# COAGULATION ANALYZERS

| Part 1 of 6 | **Bio/Data Corp.**<br>**Mary Brown** customer.service@biodatacorp.com<br>**Horsham, PA**<br>**215-441-4000** or **800-257-3282** www.biodatacorp.com | **Chrono-log Corp.**<br>**Sal Pema** sal@chronolog.com<br>**Havertown, PA**<br>**610-853-1130** or **800-247-6665** www.chronolog.com | **Chrono-log Corp.**<br>**Sal Pema** sal@chronolog.com<br>**Havertown, PA**<br>**610-853-1130** or **800-247-6665** www.chronolog.com |
|---|---|---|---|
| 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 |
| List price/Model type | $22,990/benchtop | $11,268–$26,795/benchtop | $19,909–$42,100/benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 21.5–25.5 × 19.5 × 21.7 in./40 lbs./4 sq. ft. | per each 4-channel module: 8.5 × 14 × 15 in./19.3 lbs./1.5 sq. ft. | per each 2-channel module: 8.5 × 14 × 18 in./40 lbs./1.75 sq. ft. |
| No. of units in clinical use in U.S./Outside U.S. (countries) | >500/>300 (Canada, EEC, Middle East, Asia, Far East, North Africa) | — | — |
| Composition of installs: Hospital lab/Reference lab/Other | 80%/15%/5% (unspecified) | — | — |
| Targeted daily, monthly, annual test volume | — | — | — |
| Operational type | batch, random access | discrete | discrete |
| Country where analyzer designed/Manufactured | U.S./U.S. | U.S./U.S. | U.S./U.S. |
| Company manufactures instrument | yes (also sold by möLab, Sentinel Diagnostics, Werfen, Alpha Labs, Sysmex, Analis) | yes (also sold via distribution partners) | yes (also sold via distribution partners) |
| FDA-approved clotting-based tests | — | — | — |
| FDA-approved chromogenic tests | — | — | — |
| FDA-approved immunologic tests | ristocetin cofactor activity, HIT/HIPA, RIPA; others | platelet agglutination with ristocetin | platelet agglutination with ristocetin |
| Other FDA-approved tests | platelet activation, spontaneous platelet aggregation, sticky platelets, washed platelet aggregation, others | LTA platelet aggregation, ristocetin cofactor assay | whole blood impedance platelet aggregation, LTA platelet aggregation, platelet dense granule ATP release, ristocetin cofactor assay |
| User-defined tests in clinical use | — | LTA platelet aggregation, ristocetin cofactor assay | whole blood impedance platelet aggregation, LTA platelet aggregation, platelet dense granule secretion, ristocetin cofactor assay |
| Tests in development or awaiting FDA 510(k) clearance | — | — | — |
| Methodologies supported | turbidimetric, immunologic (agglutination, Ab-Ag tests) | turbidimetric for measuring platelet aggregation in PRP and ristocetin cofactor assay | turbidimetric for measuring platelet aggregation in PRP and ristocetin cofactor assay, impedance for measuring platelet aggregation in whole blood |
| Number of different measured assays onboard simultaneously | 255 | 4–8 | 2–4 |
| Number of different assays programmed and calib. at one time | 255 | 4–8 | 2–4 |
| No. of user-definable (open) channels/No. active simultaneously | 8/8 | 4–8/4–8 | 2–4/2–4 |
| Factor assays require manual manipulation or dilutions | yes (manual manipulation and dilutions) | yes (manual dilutions) | yes (manual dilutions) |
| Test throughput per hour/Assay run time | 540 (up to 60 samples in throughput)/up to 8 hours | 6 (24–48 tests in throughput)/5 min. minimum | 6 (12–24 tests in throughput)/6 min. minimum |
| Design of sample-handling system | manual | manual | manual |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | whole blood and spun plasma |
| Reagent type | open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) |
| Reagent barcode-reading capability | yes, for all tests | no | no |
| No. of reagent containers held onboard/Reagents ready to use | —/requires operator prehandling | —/requires operator prehandling | —/requires operator prehandling |
| Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard | yes/no/no | no/no/no | no/no/no |
| Reagents, consumables loaded without interrupting testing | yes (reagents and consumables) | yes (consumables) | yes (consumables) |
| Instrument uses proprietary or third-party reagents | user's option | proprietary reagents | proprietary reagents |
| Maximum time same lot number of reagents can be used | 2 years | 18 months–3 years | 18 months–3 years |
| Walkaway capability/Walkaway duration | yes/8 specimens or 8 tests | yes/5 min. or 4–8 specimens or 4–8 tests | yes/6 min. or 2–4 specimens or 2–4 tests |
| Min.–max. specimen volume that can be aspirated at one time | — | 250–500 µL | 225–500 µL |
| Min. sample volume required for PT/PTT/Factor VIII activity | — | — | — |
| Types of disposables used | test cuvettes, micro stir bars, pipette tips, sample tubes and caps | cuvettes, stir bars, pipette tips | cuvettes, stir bars, disposable electrodes, pipette tips |
| Primary tube sampling supported/Pierces caps on primary tubes | no/no | no/no | no/no |
| Accommodates most standard tube sizes/Nonstandard sizes | no/no | no/no | no/no |
| Sample barcode-reading capability/Autodiscrimination | —/yes | no/no | no/no |
| Auto tracks product volume/Measures number of tests remaining | no/no | no/no | no/no |
| Short sample detection | no | no | no |
| Clot detection as preanalytical variable in plasma sample | no | no | no |
| Auto detects adequate reagents for aspiration or analysis | no | no | no |
| Detection or quantitation for hemolysis, turbidity, icterus, lipemia | detection for hemolysis, turbidity, icterus, lipemia | no | no |
| Dilutes 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 | no | no | no |
| User can adjust reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| User can adjust No. of reagents/Sources of reagents | yes/yes | yes/yes | yes/yes |
| User can adjust incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Read time extended for prolonged clotting times | — | yes (selectable on menus) | yes (selectable on menus) |
| Autocalibration/Calibrants stored onboard | yes/no | yes/no | yes/no |
| Multipoint calibration supported/Recommended frequency | yes/annually | yes/annually | yes/annually |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | — | — | — |
| • PT, PTT | — | — | — |
| • Fibrinogen | — | — | — |
| • Factor VIII activity assay | — | — | — |
| • D-dimer | — | — | — |
| Time delay from ordering stat to aspiration of sample | — | — | — |
| How labs get LOINC codes for results | email query | email query | email query |
| Onboard real-time QC/Onboard software capability to review QC | no/yes | yes/no | yes/no |
| Information that can be barcode-scanned on instrument | reagent lot No. | barcode scanning not offered | barcode scanning not offered |
| Compatible with laboratory automation systems | no | no | no |
| Data-management capability/LIS or EHR systems interfaced | onboard/none | onboard/none | onboard/none |
| Interface supplied by instrument vendor | no | no | no |
| Results transferred to LIS as soon as test time complete | no | no | no |
| Bidirectional interface capability | no | no | no |
| Remote servicing provided/UPS backup power supply | no/no | no/no | no/no |
| Instrument connections to transfer information | — | — | — |
| Interface standards supported | — | — | — |
| Information transferred to data-management software | — | — | — |
| Avg. time for basic user training | 1.5 days (at customer site) | — | 1.5 days (at customer site) |
| Approximate scheduled maintenance time | weekly: 15 minutes; monthly: 30 minutes | preventive maintenance and calibration by clinical engineering recommended annually | preventive maintenance and calibration by clinical engineering recommended annually |
| Maintenance records kept onboard | no | yes | yes |
| Warranty with purchase/Annual service contract cost (24/7) | yes/$2,050 | yes/— (cost dependent on contract) | yes/— (cost dependent on contract) |
| Distinguishing features (supplied by company) | 2-year instrument warranty; 3-year in-lab PC service; up to 9 reported test results per channel; hybrid annual calibration service | continuously monitors and regulates temperature and stirring; optical calibration can be performed by laboratory personnel using no-cost water samples; customized color-coding options | 3 instruments in 1: whole blood/impedance and PRP/LTA aggregometer plus luminometer to measure platelet ATP release; continuously monitors and regulates temperature and stirring; optical calibration can be performed by laboratory personnel using no-cost water samples |

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

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

| Part 2 of 6 | **Diagnostica Stago**<br>**Matthew Lyons** matthew.lyons@us.stago.com<br>**Parsippany, NJ**<br>**800-222-2624** www.stago-us.com | **Diagnostica Stago**<br>**Matthew Lyons** matthew.lyons@us.stago.com<br>**Parsippany, NJ**<br>**800-222-2624** www.stago-us.com | **Diagnostica Stago**<br>**John G. Chromczak** john.chromczak@us.stago.com<br>**Parsippany, NJ**<br>**800-222-2624** www.stago-us.com |
|---|---|---|---|
| Instrument name/First year sold | STA Compact Max/2013 | STA Satellite/2010 | STA-R Max/2015 |
| List price/Model type | $150,000/benchtop | $58,935/benchtop | $241,000/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. |
| No. of units in clinical use in U.S./Outside U.S. (countries) | ~1,850/~4,100 (France, Spain, UK, Germany, Denmark, others) | ~550/~2,100 (France, Spain, UK, Germany, Denmark, others) | ~400/~1,800 (France, Spain, UK, Germany, Denmark, others) |
| Composition of installs: Hospital lab/Reference lab/Other | ~96%/3%/1% (veterinary labs, pharmaceutical companies, academic research/educational labs) | ~98%/0/2% (veterinary labs, academic research) | ~90%/7%/3% (veterinary labs, pharmaceutical companies, academic research/educational labs) |
| Targeted daily, monthly, annual test volume | daily: >30 (moderate-volume laboratories); monthly: 900; annual: >5,000 | daily: ~40; monthly: <900; annual: <13,000 | daily: >100 (moderate- to high-volume laboratories); monthly: >2,500; annual: >25,000 |
| Operational type | continuous random access | random access | continuous random access |
| Country where analyzer designed/Manufactured | France/France | France/France | France/France |
| Company manufactures instrument | yes | yes | yes |
| FDA-approved 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-approved chromogenic tests | anti-FXa (UFH and LMWH), antithrombin, protein C, plasminogen, FVIII chromogenic | anti-FXa (UFH and LMWH), antithrombin | anti-FXa (UFH and LMWH), antithrombin, protein C, plasminogen, FVIII chromogenic |
| FDA-approved immunologic tests | D-dimer, antithrombin antigen, free protein S, total protein S, vWF antigen (all microlatex) | D-dimer | D-dimer, antithrombin antigen, free protein S, total protein S, vWF antigen (all microlatex) |
| Other FDA-approved tests | — | — | — |
| User-defined tests in clinical use | APCR, other clotting, chromogenic, and immunological tests with user-defined applications | — | APCR, other clotting, chromogenic, and immunological tests with user-defined applications |
| Tests in development or awaiting FDA 510(k) clearance | STA NeoPTimal protime reagent with ISI ~1.0 | — | STA NeoPTimal protime reagent with ISI ~1.0 |
| Methodologies supported | mechanical clot detection, chromogenic, immunologic (microlatex) | mechanical clot detection, chromogenic, immunologic (microlatex) | mechanical clot detection, chromogenic, immunologic (microlatex) |
| Number of different measured assays onboard simultaneously | 80 | 80 | 200 |
| Number of different assays programmed and calib. at one time | 80 | 80 | 200 |
| No. of user-definable (open) channels/No. active simultaneously | 80/80 | 80/80 | 200/200 |
| Factor assays require manual manipulation or dilutions | — | — | — |
| Test throughput per hour/Assay run time | 110 (2 tests in throughput)/4.6–7.3 min. (avg. 4.7 min.) | 36 (3 tests in throughput for PT, APTT, fibrinogen)/4.6–7.3 min. (avg. 4.7 min.) | 200 (2 tests in throughput)/4.6–7.3 min. (avg. 4.7 min.) |
| Design of sample-handling system | continuous loading sample drawer with continuous random access | continuous sample loading with positive sample identification, removable sample carousel for 20 primary tubes | rack with continuous specimen access |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Reagent type | self-contained single-use and multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained single-use and multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained single-use and multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) |
| Reagent barcode-reading capability | yes, for all tests | yes, for all tests | yes, for all tests |
| No. of reagent containers held onboard/Reagents ready to use | 45/variable (reagent specific) | 16/variable (reagent specific) | 70/variable (reagent specific) |
| Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard | yes/yes/yes (15°–19°C) | yes/yes/yes (15°–19°C) | yes/yes/yes (15°–19°C) |
| Reagents, consumables loaded without interrupting testing | yes (consumables) | yes (consumables) | yes (consumables) |
| Instrument uses proprietary or third-party reagents | user's option (same capabilities when third-party reagents used) | user's option (same capabilities when third-party reagents used) | user's option (same capabilities when third-party reagents used) |
| Maximum time same lot number of reagents can be used | 18 months | 18 months | 18 months |
| Walkaway capability/Walkaway duration | yes/96 specimens or 12 tests | yes/20 specimens or 12 tests | yes/215 specimens or 32 tests |
| Min.–max. specimen volume that can be aspirated at one time | 5–100 µL | 5–100 µL | 5–100 µL |
| Min. sample volume required for PT/PTT/Factor VIII activity | 50 µL/50 µL/50 µL | 50 µL/50 µL/50 µL | 50 µL/50 µL/50 µL |
| Types of disposables used | cuvettes, stir bars, cleaner solution | cuvettes, stir bars, cleaner solution | cuvettes, stir bars, cleaner solution |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/yes | yes/no | yes/yes |
| Accommodates most standard tube sizes/Nonstandard sizes | yes/no | yes/no | yes/no |
| Sample barcode-reading capability/Autodiscrimination | yes (Interleaved 2 of 5, UPC, Codabar)/— | yes (Interleaved 2 of 5, UPC, Codabar)/no | yes (Interleaved 2 of 5, UPC, Codabar)/— |
| Auto tracks product volume/Measures number of tests remaining | yes/no | yes/no | yes/no |
| Short sample detection | yes | yes | yes |
| Clot detection as preanalytical variable in plasma sample | no | no | no |
| Auto detects adequate reagents for aspiration or analysis | yes (aspiration and analysis) | yes (aspiration and analysis) | yes (aspiration and analysis) |
| Detection or quantitation for hemolysis, turbidity, icterus, lipemia | — | — | — |
| Dilutes 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 |
| User can adjust reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| User can adjust No. of reagents/Sources of reagents | yes/yes | yes/yes | yes/yes |
| User can adjust incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Read time extended for prolonged clotting times | yes (selectable on menus) | yes (selectable on menus) | yes (selectable on menus) |
| Autocalibration/Calibrants stored onboard | yes/yes | yes/yes | yes/yes |
| Multipoint calibration supported/Recommended frequency | yes/6 months | yes/6 months | yes/6 months |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | <6 minutes/~150 specimens | <6 minutes/~50 specimens | <6 minutes/~320 specimens |
| • PT, PTT | <6 minutes/~100 specimens | <6 minutes/~40 specimens | <6 minutes/~262 specimens |
| • Fibrinogen | <6 minutes/~100 specimens | <6 minutes/~40 specimens | <6 minutes/~180 specimens |
| • Factor VIII activity assay | <6 minutes/~60 specimens | — | <6 minutes/~180 specimens |
| • D-dimer | 7 minutes/~60 specimens | 7 minutes/~6 specimens | 7 minutes/~150 specimens |
| Time delay from ordering stat to aspiration of sample | <15 seconds | <15 seconds | <15 seconds |
| How labs get LOINC codes for results | email query, LOINC codes available in STA Coag Expert | email query | email query, LOINC codes available in STA Coag Expert |
| Onboard real-time QC/Onboard software capability to review QC | yes/yes | yes/yes | yes/yes |
| Information that can be barcode-scanned on instrument | specimen identifier, reagent lot No., quality control ranges, calibrator values | specimen identifier, reagent lot No., quality control ranges, calibrator values | specimen identifier, reagent lot No., quality control ranges, calibrator values |
| Compatible with laboratory automation systems | no | no | yes (Stago, Abbott, Beckman Coulter, Cerner, Inpeco, Ortho, Roche, Siemens) |
| Data-management capability/LIS or EHR systems interfaced | onboard/Cerner, Meditech, Clinisys, SCC, McKesson, Epic | onboard/Cerner, Meditech, Clinisys, SCC, McKesson, Epic | onboard/Cerner, Meditech, Clinisys, SCC, McKesson, Epic |
| Interface supplied by instrument vendor | contract dependent | contract dependent | contract dependent |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| Bidirectional interface capability | yes (broadcast download and host query) | yes (host query) | yes (broadcast download and host query) |
| Remote servicing provided/UPS backup power supply | no/yes | no/yes | no/yes |
| Instrument connections to transfer information | data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system | directly to LIS | data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system |
| Interface standards supported | ASTM 1394-91, ASTM 1381 | ASTM 1394-91, ASTM 1381 | ASTM 1394-91, ASTM 1381 |
| Information transferred to data-management software | device unique identifier, patient ID, specimen ID, result, QC identifier | device unique identifier, patient ID, specimen ID, result, QC identifier | device unique identifier, patient ID, specimen ID, result, QC identifier |
| Avg. time for basic user training | 3.5 days (at vendor office) | 2.5 days (at vendor office) | 3.5 days (at vendor office) |
| Approximate scheduled maintenance time | weekly: <15 minutes; monthly: <15 minutes | weekly: <15 minutes; monthly: <15 minutes | weekly: <15 minutes; monthly: <15 minutes |
| Maintenance records kept onboard | yes | no | yes |
| Warranty with purchase/Annual service contract cost (24/7) | yes/— (cost dependent on contract) | yes/— (cost dependent on contract) | yes/— (cost dependent on contract) |
| Distinguishing features (supplied by company) | viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, full complement of lupus anticoagulant testing; STA Coag Expert and Coag.One data managers deliver full autoverification, repeat/reflex testing, auto upload of QC to peer group | viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, 2-mL 24-hour quality control for PT, APTT, fibrinogen; small footprint for low-throughput labs with limited space | viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, full complement of lupus anticoagulant testing; STA Coag Expert and Coag.One data managers deliver full autoverification, repeat/reflex testing, auto upload of QC to peer group |

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

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

# COAGULATION ANALYZERS

| Part 3 of 6 | **HemoSonics LLC**<br>**Jeff Light** jlight@hemosonics.com<br>**Durham, NC**<br>**401-741-3265** www.hemosonics.com | **LABiTec LAbor BioMedical Technologies GmbH**<br>**M. Schramm** info@labitec.de<br>**Ahrensburg, Germany**<br>**011-49-4102-47950** www.labitec.com | **LABiTec LAbor BioMedical Technologies GmbH**<br>**M. Schramm** info@labitec.de<br>**Ahrensburg, Germany**<br>**011-49-4102-47950** www.labitec.com |
|---|---|---|---|
| Instrument name/First year sold | Quantra Hemostasis Analyzer/2019 | CoaDATA 2004 and 4004/— | CoaLAB 1000/— |
| List price/Model type | —/portable, benchtop | —/benchtop | —/benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 19 × 14 × 12 in./36 lbs./1 sq. ft. | 10 × 13 × 3.5 in./8.6 lbs./0.92 sq. ft. | 19.6 × 30.7 × 23.6 in./70.5 lbs./5 sq. ft. |
| No. of units in clinical use in U.S./Outside U.S. (countries) | >100/>100 (Germany, France, England, Spain, Austria, Japan, Hong Kong, Australia, Italy, Portugal, Belgium) | —/>1,500 (worldwide [except U.S., Canada]) | —/— (worldwide [except U.S., Canada]) |
| Composition of installs: Hospital lab/Reference lab/Other | 10%/0/90% (point of care [operating room, ICU, stat lab, more]) | — | — |
| Targeted daily, monthly, annual test volume | daily: 15–20; monthly: 1–200; annual: 1,200–2,400 | — | daily: 100–400; monthly: 2,000–8,000; annual: 24,000–95,000 |
| Operational type | random access, continuous random access | batch | batch, random access |
| Country where analyzer designed/Manufactured | U.S./U.S. | Germany/Germany | Germany/Germany |
| Company manufactures instrument | yes (also sold via distribution partners in parts of Europe, Asia) | yes (also sold via OEM distribution, local distributors) | yes (also sold via OEM distribution, local distributors) |
| FDA-approved clotting-based tests | QPlus cartridge: clot time, clot time with heparinase, clot time ratio, clot stiffness, more; QStat cartridge: clot time, clot stability to lysis, clot stiffness, platelet contribution to clot stiffness, more | — | — |
| FDA-approved chromogenic tests | — | — | — |
| FDA-approved immunologic tests | — | — | — |
| Other FDA-approved tests | — | — | — |
| User-defined tests in clinical use | — | — | — |
| Tests in development or awaiting FDA 510(k) clearance | — | — | — |
| Methodologies supported | clot detection, sonic estimation of elasticity via resonance (SEER) sonorheometry | clot detection, mechanical and optical; photometric with mechanical stirring, turbodensitometric; chromogenic; immunologic (photometric) | clot detection, mechanical and optical; photometric with mechanical stirring, turbodensitometric; chromogenic; immunologic (photometric) |
| Number of different measured assays onboard simultaneously | 11 | 15 | 15 |
| Number of different assays programmed and calib. at one time | no calibration required | 15 | 50 |
| No. of user-definable (open) channels/No. active simultaneously | — | — | 50/15 |
| Factor assays require manual manipulation or dilutions | — | yes (manual manipulation and dilutions) | — |
| Test throughput per hour/Assay run time | 5–6 (25–36 tests in throughput)/7–60 min. (avg. 12.5 min.) | CoaDATA 2004: ~60 PT tests (1 test in throughput); CoaDATA 4004: ~120 PT tests (1 test in throughput)/— | 120 PT tests/— |
| Design of sample-handling system | sealed room-temperature-stable cartridges accept a standard 3.2% citrate blue top tube, manually affixed to cartridge | semiautomated analyzer with 2 and 4 channels | cuvette ring, sample cups |
| Operates on whole blood or spun plasma | whole blood | spun plasma | spun plasma |
| Reagent type | self-contained single-use cartridges (lyophilized [reconstituted manually]) | self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually]) |
| Reagent barcode-reading capability | yes, for all tests | yes, for all tests | yes, for some tests |
| No. of reagent containers held onboard/Reagents ready to use | 1 cartridge/yes | 4/variable (reagent specific) | 15/yes |
| Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard | yes/no/no (20°–25°C) | yes/—/no | yes/yes/no |
| Reagents, consumables loaded without interrupting testing | no | yes (reagents and consumables) | yes (reagents) |
| Instrument uses proprietary or third-party reagents | proprietary reagents | user's option | user's option (same capabilities when third-party reagents used) |
| Maximum time same lot number of reagents can be used | — | — | — |
| Walkaway capability/Walkaway duration | yes/~12.5 min. or 1 specimen or 5–6 tests | no/— | yes/22 samples plus 3 stat (reagent dependent) |
| Min.–max. specimen volume that can be aspirated at one time | — | 50–150 µL (total volume) | 2–275 µL |
| Min. sample volume required for PT/PTT/Factor VIII activity | — | 50 µL/50 µL/reagent dependent | 50 µL/50 µL/assay dependent |
| Types of disposables used | single use cartridges, weekly cleaning cartridge, QC level 1 and 2 | cuvettes, pipette tips, stir bars | — |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/yes | —/no | yes/no |
| Accommodates most standard tube sizes/Nonstandard sizes | yes/— | no/no | yes/no |
| Sample barcode-reading capability/Autodiscrimination | yes/— | yes/no | yes (Interleaved 2 of 5, UPC, Codabar, Code 39, Code 128)/no |
| Auto tracks product volume/Measures number of tests remaining | — | no/no | yes/yes |
| Short sample detection | — | no | yes |
| Clot detection as preanalytical variable in plasma sample | — | no | no |
| Auto detects adequate reagents for aspiration or analysis | — | no | yes (aspiration and analysis) |
| Detection or quantitation for hemolysis, turbidity, icterus, lipemia | no | detection for hemolysis, turbidity, icterus, lipemia | no |
| Dilutes patient samples onboard | no | no | yes |
| Automatic rerun capability/Auto reflex testing capability | no/no | no/no | yes/no |
| Lag time during which hypercoagulable sample not detected | no | no | no |
| User can adjust reagent volumes/Sample volumes | no/no | yes/yes | yes/yes |
| User can adjust No. of reagents/Sources of reagents | yes/yes | no/no | yes/yes |
| User can adjust incubation times/Reading times | no/variable | yes/yes | yes/yes |
| Read time extended for prolonged clotting times | — | no | yes (selectable on menus) |
| Autocalibration/Calibrants stored onboard | — | no/no | yes/yes |
| Multipoint calibration supported/Recommended frequency | no calibration required | yes/— | yes/with lot change |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | — | — | <2 minutes/120 specimens |
| • PT, PTT | — | — | <5 minutes/71 specimens |
| • Fibrinogen | fibrinogen contribution to clot stiffness: ~12.5 min./— | — | <5 minutes/50 specimens |
| • Factor VIII activity assay | — | — | <6 minutes/— |
| • D-dimer | — | — | <6 minutes/— |
| Time delay from ordering stat to aspiration of sample | none | — | 3 minutes |
| How labs get LOINC codes for results | email query, included in Quantra implementation guide, addressed during training | functionality not provided | functionality not provided |
| Onboard real-time QC/Onboard software capability to review QC | yes/yes | no/no | yes/yes |
| Information that can be barcode-scanned on instrument | operator identifier, specimen identifier, reagent lot No., lot specific QC target ranges | specimen identifier, reagent lot No. | specimen identifier |
| Compatible with laboratory automation systems | no | no | no |
| Data-management capability/LIS or EHR systems interfaced | onboard/— | no/— | onboard/— |
| Interface supplied by instrument vendor | yes | yes (included in analyzer price) | no |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| Bidirectional interface capability | yes (broadcast download) | no | yes (host query) |
| Remote servicing provided/UPS backup power supply | no/no | no/no | no/no |
| Instrument connections to transfer information | directly to LIS; commercial middleware (RALS, Telcor, UniPOC, Cobas Infinity, DI Data Innovations) | directly to LIS; directly to EHR | data-management system, which in turn connects to LIS; directly to LIS |
| Interface standards supported | LIS: compliant to CLSI LIS02-A2; POC testing middleware: compliant to CLSI POCT01-A2 | — | LAN connection provides FTP result file transfer |
| Information transferred to data-management software | device unique identifier, operator ID, patient ID, result, QC identifier, date and time of assay start, more | patient ID, result | device unique identifier, patient ID, specimen ID, result |
| Avg. time for basic user training | up to 5 days (approx. 2 days at vendor office) | 1 day (at vendor office, on request) | 3 days (at customer and vendor offices) |
| Approximate scheduled maintenance time | weekly: 3 minutes; monthly: 12 minutes | per shift: <1 minute; daily: <1 minute; weekly: <1 minute; monthly: <3 minutes | per shift: 1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: 15 minutes |
| Maintenance records kept onboard | yes | no | yes |
| Warranty with purchase/Annual service contract cost (24/7) | yes/— (cost dependent on contract) | yes/— | yes/— |
| Distinguishing features (supplied by company) | ultrasound measure of whole blood hemostasis directly measures physical properties of a developing clot; wide range of clinical indications with simplified interpretation allows for better communication; novel technology allows for parameters not available in other systems, e.g. platelet contribution to clot | advanced coagulation diagnostics by selectable dual wavelength optics (405/750 nm) for each measuring channel; more sensitive to interferences from hemolysis, icteric, and lipemic samples; intuitive flexible user software; minimum maintenance, repair times, and costs (incl. printer) | easy-to-use, standalone device with small footprint; onboard user and service software, no external PC required; optimized for small to mid-sized labs |

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

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

| Part 4 of 6 | **Siemens Healthineers**<br>**Aura Fucci** aura.fucci@siemens-healthineers.com<br>**Tarrytown, NY**<br>**914-631-8000** siemens-healthineers.us.com | **Siemens Healthineers**<br>**Aura Fucci** aura.fucci@siemens-healthineers.com<br>**Tarrytown, NY**<br>**914-631-8000** siemens-healthineers.us.com | **Siemens Healthineers**<br>**Aura Fucci** aura.fucci@siemens-healthineers.com<br>**Tarrytown, NY**<br>**914-631-8000** siemens-healthineers.us.com |
|---|---|---|---|
| Instrument name/First year sold | BCS XP Analyzer/2006 | BFT II Analyzer/1999 | Sysmex CA-600 Series Systems/2012 |
| List price/Model type | $171,000/benchtop | $8,500/benchtop | CA-620: $42,000; CA-660: $55,000/benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 37 × 49 × 25 in./330 lbs./8.5 sq. ft. | 3.9 × 7.9 × 11.8 in./8.4 lbs./0.65 sq. ft. | 22.5 × 19.5 × 19.5 in./94.6 lbs./3.1 sq. ft. |
| No. of units in clinical use in U.S./Outside U.S. (countries) | >350/>1,000 (worldwide) | —/— (worldwide) | >2,000/>5,000 (worldwide) |
| Composition of installs: Hospital lab/Reference lab/Other | — | — | — |
| Targeted daily, monthly, annual test volume | daily: >300 | daily: 1 | daily: <25 |
| Operational type | continuous random access | batch | continuous random access |
| Country where analyzer designed/Manufactured | Germany/Germany | Germany/Germany | Japan/Japan |
| Company manufactures instrument | yes | yes | no (manufactured by Sysmex) |
| FDA-approved clotting-based tests | PT, APTT, fibrinogen, factors II, V, VII, VIII, IX, X, XI, XII, protein C, protein S, lupus, factor V Leiden, TT, batroxobin time | PT, APTT, fibrinogen | PT, APTT, fibrinogen, factors VII, VIII, protein C, TT, batroxobin time |
| FDA-approved chromogenic tests | antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin | — | Sysmex CA-660 only: antithrombin, protein C, Innovance heparin |
| FDA-approved immunologic tests | Innovance VWF Ac, Innovance D-dimer, von Willebrand factor-ristocetin cofactor assay | — | Sysmex CA-660 only: Innovance D-dimer |
| Other FDA-approved tests | — | — | — |
| User-defined tests in clinical use | — | — | — |
| Tests in development or awaiting FDA 510(k) clearance | — | — | — |
| Methodologies supported | clot detection, optical; chromogenic; immunologic | clot detection, mechanical and optical | clot detection, optical; chromogenic; immunologic |
| Number of different measured assays onboard simultaneously | >100 | 1 | 5 |
| Number of different assays programmed and calib. at one time | 99 | 3 | 7 |
| No. of user-definable (open) channels/No. active simultaneously | 7,999/>100 | — | 7/5 |
| Factor assays require manual manipulation or dilutions | — | — | — |
| Test throughput per hour/Assay run time | 380 (1 test in throughput)/1–3 min. (avg. 5 min.) | —/5 min. | 60 (1 test in throughput)/1–3 min. (avg. 5 min.) |
| Design of sample-handling system | continuous loading uncapped primary sample tubes and cups in same rack; 10-tube position sample rack | manual | 10-tube position sample rack |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Reagent type | self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually]) |
| Reagent barcode-reading capability | yes, for all tests | no | yes, for all tests |
| No. of reagent containers held onboard/Reagents ready to use | 90/yes | 4/yes | 11/yes |
| Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard | yes/yes/yes (15°C ± 2°C) | no/no/no | yes/yes/no (15°C ± 2°C) |
| Reagents, consumables loaded without interrupting testing | yes (reagents and consumables) | yes (reagents and consumables) | no |
| Instrument uses proprietary or third-party reagents | user's option (same capabilities when third-party reagents used) | proprietary reagents, third-party reagents, user's option | user's option (same capabilities when third-party reagents used) |
| Maximum time same lot number of reagents can be used | 1 year | 1 year | 1 year |
| Walkaway capability/Walkaway duration | yes/100 specimens or up to 400 tests | no/— | yes/10 specimens or up to 50 tests |
| Min.–max. specimen volume that can be aspirated at one time | 3 µL minimum | — | 5 µL minimum |
| Min. sample volume required for PT/PTT/Factor VIII activity | 50 µL/50 µL/5 µL (standard) | 50 µL/50 µL/— | 50 µL/50 µL/5 µL (standard) |
| Types of disposables used | rotors and wash solution | cuvettes | reaction tubes, CA clean I and II |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/no | no/no | yes/no |
| Accommodates most standard tube sizes/Nonstandard sizes | yes/yes | no/no | yes/yes |
| Sample barcode-reading capability/Autodiscrimination | yes/— | no/— | yes/— |
| Auto tracks product volume/Measures number of tests remaining | yes/yes | no/no | yes/no |
| Short sample detection | yes | no | yes |
| Clot detection as preanalytical variable in plasma sample | no | no | no |
| Auto detects adequate reagents for aspiration or analysis | yes (aspiration and analysis) | no | no |
| Detection or quantitation for hemolysis, turbidity, icterus, lipemia | no | no | no |
| Dilutes patient samples onboard | yes | no | yes |
| Automatic rerun capability/Auto reflex testing capability | yes/yes | no/no | no/no |
| Lag time during which hypercoagulable sample not detected | yes (PT and PTT: 7 seconds) | no | yes (PT: 7 seconds; PTT: 15 seconds) |
| User can adjust reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| User can adjust No. of reagents/Sources of reagents | yes/yes | yes/yes | yes/yes |
| User can adjust incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Read time extended for prolonged clotting times | yes | yes | yes |
| Autocalibration/Calibrants stored onboard | yes/yes | no/yes | no/yes |
| Multipoint calibration supported/Recommended frequency | yes/6 months, per regulatory guidelines | yes/6 months, per regulatory guidelines | yes/6 months, per regulatory guidelines |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | 5 minutes/380 specimens | 1 minute/1 specimen | 7 minutes/60 specimens |
| • PT, PTT | 5 minutes/325 specimens | — | 8 minutes/24 specimens |
| • Fibrinogen | 5 minutes/315 specimens | 1 minute/1 specimen | 7 minutes/60 specimens |
| • Factor VIII activity assay | 5 minutes/280 specimens | — | 5 minutes/— |
| • D-dimer | 5 minutes/— | — | 6 minutes/12 specimens |
| Time delay from ordering stat to aspiration of sample | 1 minute | — | 1 minute |
| How labs get LOINC codes for results | website | website | website |
| Onboard real-time QC/Onboard software capability to review QC | yes/yes | no/no | yes/yes |
| Information that can be barcode-scanned on instrument | operator identifier, specimen identifier, reagent lot No. | — | specimen identifier, reagent lot No. |
| Compatible with laboratory automation systems | no | no | no |
| Data-management capability/LIS or EHR systems interfaced | onboard/most major vendors | no/no | onboard/most major vendors |
| Interface supplied by instrument vendor | contract dependent | no | contract dependent |
| Results transferred to LIS as soon as test time complete | yes | no | yes |
| Bidirectional interface capability | yes (host query) | no | yes (host query) |
| Remote servicing provided/UPS backup power supply | no/yes | no/no | no/no |
| Instrument connections to transfer information | data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies) | commercial middleware (most major companies) | data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies) |
| Interface standards supported | ASTM 1394-91, ASTM 1381, HL7 | — | ASTM 1394-91, ASTM 1381, HL7, CA-1000 protocol |
| Information transferred to data-management software | device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks | — | device unique identifier, patient ID, specimen ID, result, QC identifier |
| Avg. time for basic user training | varies at customer site, 3 days at vendor office | Siemens PEPconnect online | 2 days (at customer site) |
| Approximate scheduled maintenance time | daily: 5 minutes; weekly: 10 minutes; monthly: 15 minutes | daily: 1 minute | daily: 8 minutes |
| Maintenance records kept onboard | no | no | no |
| Warranty with purchase/Annual service contract cost (24/7) | yes/— (cost dependent on contract) | yes/— | yes/— (cost dependent on contract) |
| Distinguishing features (supplied by company) | user-definable calibration curve expiration and prewarning alerts; user-definable barcode utility enables customizable reagent protocols; user-friendly Windows 10 software | 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 | maximizes counter space with compact footprint in low-volume labs; increases uptime and reduces service expenses; CA-620 system for routine clotting-based testing, CA-660 system for clotting, chromogenic, and immunologic testing |

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

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

# COAGULATION ANALYZERS

| Part 5 of 6 | **Siemens Healthineers**<br>**Aura Fucci** aura.fucci@siemens-healthineers.com<br>**Tarrytown, NY**<br>**914-631-8000** siemens-healthineers.us.com | **Siemens Healthineers**<br>**Aura Fucci** aura.fucci@siemens-healthineers.com<br>**Tarrytown, NY**<br>**914-631-8000** siemens-healthineers.us.com | **Werfen**<br>**V. Shirley** vshirley@werfen.com<br>**Bedford, MA**<br>**781-674-3221** www.werfen.com |
|---|---|---|---|
| Instrument name/First year sold | Sysmex CS-2500 System/2016 | Sysmex CS-5100 System/2016 | ACL AcuStar/2010 |
| List price/Model type | $155,000/benchtop | $205,000/floor standing | —/benchtop |
| Dimensions (H × W × D)/Weight/Instrument footprint | 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. | 21 × 34 × 24 in./170 lbs./10 sq. ft. |
| No. of units in clinical use in U.S./Outside U.S. (countries) | >500/>2,000 (worldwide) | >100/>1,000 (worldwide) | 5/196 (available in most countries) |
| Composition of installs: Hospital lab/Reference lab/Other | — | — | 100%/0/0 |
| Targeted daily, monthly, annual test volume | daily: 25–300 | daily: >300 | daily: 20–150; monthly: 600–4,500; annual: 36,000–54,000 |
| Operational type | continuous random access | continuous random access | random access |
| Country where analyzer designed/Manufactured | Japan/Japan | Japan/Japan | U.S./U.S. |
| Company manufactures instrument | no (manufactured by Sysmex) | no (manufactured by Sysmex) | no |
| FDA-approved 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-approved chromogenic tests | antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin | antithrombin, protein C, Innovance free protein S antigen, plasminogen, Innovance heparin, factor VIII chromogenic, alpha-2-antiplasmin | — |
| FDA-approved immunologic tests | Innovance VWF Ac, Innovance D-dimer | Innovance VWF Ac, Innovance D-dimer | HIT IgG, domain 1, anticardiolipin IgG, anticardiolipin IgM, B2GPI IgG, B2GPI IgM |
| Other FDA-approved tests | — | — | — |
| User-defined tests in clinical use | platelet aggregation, anti-Xa rivaroxaban RUO | platelet aggregation, anti-Xa rivaroxaban RUO | — |
| Tests in development or awaiting FDA 510(k) clearance | von Willebrand factor | von Willebrand factor | ADAMTS13, von Willebrand factor ristocetin cofactor, von Willebrand antigen |
| Methodologies supported | clot detection, optical; chromogenic; immunologic | clot detection, optical; chromogenic; immunologic | immunologic (chemiluminescent) |
| Number of different measured assays onboard simultaneously | 60 | 60 | 20 |
| Number of different assays programmed and calib. at one time | 60 | 60 | 20 |
| No. of user-definable (open) channels/No. active simultaneously | 80,000/60 | 80,000/60 | 0/0 |
| Factor assays require manual manipulation or dilutions | — | — | — |
| Test throughput per hour/Assay run time | 180 (2 tests in throughput)/1–10 min. (avg. 5 min.) | 400 (2 tests in throughput)/1–10 min. (avg. 5 min.) | 60 (1 test in throughput)/30 min. |
| Design of sample-handling system | continuous loading capped and uncapped primary sample tubes and cups in same rack; 10-tube position sample rack × 5 | continuous loading capped and uncapped primary sample tubes and cups in same rack; 10-tube position sample rack × 10 | samples loaded into carousel rack |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Reagent type | self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained single-use vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained multiuse cartridges (liquid) |
| Reagent barcode-reading capability | yes, for all tests | yes, for all tests | yes, for all tests |
| No. of reagent containers held onboard/Reagents ready to use | 40/yes | 40/yes | 20/yes |
| Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard | yes/yes/yes (10°C ± 2°C) | yes/yes/yes (10°C ± 2°C) | yes/yes/yes |
| Reagents, consumables loaded without interrupting testing | yes (reagents and consumables) | yes (reagents and consumables) | yes (reagents and consumables) |
| Instrument uses proprietary or third-party reagents | user's option (same capabilities when third-party reagents used) | user's option (same capabilities when third-party reagents used) | proprietary reagents |
| Maximum time same lot number of reagents can be used | 1 year | 1 year | 6 months |
| Walkaway capability/Walkaway duration | yes/50 specimens or up to 500 tests | yes/100 specimens or up to 1,000 tests | yes/30 specimens or 280 tests |
| Min.–max. specimen volume that can be aspirated at one time | 5 µL minimum | 5 µL minimum | 2–250 µL |
| Min. sample volume required for PT/PTT/Factor VIII activity | 50 µL/50 µL/5 µL (standard) | 50 µL/50 µL/5 µL (standard) | 50 µL/50 µL/50 µL |
| Types of disposables used | reaction tubes, CA clean I and II | reaction tubes, CA clean I and II | cuvettes, trigger, solutions |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/yes | yes/yes | yes/no |
| Accommodates most standard tube sizes/Nonstandard sizes | yes/yes | yes/yes | yes/no |
| Sample barcode-reading capability/Autodiscrimination | yes/— | yes/— | yes/yes |
| Auto tracks product volume/Measures number of tests remaining | yes/yes | yes/yes | yes/yes |
| Short sample detection | yes | yes | yes |
| Clot detection as preanalytical variable in plasma sample | yes | yes | no |
| Auto detects adequate reagents for aspiration or analysis | yes (aspiration and analysis) | yes (aspiration and analysis) | yes (aspiration and analysis) |
| Detection or quantitation for hemolysis, turbidity, icterus, lipemia | detection and quantitation for hemolysis, turbidity, icterus, lipemia | detection and quantitation for hemolysis, turbidity, icterus, lipemia | — |
| Dilutes 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 | yes (PT: 7 seconds; PTT: 15 seconds) | yes (PT: 7 seconds; PTT: 15 seconds) | — |
| User can adjust reagent volumes/Sample volumes | yes/yes | yes/yes | no/no |
| User can adjust No. of reagents/Sources of reagents | yes/yes | yes/yes | no/no |
| User can adjust incubation times/Reading times | yes/yes | yes/yes | no/no |
| Read time extended for prolonged clotting times | yes (selectable on menus) | yes (selectable on menus) | no |
| Autocalibration/Calibrants stored onboard | no/yes | no/yes | no/no |
| Multipoint calibration supported/Recommended frequency | yes/6 months, per regulatory guidelines | yes/6 months, per regulatory guidelines | yes/6 months |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | 5 minutes/180 specimens | 5 minutes/400 specimens | — |
| • PT, PTT | 5 minutes/90 specimens | 5 minutes/200 specimens | — |
| • Fibrinogen | 5 minutes/180 specimens | 5 minutes/201 specimens | — |
| • Factor VIII activity assay | 5 minutes/— | 5 minutes/— | — |
| • D-dimer | 5 minutes/90 specimens | 5 minutes/202 specimens | — |
| Time delay from ordering stat to aspiration of sample | 1 minute | 1 minute | <1 minute |
| How labs get LOINC codes for results | website | website | functionality not provided |
| Onboard real-time QC/Onboard software capability to review QC | yes/yes | yes/yes | yes/yes |
| Information that can be barcode-scanned on instrument | operator identifier, specimen identifier, reagent lot No. | operator identifier, specimen identifier, reagent lot No. | specimen identifier, reagent lot No. |
| Compatible with laboratory automation systems | no | yes (Siemens Aptio Automation) | no |
| Data-management capability/LIS or EHR systems interfaced | onboard/most major vendors | onboard/most major vendors | onboard/Meditech |
| Interface supplied by instrument vendor | contract dependent | contract dependent | contract dependent |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| Bidirectional interface capability | yes (host query) | yes (host query) | yes (broadcast download and host query) |
| Remote servicing provided/UPS backup power supply | yes/yes | yes/yes | no/yes |
| Instrument connections to transfer information | data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies) | data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies) | data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Werfen, Beckman) |
| Interface standards supported | ASTM 1394-91, ASTM 1381 | ASTM 1394-91, ASTM 1381 | ASTM 1394-91 |
| Information transferred to data-management software | device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks | device unique identifier, operator ID, patient ID, specimen ID, result, QC identifier, PSI checks | specimen ID |
| Avg. time for basic user training | varies at customer site, 3 days at vendor office | varies at customer site, 3 days at vendor office | 4 days (at customer site) |
| Approximate scheduled maintenance time | daily: 5 minutes; weekly: 1 minute; monthly: 1 minute | daily: 5 minutes; weekly: 1 minute; monthly: 1 minute | daily: 5 minutes; weekly: 5 minutes |
| Maintenance records kept onboard | yes | yes | yes |
| Warranty with purchase/Annual service contract cost (24/7) | yes/— (cost dependent on contract) | yes/— (cost dependent on contract) | yes/— (cost dependent on contract) |
| Distinguishing features (supplied by company) | confidence: simultaneous multiwavelength detection and PSI technology designed to ensure high-quality first-run results; operational efficiency: user-friendly software on Windows 10; tilted reagent vials for 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 10; tilted reagent vials for efficiency; consistency: for multisite patient monitoring, with sample result traceability for in-depth audit capabilities | on-demand HIT IgG testing with results available in 30 minutes; uses sensitive chemiluminescent technology, improving sensitivity; reagents are ready to use with onboard stability up to 12 weeks |
| *Note: a dash in lieu of an answer means company did not answer question or question is not applicable* | | | |

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.

| Part 6 of 6 | **Werfen**<br>**V. Shirley** vshirley@werfen.com<br>**Bedford, MA**<br>**781-674-3221** www.werfen.com | **Werfen**<br>**V. Shirley** vshirley@werfen.com<br>**Bedford, MA**<br>**781-674-3221** www.werfen.com | **Werfen**<br>**V. Shirley** vshirley@werfen.com<br>**Bedford, MA**<br>**781-674-3221** www.werfen.com |
|---|---|---|---|
| Instrument name/First year sold | ACL TOP 350/2016 | ACL TOP 550 CTS/2016 | ACL TOP 750 Series/2016 |
| List price/Model type | —/benchtop | —/benchtop | —/floor standing |
| Dimensions (H × W × D)/Weight/Instrument footprint | 29 × 32 × 33 in./200 lbs./8 sq. ft. | 29 × 43 × 35 in./312 lbs./14 sq. ft. | 29 × 60 × 35 in./356 lbs./21 sq. ft. |
| No. of units in clinical use in U.S./Outside U.S. (countries) | 1,309/3,700 (available in most countries) | 737/3,400 (available in most countries) | 737/3,200 (available in most countries) |
| Composition of installs: Hospital lab/Reference lab/Other | 95%/5%/— | 85%/12%/3% (pharmaceutical or medical device labs) | 85%/12%/3% (pharmaceutical or medical device labs) |
| Targeted daily, monthly, annual test volume | daily: 20–150; monthly: 600–4,500; annual: 36,000–54,000 | daily: 100–200; monthly: 3,000–6,000; annual: 36,000–72,000 | daily: 200–400; monthly: 6,000–12,000; annual: 72,000–144,000 |
| Operational type | random access | random access | random access |
| Country where analyzer designed/Manufactured | U.S./U.S. | U.S./U.S. | U.S./U.S. |
| Company manufactures instrument | yes | yes | yes |
| FDA-approved clotting-based tests | PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C | PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C | PT, APTT, fibrinogen, thrombin time, factor assays, lupus anticoagulant (dRVVT and silica clotting time), protein S, protein C |
| FDA-approved chromogenic tests | anti-Xa, apixaban, protein C, antithrombin, plasminogen, plasmin inhibitor | anti-Xa, apixaban, protein C, antithrombin, plasminogen, plasmin inhibitor | anti-Xa, apixaban, protein C, antithrombin, plasminogen, plasmin inhibitor |
| FDA-approved immunologic tests | high specificity D-dimer, standard D-dimer, heparin induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine | high specificity D-dimer, standard D-dimer, heparin induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine | high specificity D-dimer, standard D-dimer, heparin induced thrombocytopenia, von Willebrand factor antigen, von Willebrand factor activity, free protein S, factor XIII antigen, homocysteine |
| Other FDA-approved tests | — | — | — |
| User-defined tests in clinical use | DOAC assays, chromogenic factor VIII | DOAC assays, chromogenic factor VIII | DOAC assays, chromogenic factor VIII |
| Tests in development or awaiting FDA 510(k) clearance | von Willebrand factor ristocetin cofactor, dabigatran, rivaroxaban, apixaban | von Willebrand factor ristocetin cofactor, dabigatran, rivaroxaban, apixaban | von Willebrand factor ristocetin cofactor, dabigatran, rivaroxaban, apixaban |
| Methodologies supported | clot detection, optical; chromogenic; immunologic (immunoturbidimetric) | clot detection, optical; chromogenic; immunologic (immunoturbidimetric) | clot detection, optical; chromogenic; immunologic (immunoturbidimetric) |
| Number of different measured assays onboard simultaneously | 30 | 30 | 30 |
| Number of different assays programmed and calib. at one time | 500 | 500 | 500 |
| No. of user-definable (open) channels/No. active simultaneously | 250/250 | 250/250 | 250/250 |
| Factor assays require manual manipulation or dilutions | — | — | — |
| Test throughput per hour/Assay run time | 110 (1 test in throughput)/3–6 min. (avg. 4 min.) | 240 (1 test in throughput)/3–6 min. (avg. 4 min.) | 360 (1 test in throughput)/3–6 min. (avg. 4 min.) |
| Design of sample-handling system | samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification | samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification | samples loaded into rack; system uses integrated sample barcode reader to eliminate any post-draw sample misidentification |
| Operates on whole blood or spun plasma | spun plasma | spun plasma | spun plasma |
| Reagent type | self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) | self-contained multiuse vials; open reagent system (liquid, lyophilized [reconstituted manually]) |
| Reagent barcode-reading capability | yes, for all tests | yes, for all tests | yes, for all tests |
| No. of reagent containers held onboard/Reagents ready to use | 24/variable (reagent specific) | 40/variable (reagent specific) | 60/variable (reagent specific) |
| Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard | yes/yes/yes | yes/yes/yes | yes/yes/yes |
| Reagents, consumables loaded without interrupting testing | yes (reagents and consumables) | yes (reagents and consumables) | yes (reagents and consumables) |
| Instrument uses proprietary or third-party reagents | user's option (same capabilities when third-party reagents used) | user's option (same capabilities when third-party reagents used) | user's option (same capabilities when third-party reagents used) |
| Maximum time same lot number of reagents can be used | 18 months | 18 months | 18 months |
| Walkaway capability/Walkaway duration | yes/40 specimens or 800 tests | yes/80 specimens or 800 tests | yes/120 specimens or 800 tests |
| Min.–max. specimen volume that can be aspirated at one time | 2–250 µL | 2–250 µL | 2–250 µL |
| Min. sample volume required for PT/PTT/Factor VIII activity | 50 µL/50 µL/50 µL | 50 µL/50 µL/50 µL | 50 µL/50 µL/50 µL |
| Types of disposables used | cuvettes, clean A/B, rinse | cuvettes, clean A/B, rinse | cuvettes, clean A/B, rinse |
| Primary tube sampling supported/Pierces caps on primary tubes | yes/yes | yes/yes | yes/yes |
| Accommodates most standard tube sizes/Nonstandard sizes | yes/yes | yes/yes | yes/yes |
| Sample barcode-reading capability/Autodiscrimination | yes (Interleaved 2 of 5, Code 39, Code 128)/yes | yes (Interleaved 2 of 5, Code 39, Code 128)/yes | yes (Interleaved 2 of 5, Code 39, Code 128)/yes |
| Auto tracks product volume/Measures number of tests remaining | yes/yes | yes/yes | yes/yes |
| Short sample detection | yes | yes | yes |
| Clot detection as preanalytical variable in plasma sample | yes | yes | yes |
| Auto detects adequate reagents for aspiration or analysis | yes (aspiration and analysis) | yes (aspiration and analysis) | yes (aspiration and analysis) |
| Detection or quantitation for hemolysis, turbidity, icterus, lipemia | detection and quantitation for hemolysis, turbidity, icterus, lipemia | detection and quantitation for hemolysis, turbidity, icterus, lipemia | detection and quantitation for hemolysis, turbidity, icterus, lipemia |
| Dilutes 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 |
| User can adjust reagent volumes/Sample volumes | yes/yes | yes/yes | yes/yes |
| User can adjust No. of reagents/Sources of reagents | yes/yes | yes/yes | yes/yes |
| User can adjust incubation times/Reading times | yes/yes | yes/yes | yes/yes |
| Read time extended for prolonged clotting times | yes (selectable on menus) | yes (selectable on menus) | yes (selectable on menus) |
| Autocalibration/Calibrants stored onboard | no/no | no/no | no/no |
| Multipoint calibration supported/Recommended frequency | yes/6 months | yes/6 months | yes/6 months |
| Stat time to complete all analytes/Throughput per hour for: | | | |
| • PT alone | <3 minutes/110 specimens | <3 minutes/240 specimens | <3 minutes/360 specimens |
| • PT, PTT | <6 minutes/55 specimens | <6 minutes/90 specimens | <6 minutes/165 specimens |
| • Fibrinogen | <3 minutes/60 specimens | <3 minutes/78 specimens | <3 minutes/108 specimens |
| • Factor VIII activity assay | 8 minutes/38 specimens | 8 minutes/77 specimens | 8 minutes/100 specimens |
| • D-dimer | 5 minutes/55 specimens | 5 minutes/75 specimens | 5 minutes/100 specimens |
| Time delay from ordering stat to aspiration of sample | none | none | none |
| How labs get LOINC codes for results | functionality not provided | functionality not provided | functionality not provided |
| Onboard real-time QC/Onboard software capability to review QC | yes/yes | yes/yes | yes/yes |
| Information that can be barcode-scanned on instrument | specimen identifier, reagent lot No. | specimen identifier, reagent lot No. | specimen identifier, reagent lot No. |
| Compatible with laboratory automation systems | no | no | yes (HemoCell, Beckman, Siemens, Abbott, Thermo Fisher, others) |
| Data-management capability/LIS or EHR systems interfaced | onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Clinisys, Vista | onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Clinisys, Vista | onboard/Cerner, CompuLab, CPSI, HBOC, HMS, McKesson, Meditech, Novius, SMS, SCC, Clinisys, Vista |
| Interface supplied by instrument vendor | contract dependent | contract dependent | contract dependent |
| Results transferred to LIS as soon as test time complete | yes | yes | yes |
| Bidirectional interface capability | yes (broadcast download and host query) | yes (broadcast download and host query) | yes (broadcast download and host query) |
| Remote servicing provided/UPS backup power supply | yes/yes | yes/yes | yes/yes |
| Instrument connections to transfer information | data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman) | data-management system, which in turn connects to LIS; directly to LIS; commercial middleware (Beckman) | data-management system, which in turn connects to LIS; directly to LIS; directly to lab automation system; commercial middleware (Beckman) |
| Interface standards supported | ASTM 1394-91 | ASTM 1394-91 | ASTM 1394-91 |
| Information transferred to data-management software | specimen ID | specimen ID | specimen ID |
| Avg. time for basic user training | 9 days (5 days at customer site, 4 days at vendor office) | 14 days (10 days at customer site, 4 days at vendor office) | 14 days (10 days at customer site, 4 days at vendor office) |
| Approximate scheduled maintenance time | daily: <5 minutes; weekly: <10 minutes | daily: <5 minutes; weekly: <10 minutes | daily: <5 minutes; weekly: <10 minutes |
| Maintenance records kept onboard | yes | yes | yes |
| Warranty with purchase/Annual service contract cost (24/7) | yes/— (cost dependent on contract) | yes/— (cost dependent on contract) | yes/— (cost dependent on contract) |
| Distinguishing features (supplied by company) | FDA 510(k) approved; improves patient care, lab efficiencies, and costs; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); best-in-class reagents; liquid format for PT/APTT (10-day onboard stability), high specificity D-dimer, on-demand HIT testing | FDA 510(k) approved; improves patient care, lab efficiencies, and costs; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); liquid format for PT/APTT (10-day onboard stability), high specificity D-dimer, on-demand HIT testing | FDA 510(k) approved; improves patient care, lab efficiencies, and costs; supports lab's policy on sample acceptance with quantitative HIL, sample fill detection, aspiration errors (clots); liquid format for PT/APTT (10-day onboard stability), high specificity D-dimer, on-demand HIT testing |

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

All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.