volume clot-based technology; opto-mechanical detection accurate on lipemic, icteric samples; automatic INR calculation, curve storage, built-in thermal printer; effective for low-volume testing, backup to larger systems | user-definable calibration curve expiration and prewarning alerts; user-definable barcode utility enables customizable reagent protocols; user-friendly Windows XP software |
| <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i> | | | |