

## Coagulation Analyzers

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|---|---|---|--|
| <b>Part 1 of 11</b>   | American Labor/Lab A.C.M. Inc.<br>Mike Shifflett mshifflett@americanlabor.org<br>1308 Broad St., Durham, NC 27705<br>919-286-0726 or (tech support) 800-424-0443<br>www.americanlabor.org & www.labitec.de  | American Labor/Lab A.C.M. Inc.<br>Mike Shifflett mshifflett@americanlabor.org<br>1308 Broad St., Durham, NC 27705<br>919-286-0726 or (tech support) 800-424-0443<br>www.americanlabor.org & www.labitec.de  | American Labor/Lab A.C.M. Inc.<br>Mike Shifflett mshifflett@americanlabor.org<br>1308 Broad St., Durham, NC 27705<br>919-286-0726 or (tech support) 800-424-0443<br>www.americanlabor.org & www.labitec.de                                 |
| Instrument name/first year sold   | CD2000/1986   | CoaData 4001/FDA clearance pending  | CoaLab 6000/available spring 2003  |
| No. of units installed in U.S./outside U.S.<br>Country where analyzer designed/manufactured<br>Operational type<br>Reagent type<br>Operates on whole blood or spun plasma<br>Sample handling system<br>Model type<br>Dimensions (H x W x D)/weight/instrument footprint   | >500/>1,000<br>Germany/Germany<br>batch, discrete<br>open reagent system (reconst. manually)<br>spun plasma<br>cuvette, semiautomated<br>benchtop<br>5 x 12 x 8.5 in/9.2 lbs/1 sq ft  | 0/<500<br>Germany/Germany<br>discrete<br>open reagent system (reconst. manually)<br>spun plasma<br>cuvette, semiautomated<br>benchtop<br>11 x 14 x 5 in/9 lbs/—   | 0/<500<br>Germany/Germany<br>discrete, batch<br>cuvette bar—open reagent system<br>spun plasma<br>automated<br>benchtop<br>28 x 18 x 22 in/44 lbs/—  |
| FDA-cleared clotting-based tests<br>FDA-cleared chromogenic tests<br>FDA-cleared immunologic tests<br>Other FDA-cleared tests<br>User-defined tests in clinical use<br>Tests submitted for 510(k) clearance<br>Tests in development but not yet submitted   | PT, PTT, fib., any citrated plasma clot-based assay<br>none<br>none<br>none<br>none<br>none<br>none   | FDA clearance pending   | FDA clearance pending<br><br><br><br><br><br>PT, APTT, fib. (FDA pending)  |
| Methodologies supported<br>Oper. must load sep. reag. pack for ea. specimen/test run<br>No. of different measured assays onboard simultaneously<br>No. of different assays programmed and calibrated at one time<br>No. of user-definable (open) channels<br>Of those defined, No. active simultaneously<br>Factor assays require manual manipulation or dilutions<br>No. of reag. containers onboard at one time/tests per container<br>Reagents refrigerated onboard<br>Multiple reag. configurations supported<br>Reag., consumables loaded without interrupting testing<br>Same capabilities when 3rd-party reag. used<br>Max. time same lot number of reag. can be used<br>Walkaway capacity: No. of specimens/No. of tests<br>Min. sample vol. aspirated precisely at one time<br>Standard specimen vol. required to run PT or PTT/factor VIII activity<br>Disposables used/price of each   | clot detection, optical; turbidensitometry stir bar<br>mixing—optical detection<br>no/no<br>2 (PT, APTT)<br>1 (fib.)<br>2<br>2<br>yes<br>5 or more/ reag. mfr. dependent<br>no<br>yes<br>yes<br>yes<br>laboratory dependent<br>no<br>manual pipetting<br>50 µL, min. 50 µL/50 µL, min. 50 µL<br>500 microcuvette w/ mixers in trays/11.6¢ ea., bulk<br>11¢ ea.; 500 macrocuvette w/ mixers in trays/12¢ ea.,<br>bulk 10.6¢ ea.; 2,304 pipette tips-trayed/5.1¢ ea., 3,000<br>tips bulk/3.9¢ ea. | optical-turbidensitometry<br>no/no<br>1<br>1<br>4<br>4<br>yes<br>4/1<br>no<br>yes<br>yes<br>yes<br>mfr. dependent<br>no<br>manual<br>50 µL, min. 50 µL/50 µL, min. 50 µL<br>microcuvette (150–250) UL 7¢ ea.; 2,304 pipette tips<br>trayed/5.1¢ ea., 3,000 tips bulk/3.9¢ ea. | optical-turbidensitometry<br>1st batch only<br>up to 7<br>all<br>6<br>all<br>no<br>6/1<br>no<br>yes<br>yes<br>yes<br>mfr. dependent<br>18/3<br>50 µL<br>50 µL, min. 50 µL/50 µL, min. 50 µL<br>cuvette rack w/ 6 cuvettes (125–250)/7¢ ea. |
| Supports direct-from-track sampling<br>Primary tube sampling supported/pierces caps on primary tubes<br>Sample bar-code reading capability<br>Reagent bar-code reading capability<br>Onboard test automatic inventory<br>Measures No. of tests remaining<br>Short sample detection<br>Clot detection as preanalytical variable in plasma sample<br>Auto. detection of adequate reag. for aspir. & anal.<br>Hemolysis/turbidity detection-quantitation<br>Dilution of patient samples onboard<br>Automatic rerun capability/auto reflex testing capability<br>Lag time during which hypercoagulable samples will not be detected<br>Read time extended for prolonged clotting times<br>User can set different-than-standard:<br>• Reag. volumes/sample volumes<br>• No. and sources of reag.<br>• Incub. times/reading times<br>Autocalibration or autocalb. alert/multipoint calibration supported<br>Auto shutdown/auto startup programmable | no<br>no/no<br>no<br>no<br>no<br>no<br>no<br>no<br>no<br>no/no<br>no<br>no/no<br>yes (3 sec)<br>yes, up to 999 sec<br>yes/yes<br>yes<br>yes/yes<br>no/no<br>no/no   | no<br>no/no<br>no<br>no<br>no<br>no<br>no<br>no<br>no<br>no/no<br>no<br>no/no<br>yes (3 sec)<br>yes, up to 999 sec (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>no/no<br>no/no   | no<br>no/no<br>yes<br>yes<br>yes<br>yes<br>yes<br>no/no<br>no/no<br>yes (3 sec)<br>yes, up to 999 sec (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>no/no<br>no/no   |
| Stat time to completion of all analytes and throughput per hour for:<br>• PT alone<br>• PT, PTT<br>• Fibrinogen<br>• Factor VIII activity assay<br>Time delay from ordering stat to aspir. of sample<br>Auto. transfer of QC results to LIS<br>Data management capability<br>Interface supplied by instrument vendor<br>Interfaces in active user sites for:<br>Bidirectional interface capability<br>Results transferred to LIS as soon as test time complete<br>LOINC codes transmitted with all results<br>How labs get LOINC codes for reagent kits<br>Electronic interface available (or will be) to automated<br>(or robotic) specimen handling system  | 120 sec/user defined<br>240 sec/user defined<br>300 sec/user defined<br>300 sec/user defined<br>none—all preanalytical<br>no<br>no<br>no<br>call technical support for inquiry<br>no<br>yes<br>no<br>n/a<br>yes   | 120 sec/open, reag. mfr. defined<br>240 sec/open, reag. mfr. defined<br>300 sec/open, reag. mfr. defined<br>300 sec/open, reag. mfr. defined<br>none<br>no<br>no<br>no<br>call technical support for inquiry<br>no<br>no<br>n/a<br>no   | >120 PT, open, reag. mfr. defined<br>open, reag. mfr. defined<br>open, reag. mfr. defined<br>open, reag. mfr. defined<br><60 sec<br>yes<br>yes<br>yes<br>call technical support for inquiry<br>no<br>yes—end of run<br>no<br>n/a<br>no     |
| Modem servicing<br>Time required for maintenance by lab personnel<br>Onboard maintenance records<br>Training provided with purchase<br>Approx. No. of training hours needed per tech  | no<br>daily: 30 sec (temp. check, cloth cleaning); weekly: 30<br>sec; monthly: 5 min (temp. calib. if needed)<br>no<br>yes<br>2 h   | no<br>daily: 5 min; weekly: 15 min; monthly: 15 min<br>no<br>yes<br>2 h   | no<br>daily: 5 min; weekly: 15 min; monthly: 15 min<br>no<br>yes<br>2 h  |
| List price<br>Ann. svc. contract cost (24 h/7 d)/warranty with purchase   | \$4,200, special pricing available upon written request<br>for quotation<br>additional 2-yr initial contract \$900 (optional)/1 yr  | TBD<br>TBD  | TBD<br>TBD   |
| Unique advantages   | • smaller clinic; office, private, vet labs<br>• low acquisition & service cost, low maintenance<br>• refurbished units available at reduced prices<br>• able to handle turbid/colored samples  | • economic, semiautomated coagulation analyzer for<br>routine laboratories & backup for automated<br>analyzers/confirmation testing   | • the smallest automatic coagulation batch analyzer for<br>emergency/stat/routine requirements   |

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

Survey editor: Raymond Aller, MD

SURVEY OF  
INSTRUMENTS

## Coagulation Analyzers

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|--|--|--|---|
| <b>Part 2 of 11</b><br><br><i>See accompanying article, page 18</i>  | <b>BioMérieux Inc.</b><br>Ginny Melhaus ginny.melhaus@na.biomerieux.com<br>100 Rodolphe St., Durham, NC 27712<br>919-620-2000<br>www.biomerieux-usa.com  | <b>BioMérieux Inc.</b><br>Ginny Melhaus ginny.melhaus@na.biomerieux.com<br>100 Rodolphe St., Durham, NC 27712<br>919-620-2000<br>www.biomerieux-usa.com  | <b>BioMérieux Inc.</b><br>Ginny Melhaus ginny.melhaus@na.biomerieux.com<br>100 Rodolphe St., Durham, NC 27712<br>919-620-2000<br>www.biomerieux-usa.com   |
| Instrument name/first year sold  | Coag-A-Mate Max/1999   | Coag-A-Mate MTX II/1999 (sold as MTX since 1997)   | Coag-A-Mate XM/1989   |
| No. of units installed in U.S./outside U.S.<br>Country where analyzer designed/manufactured<br>Operational type<br>Reagent type<br>Operates on whole blood or spun plasma<br>Sample handling system<br>Model type<br>Dimensions (H x W x D)/weight/instrument footprint  | >185 worldwide<br>Germany/Germany<br>random access<br>open reagent system<br>spun plasma<br>2 rotors (31 positions each)<br>benchtop<br>15.3 x 40.2 x 28.3 in/134.5 lbs/8 sq ft, 11 w/ PC  | >500 worldwide<br>Germany & U.S./Germany<br>random access<br>open reagent system<br>spun plasma<br>rotor (32 positions)<br>benchtop<br>19.7 x 30.7 x 21.3 in/100 lbs/5 sq ft, 8 w/ PC  | >2,000 worldwide<br>U.S./U.S.<br>discrete<br>open reagent system<br>spun plasma<br>manual pipetting into cuvette (4 wells at a time)<br>benchtop<br>4.6 x 14.7 x 20 in/20 lbs/2 sq ft   |
| FDA-cleared clotting-based tests<br>FDA-cleared chromogenic tests<br>FDA-cleared immunologic tests<br>Other FDA-cleared tests<br>User-defined tests in clinical use<br><br>Tests submitted for 510(k) clearance<br>Tests in development but not yet submitted  | PT, APTT, TT, fib., PT & APTT factors<br>AT III, hep. antifactor Xa<br>none<br>none<br>PT mix, APTT mix, lupus (DRVVT screen & confirm.),<br>reptilase, proteins C & S (clotting), protein C<br>(chromo.), APCR, LMWH (antifactor Xa)<br>none<br>—   | PT, APTT, TT, fib., PT & APTT factor assays<br>AT III, hep. antifactor Xa, protein C<br>none (latex immunologic assay in development)<br>none<br>alpha-2 antiplasmin, plasminogen, PT mix, APTT<br>mix, LMWH (antifactor Xa)<br>none<br>quantitative D-dimer immunoassay   | PT, APTT, TT, fib., PT & APTT factor assays<br>none<br>none (latex immunologic assay in development)<br>none<br>none<br>—   |
| Methodologies supported<br>Oper. must load sep. reagent pack for ea. specimen/test run<br>No. of different measured assays onboard simultaneously<br>No. of different assays programmed and calibrated at one time<br>No. of user-definable (open) channels<br>Of those defined, No. active simultaneously<br>Factor assays require manual manipulation or dilutions<br>No. of reagent containers onboard at one time/tests per container<br>Reagents refrigerated onboard<br>Multiple reagent configurations supported<br>Reagent, consumables loaded without interrupting testing<br>Same capabilities when 3rd-party reagent used<br>Max. time same lot number of reagent can be used<br>Walkaway capacity: No. of specimens/No. of tests<br>Min. sample vol. aspirated precisely at one time<br>Standard specimen vol. required to run PT or PTT/factor VIII activity<br>Disposables used/price of each  | clotting, chromogenic assays; photo-optical<br>no/no<br>10<br>40<br>18<br>10<br>no<br>21 cooled, 16 for reagents, 5 for controls/15–160<br>yes (18°C)<br>yes<br>consumables yes, reagents no<br>yes<br>12–18 mos<br>62/232<br>5 µL<br>60 µL/10 µL<br>cuvette racks, probe cleaner, predilution<br>strips/prices available upon request | clotting, chromogenic assays; photo-optical<br>no/no<br>8<br>32<br>up to 32<br>8<br>no<br>16 cooled, 12 room temp. total 28/25–200<br>yes (15°C)<br>yes<br>no<br>yes<br>12–18 mos<br>32/32<br>2 µL<br>50 µL/5 µL, min. 2 µL<br>cuvette rings, pipettor wash solution, cleaning<br>solution/prices available on request | clotting assays; photo-optical<br>no/no<br>2<br>16<br>16<br>2<br>yes<br>4/30–100<br>no<br>yes<br>yes<br>yes<br>12–18 mos<br>4/4<br>n/a<br>100 µL/10 µL, min. 10 µL<br>cuvettes, stir bars, optional: printer & paper/prices<br>available on request |
| Supports direct-from-track sampling<br>Primary tube sampling supported/pierces caps on primary tubes<br>Sample bar-code reading capability<br>Reagent bar-code reading capability<br>Onboard test automatic inventory<br>Measures No. of tests remaining<br>Short sample detection<br>Clot detection as preanalytical variable in plasma sample<br>Auto. detection of adequate reagent for aspir. & anal.<br>Hemolysis/turbidity detection-quantitation<br>Dilution of patient samples onboard<br>Automatic rerun capability/auto reflex testing capability<br>Lag time during which hypercoagulable samples will not be detected<br>Read time extended for prolonged clotting times<br>User can set different-than-standard:<br>• Reagent volumes/sample volumes<br>• No. and sources of reagent<br>• Incub. times/reading times<br>Autocalibration or autocalib. alert/multipoint calibration supported<br>Auto shutdown/auto startup programmable | no<br>yes/no<br>yes (2 internal bar-code scanners)<br>no<br>yes<br>yes<br>no<br>no<br>yes<br>no/no<br>yes<br>yes/yes<br>yes (PT: 9 sec, APTT: 15 sec)<br>yes<br>yes/yes<br>yes<br>no/yes<br>yes/yes<br>no/no   | no<br>yes/no<br>yes<br>no<br>yes<br>yes<br>no<br>yes<br>yes/no<br>yes (PT: 3 sec, APTT: 5 sec)<br>yes<br>yes/yes<br>yes<br>yes/yes<br>yes/yes<br>no/no   | no<br>no/no<br>no<br>no<br>no<br>no<br>no<br>no<br>yes (PT: 7 sec, APTT: 20 sec)<br>yes<br>yes/yes<br>yes<br>yes/yes<br>yes/yes<br>no/no  |
| Stat time to completion of all analytes and throughput per hour for:<br>• PT alone<br>• PT, PTT<br>• Fibrinogen<br>• Factor VIII activity assay<br>Time delay from ordering stat to aspir. of sample<br>Auto. transfer of QC results to LIS<br>Data management capability<br>Interface supplied by instrument vendor<br>Interfaces in active user sites for:<br>Bidirectional interface capability<br>Results transferred to LIS as soon as test time complete<br>LOINC codes transmitted with all results<br>How labs get LOINC codes for reagent kits<br>Electronic interface available (or will be) to automated<br>(or robotic) specimen handling system   | <7 min/180 results<br><7 min/120–140 results<br><7 min/140–180 results<br><7 min/120–140 results<br><3 min<br>yes<br>yes (incl. QC: L-J)<br>yes (additional cost)<br>all commonly used LISs in North America<br>yes<br>yes<br>no<br>n/a<br>no  | 2 min/90 results<br>5 min/60 results<br>2 min/75 results<br>5 min/60 results<br>30–60 sec<br>yes<br>yes (incl. QC: L-J)<br>yes (additional cost)<br>all commonly used LISs in North America<br>yes<br>yes<br>no<br>n/a<br>no   | 2 min/200 results (manual)<br>5 min/50 PTT results (manual)<br>2–3 min/100 results (manual)<br>5 min/50 results (manual)<br>≤ 2 min<br>no<br>no<br>no<br>n/a<br>no<br>no<br>n/a<br>no   |
| Modem servicing<br>Time required for maintenance by lab personnel<br>Onboard maintenance records<br>Training provided with purchase<br>Approx. No. of training hours needed per tech   | no<br>daily: 5 min; weekly: 30 min; monthly <5 min<br>no<br>3 days at vendor offices<br>1–2 h/30 min or less for basic operation   | no<br>daily: ~5 min; weekly: ~1 min; monthly: ~5 min<br>no<br>3 days at vendor offices<br>2–3 h  | no<br>daily: none; weekly: ~5 min; monthly: none<br>no<br>1/2 day on site<br>1–2 h  |
| List price   | \$55,000   | \$49,995   | \$5,198   |
| Ann. svc. contract cost (24 h/7 d)/warranty with purchase  | \$6,300/1 yr   | \$7,300/1 yr   | depot service (repair)/1 yr   |
| Unique advantages  | • normalization of PT & APTT assays with other<br>BioMérieux automated systems<br>• workhorse analyzer for medium- to high-volume<br>routine workload<br>• easy operation & simple software means minimal<br>training required   | • normalization of PT & APTT results between<br>BioMérieux automated systems<br>• stat results within 2–5 min<br>• flexibility: MTX can support new assays easily<br>through user-programmable method files<br>• internal bar-code reader for sample & test<br>identification  | • simple to operate: clot detection starts<br>automatically on addition of start reagent<br>• flexibility: test params. can be modified to<br>accommodate various reagent systems   |

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## Coagulation Analyzers

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| <b>Part 3 of 11</b>  | <b>BioMérieux Inc.</b><br>Ginny Melhaus genny.melhaus@na.biomerieux.com<br>100 Rodolphe St., Durham, NC 27712<br>919-620-2000<br>www.biomerieux-usa.com  | <b>Dade Behring Inc.</b><br>Jackie Hauser jackie_hauser@dadebehring.com<br>1717 Deerfield Rd., Deerfield, IL 60015<br>847-267-5383<br>www.dadebehring.com   | <b>Dade Behring Inc.</b><br>Jackie Hauser jackie_hauser@dadebehring.com<br>1717 Deerfield Rd., Deerfield, IL 60015<br>847-267-5383<br>www.dadebehring.com   |
| <i>See accompanying article, page 18</i>   |  |   |   |
| <b>Instrument name/first year sold</b>   | MDA II/1999  | BFT II/U.S.: 1999   | Sysmex CA-500/U.S.: 1998  |
| <b>No. of units installed in U.S./outside U.S.</b><br><b>Country where analyzer designed/manufactured</b><br><b>Operational type</b><br><b>Reagent type</b>  | >400 worldwide<br>U.S./U.S.<br>continuous random access<br>open reagent system   | 160/2,172<br>Germany/Germany<br>batch<br>open reagent system (reconst. manually)  | 1,130/2,544<br>Japan/Japan<br>batch, continuous random access<br>open reagent system (reconst. manually), optimized for Dade Behring instruments  |
| <b>Operates on whole blood or spun plasma</b><br><b>Sample handling system</b><br><b>Model type</b><br><b>Dimensions (H x W x D)/weight/instrument footprint</b>   | spun plasma<br>racks<br>floor-standing<br>58 x 75 x 31 in/840 lbs/18 sq ft w/PC  | spun plasma<br>manual<br>benchtop<br>3.9 x 7.9 x 11.8 in/8.4 lbs/1.5 sq ft  | spun plasma<br>10-tube position sample rack<br>benchtop<br>19 x 21 x 18.5 in/99 lbs/9 sq ft   |
| <b>FDA-cleared clotting-based tests</b><br><b>FDA-cleared chromogenic tests</b><br><b>FDA-cleared immunologic tests</b><br><b>Other FDA-cleared tests</b><br><b>User-defined tests in clinical use</b>   | PT screening (moderate & low ISI), PT factors, quick%, APTT screening, APTT factors, PT mix, APTT mix, TT, fib. hep. antifactor Xa, AT III, protein C, plasminogen, alpha-2 antipaplasmin, lupus (dRVVT screen and confirm.), APCR<br>D-dimer (latex immunoassay)<br>none<br>clottable C & S, PNP, P & P (1 & 2), vWF, open assays-user definable for clotting, chrom. & microlatex assays<br>none<br>none | PT, APTT, fib.<br>none<br>none<br>none<br>none  | PT, APTT, fib., TT, factor assays, reptilase time, protein C<br>AT III, protein C chromo, heparin<br>none<br>none<br>n/a  |
| <b>Tests submitted for 510(k) clearance</b><br><b>Tests in development but not yet submitted</b>   | none<br>none   | none<br>none  | none<br>n/a   |
| <b>Methodologies supported</b><br><b>Oper. must load sep. reag. pack for ea. specimen/test run</b><br><b>No. of different measured assays onboard simultaneously</b><br><b>No. of different assays programmed and calibrated at one time</b><br><b>No. of user-definable (open) channels</b><br><b>Of those defined, No. active simultaneously</b><br><b>Factor assays require manual manipulation or dilutions</b><br><b>No. of reag. containers onboard at one time/tests per container</b><br><b>Reagents refrigerated onboard</b><br><b>Multiple reag. configurations supported</b><br><b>Reag., consumables loaded without interrupting testing</b><br><b>Same capabilities when 3rd-party reag. used</b><br><b>Max. time same lot number of reag. can be used</b><br><b>Walkaway capacity: No. of specimens/No. of tests</b><br><b>Min. sample vol. aspirated precisely at one time</b><br><b>Standard specimen vol. required to run PT or PTT/factor VIII activity</b><br><b>Disposables used/price of each</b>   | clotting; chromogenic; immunoassay; photo-optical<br>no/no<br>16<br>72<br>20<br>16<br>no<br>30/25-400<br>yes (8-15°C)<br>yes<br>yes<br>consumables yes, reagents no<br>yes<br>12-18 mos<br>170/480<br>5 µL<br>50 µL/10 µL<br>cuvettes, bar-code labels, MDA probe cleaner/prices available on request  | clot detection, opto-mechanical<br>no/no<br>1<br>3<br>n/a<br>1<br>n/a<br>4/up to 2,000<br>no<br>yes<br>yes<br>yes<br>12 mos<br>1/1<br>50 µL<br>50 µL<br>cuvettes, printer paper/price varies with volume  | clot detection: optical light scatter, chromogenic<br>no/no<br>5<br>7<br>7<br>5<br>n/a<br>10/varies, up to 200<br>yes (15°C)<br>yes<br>consumables yes, reagents no<br>yes<br>12 mos<br>10/50<br>10 µL<br>50 µL/n/a<br>reaction tubes, CA clean I, thermal paper/price varies with volume |
| <b>Supports direct-from-track sampling</b><br><b>Primary tube sampling supported/pierces caps on primary tubes</b><br><b>Sample bar-code reading capability</b><br><b>Reagent bar-code reading capability</b><br><b>Onboard test automatic inventory</b><br><b>Measures No. of tests remaining</b><br><b>Short sample detection</b><br><b>Clot detection as preanalytical variable in plasma sample</b><br><b>Auto. detection of adequate reag. for aspir. &amp; anal.</b><br><b>Hemolysis/turbidity detection-quantitation</b><br><b>Dilution of patient samples onboard</b><br><b>Automatic rerun capability/auto reflex testing capability</b><br><b>Lag time during which hypercoagulable samples will not be detected</b><br><b>Read time extended for prolonged clotting times</b><br><b>User can set different-than-standard:</b><br>• Reag. volumes/sample volumes<br>• No. and sources of reag.<br>• Incub. times/reading times<br><b>Autocalibration or autocallib. alert/multipoint calibration supported</b><br><b>Auto shutdown/auto startup programmable</b> | no<br>yes/yes<br>yes (internal bar-code scanner)<br>yes<br>yes<br>yes<br>yes<br>no<br>yes<br>yes/yes (detects bilirubin, corrects for lipemia)<br>yes<br>no/no<br>yes<br>yes (PT: default 3 sec, APTT: default 5 sec)<br>yes (selectable on menus)<br>yes/yes<br>yes<br>no/yes<br>yes/yes<br>yes/yes<br>yes/yes  | no<br>no<br>no<br>no<br>no<br>no<br>no<br>no<br>no<br>no/no<br>no<br>yes (PT: 5 sec, APTT: 15 sec)<br>no<br>yes/yes<br>yes<br>yes/yes<br>yes/yes<br>no/no   | no<br>yes (3-5 mL)/no<br>yes<br>no<br>yes<br>yes<br>yes<br>no<br>yes<br>no/yes<br>yes<br>no/PT: <7 sec, PTT: <15 sec<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>—/yes<br>no/no  |
| <b>Stat time to completion of all analytes and throughput per hour for:</b><br>• PT alone<br>• PT, PTT<br>• Fibrinogen<br>• Factor VIII activity assay<br><b>Time delay from ordering stat to aspir. of sample</b><br><b>Auto. transfer of QC results to LIS</b><br><b>Data management capability</b><br><b>Interface supplied by instrument vendor</b><br><b>Interfaces in active user sites for:</b><br><b>Bidirectional interface capability</b><br><b>Results transferred to LIS as soon as test time complete</b><br><b>LOINC codes transmitted with all results</b><br><b>How labs get LOINC codes for reagent kits</b><br><b>Electronic interface available (or will be) to automated (or robotic) specimen handling system</b>   | 12 min/180 results<br>12 min/180 results<br>12 min/180 results<br>12 min/180 results<br><1 min<br>yes<br>onboard (incl. QC: L-J, Westgard)<br>yes (additional cost)<br>all commonly used LISs in North America<br>yes (broadcast download & host query)<br>yes<br>no<br>n/a<br>yes   | 1 min/n/a manual<br>n/a manual<br><1 min/n/a manual<br>n/a<br>n/a<br>no<br>no<br>n/a<br>no<br>no<br>no<br>—<br>no   | 7 min/50 specimens<br>8 min/33 specimens<br>7 min/50 specimens<br>n/a/n/a<br>2 min<br>yes<br>onboard (incl. QC: L-J)<br>no<br>Cerner, Sunquest, others<br>yes (host query)<br>yes<br>no<br>—<br>no  |
| <b>Modem servicing</b><br><b>Time required for maintenance by lab personnel</b><br><b>Onboard maintenance records</b><br><b>Training provided with purchase</b><br><b>Approx. No. of training hours needed per tech</b>  | yes<br>daily: ~35 min; weekly: 45 min; monthly: 10 min<br>no<br>3-5 days on site, 4 days at vendor offices<br>4-5 h  | no<br>daily: 1 min<br>no<br>video<br>2 h  | no<br>daily: <5 min<br>no<br>2 days on site<br>2 h  |
| <b>List price</b><br><b>Ann. svc. contract cost (24 h/7 d)/warranty with purchase</b>  | \$92,295<br>\$12,600/1 yr  | \$6,877.50<br>depot service (repair)/1 yr   | \$34,474.65<br>\$4,962/1 yr   |
| <b>Unique advantages</b>   | • patented waveform analysis technology with flags for identifying abnormal waveforms (e.g., biphasic samples)<br>• sensitive quantitative D-dimer assay for use in diagnosis of VTE<br>• dyes in routine reagents for volume delivery check<br>• throughput remains the same regardless of test mix   | • 2-channel micro reagent volume clot-based technology<br>• opto-mechanical detection accurate on lipemic, icteric samples<br>• automatic INR calculation, curve storage, built-in thermal printer<br>• perfect for low-vol. testing/backup to larger systems | • 5-parameter true random access clotting/chromogenic<br>• small footprint, complete automation<br>• low-operating expense  |

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

## Coagulation Analyzers

|   |  |   |  |
|---|--|---|--|
| <b>Part 4 of 11</b>   | Dade Behring Inc.<br>Jackie Hauser jackie_hauser@dadebehring.com<br>1717 Deerfield Rd., Deerfield, IL 60015<br>847-267-5383<br>www.dadebehring.com   | Dade Behring Inc.<br>Jackie Hauser jackie_hauser@dadebehring.com<br>1717 Deerfield Rd., Deerfield, IL 60015<br>847-267-5383<br>www.dadebehring.com  | Dade Behring Inc.<br>Jackie Hauser jackie_hauser@dadebehring.com<br>1717 Deerfield Rd., Deerfield, IL 60015<br>847-267-5383<br>www.dadebehring.com   |
| See accompanying article, page 18   |  |   |  |
| Instrument name/first year sold   | Sysmex CA-1500/U.S.: 2000/worldwide: 1999  | BCS/U.S.: 1998  | Sysmex CA-7000/2002  |
| No. of units installed in U.S./outside U.S.<br>Country where analyzer designed/manufactured<br>Operational type<br>Reagent type<br><br>Operates on whole blood or spun plasma<br>Sample handling system<br>Model type<br>Dimensions (H x W x D)/weight/instrument footprint   | 482/275<br>Japan/Japan<br>continuous random access<br>open reagent system (lyoph., reconst. manually),<br>optimized for Dade Behring instruments<br>spun plasma<br>10-tube position sample rack x 5<br>benchtop<br>20 x 31.2 x 31.2 in/186 lbs/6.8 sq ft   | 276/927<br>Germany/Germany<br>batch, continuous random access<br>open reagent system (reconst. manually), optimized<br>for Dade Behring instruments<br>spun plasma<br>rack<br>benchtop<br>37 x 49 x 25 in/330 lbs/14 sq ft  | 2/40<br>Japan/Japan<br>continuous random access<br>open reagent system<br><br>spun plasma<br>rack<br>benchtop<br>24.8 x 42 x 43.8 in/345.4 lbs/12.78 sq ft   |
| FDA-cleared clotting-based tests<br><br>FDA-cleared chromogenic tests<br><br>FDA-cleared immunologic tests<br>Other FDA-cleared tests<br><br>User-defined tests in clinical use<br>Tests submitted for 510(k) clearance<br>Tests in development but not yet submitted   | PT, APTT, fib., factor assays, protein C, reptilase time,<br>thrombin time<br>protein S activity, AT III, plasminogen, factor VIII<br>chromo, alpha-2 antiplasmin, protein C chromo, heparin<br>advanced D-dimer<br>none<br>n/a<br>n/a<br>dRVVT screen and confirm, factor V Leiden  | PT, APTT, fib., TT, factor assays, reptilase time,<br>protein C, dRVVT screen & confirm., factor V Leiden<br>AT III, alpha-2 antiplasmin, plasminogen, protein C<br>chromo, heparin, protein S activity<br>advanced D-dimer<br>BC von Willebrand-ristocetin cofactor assay (agglut.<br>of fixed Pits.)<br>n/a<br>n/a<br>n/a   | PT, APTT, fib., factor assays, protein C clotting, TT,<br>Lupus, dRVVT, batroxobin<br>protein S activity, heparin AT III, factor VIII chromogenic,<br>plasminogen, alpha-2 antiplasmin, protein C chromogenic<br>D-dimer<br>n/a<br>n/a<br>factor V Leiden assay  |
| Methodologies supported<br><br>Oper. must load sep. reag. pack for ea. specimen/test run<br>No. of different measured assays onboard simultaneously<br>No. of different assays programmed and calibrated at one time<br>No. of user-definable (open) channels<br>Of those defined, No. active simultaneously<br>Factor assays require manual manipulation or dilutions<br>No. of reag. containers onboard at one time/tests per container<br>Reagents refrigerated onboard<br>Multiple reag. configurations supported<br>Reag., consumables loaded without interrupting testing<br>Same capabilities when 3rd-party reag. used<br>Max. time same lot number of reag. can be used<br>Walkaway capacity: No. of specimens/No. of tests<br>Min. sample vol. aspirated precisely at one time<br>Standard specimen vol. required to run PT or PTT/factor VIII activity<br>Disposables used/price of each   | clot detection, optical, turbidimetric; chromogenic;<br>immunologic (latex agglutination)<br>no/no<br>15<br>25<br>25<br>15<br>no<br>39/up to 200<br>yes (15°C)<br>yes<br>some consumables yes, reagents no<br>yes<br>12 mos<br>50/up to 1,000<br>5 µL<br>50 µL/10 µL<br>reaction tubes, sample plates, CA clean I & II, system<br>buffer, halogen lamp, closed container sample<br>replacement needles/prices vary with volume | clot detection: optical; xenon flasher lamp;<br>chromogenic; immunologic (ristocetin cofactor)<br>no/no<br>>20 tests/sample (theoretically 9,999)<br>99<br>8,999 (Nos. 1–1,000 are factory set & unalterable)<br>>100<br>no<br>18–78/variable-micro volume assay format<br>yes (<15°C)<br>yes<br>yes<br>yes<br>12 mos<br>110 samples/400 cuvettes<br>5 µL<br>50 µL, min. 100 µL (incl. dead vols.)/50 µL, min. 100 µL<br>cuvette rotors, washing solution, terralin disinfectant,<br>BC validation kit/price varies with volume | clot detection, optical, turbidimetric; chromogenic;<br>immunologic (latex, transmitted light)<br>no/no<br>20<br>40<br>40<br>20<br>no<br>58/variable up to 200<br>yes (15°C)<br>yes<br>yes<br>yes<br>12 mos<br>100/550 per hour PT and APTT, 300 per hour PT<br>5 µL<br>50 µL/10 µL<br>reaction tubes, CA clean I & II, system buffer, halogen<br>lamp, closed container sample replacement<br>needles/prices vary with volume |
| Supports direct-from-track sampling<br>Primary tube sampling supported/pierces caps on primary tubes<br>Sample bar-code reading capability<br>Reagent bar-code reading capability<br>Onboard test automatic inventory<br>Measures No. of tests remaining<br>Short sample detection<br>Clot detection as preanalytical variable in plasma sample<br>Auto. detection of adequate reag. for aspir. & anal.<br>Hemolysis/turbidity detection-quantitation<br>Dilution of patient samples onboard<br>Automatic rerun capability/auto reflex testing capability<br>Lag time during which hypercoagulable samples will not be detected<br>Read time extended for prolonged clotting times<br>User can set different-than-standard:<br>• Reag. volumes/sample volumes<br>• No. and sources of reag.<br>• Incub. times/reading times<br>Autocalibration or autocallib. alert/multipoint calibration supported<br>Auto shutdown/auto startup programmable | yes (Sysmex CST series)<br>yes (3–5 mL)/yes<br>yes<br>yes<br>yes<br>yes<br>yes<br>no<br>yes<br>no/yes<br>yes<br>yes/yes<br>yes (PT: 7 sec, PTT: 15 sec)<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>no/yes<br>no/no   | no<br>yes (all up to 100 mm long, ext. diam. 10–16 mm)/no<br>yes<br>yes (avail. for user-defined tests)<br>yes<br>yes<br>yes<br>yes<br>yes<br>yes/yes<br>yes (PT & PTT: 7 sec)<br>no<br>yes/yes<br>yes<br>yes/no<br>yes/yes<br>no/no  | yes (custom automation solutions available)<br>yes (3–5 mL)/yes<br>yes<br>yes<br>yes<br>yes<br>yes<br>no<br>yes<br>no/yes<br>yes<br>yes/yes<br>yes (PT: 7 sec, PTT: 15 sec)<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>no/yes<br>no/no   |
| Stat time to completion of all analytes and throughput per hour for:<br>• PT alone<br>• PT, PTT<br>• Fibrinogen<br>• Factor VIII activity assay<br>Time delay from ordering stat to aspir. of sample<br>Auto. transfer of QC results to LIS<br>Data management capability<br>Interface supplied by instrument vendor<br>Interfaces in active user sites for:<br>Bidirectional interface capability<br>Results transferred to LIS as soon as test time complete<br>LOINC codes transmitted with all results<br>How labs get LOINC codes for reagent kits<br>Electronic interface available (or will be) to automated<br>(or robotic) specimen handling system  | 7 min/80 specimens<br>8 min/120 specimens<br>8 min/80 specimens<br>8 min/n/a<br>2 min<br>yes<br>onboard (incl. QC: L-J & Westgard)<br>no<br>Cerner, Sunquest, others<br>yes (host query)<br>yes<br>no<br>n/a<br>yes (Sysmex CST series)  | <5 min/-350 specimens (incl. abnormal)<br><5 min/-160 specimens (incl. abnormal)<br><5 min (if curve avail.)/-350 specimens<br><5 min (if curve avail.)/-280 specimens<br>varies by test in progress, approx. <5 min<br>yes<br>limited<br>no<br>Cerner, Sunquest, Mediatech, others<br>yes (host query)<br>yes<br>no<br>n/a<br>possible future upgrade (not avail.)   | 7 min/300 specimens<br>8 min/550 specimens<br>8 min/300 specimens<br>8 min/300 specimens<br>2 min<br>yes<br>onboard (incl. QC: L-J & Westgard)<br>no<br>Cerner, others in development<br>yes (host query)<br>yes<br>no<br>n/a<br>yes (custom automation solutions available)   |
| Modem servicing<br>Time required for maintenance by lab personnel<br><br>Onboard maintenance records<br>Training provided with purchase<br>Approx. No. of training hours needed per tech  | no<br>daily: <5 min; weekly: <40 min; monthly: 1 min<br><br>no<br>varies on site, 4 days at vendor offices<br>6 h  | yes<br>daily: <5 min; weekly: <10 min; monthly: 15 min<br><br>no<br>varies on site, 5 days at vendor offices<br>8 h on site   | no<br>per shift: <5 min; daily: <10 min; weekly: 1 min;<br>quarterly: 5 min<br>no<br>varies on site, 5 days at vendor offices<br>8 h on site   |
| List price<br>Ann. svc. contract cost (24 hr/7 d)/warranty with purchase  | \$85,995 standard model; \$97,461 cap-piercing model<br>\$12,590 standard model; \$13,572 cap-piercing/1 yr  | \$131,859<br>\$18,480/1 yr  | \$157,500 standard; \$173,250 with cap piercer<br>\$18,522/1 yr  |
| Unique advantages   | • adapts easily to lab automation<br>• simultaneous curve calibrating & patient testing<br>• ability to load multiple bottles or multiple lots of reagent  | • continuous loading of bar-coded reagent & samples<br>• multi-lot, multi-curve reagent management<br>• PT/APTT/fib./AT III/D-dimer in <10 min<br>• simultaneous curve calibration & patient testing  | • fastest throughput available for routine testing; PT,<br>APTT results every 7 sec<br>• continuous loading of reagents, consumables, &<br>patient samples without interruption  |

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

## Coagulation Analyzers

|  |  |  |   |
|--|--|--|---|
| <b>Part 5 of 11</b><br><br><i>See accompanying article, page 18</i>  | <b>Diagnostica Stago Inc.</b><br>Pascal Boulanger pascal.boulanger@stago-us.com<br>5 Century Dr., Parsippany, NJ 07054<br>800-222-COAG<br>www.stago-us.com   | <b>Diagnostica Stago Inc.</b><br>Pascal Boulanger pascal.boulanger@stago-us.com<br>5 Century Dr., Parsippany, NJ 07054<br>800-222-COAG<br>www.stago-us.com   | <b>Diagnostica Stago Inc.</b><br>Pascal Boulanger pascal.boulanger@stago-us.com<br>5 Century Dr., Parsippany, NJ 07054<br>800-222-COAG<br>www.stago-us.com  |
| <b>Instrument name/first year sold</b>   | STA-R Hemostasis System/1998   | STA Hemostasis System/1993   | STA Compact Hemostasis System/1996  |
| <b>No. of units installed in U.S./outside U.S.</b><br><b>Country where analyzer designed/manufactured</b><br><b>Operational type</b><br><b>Reagent type</b><br><b>Operates on whole blood or spun plasma</b><br><b>Sample handling system</b><br><b>Model type</b><br><b>Dimensions (H x W x D)/weight/instrument footprint</b>  | 159/889<br>France/France<br>continuous random access<br>open reagent system (lyoph., reconst. manually)<br>spun plasma<br>rack with continuous specimen access<br>floor-standing<br>49.2 x 47.6 x 32.2 in/441 lbs/26.8 sq ft   | 210/1,550<br>France/France<br>continuous random access<br>open reagent system (lyoph., reconst. manually)<br>spun plasma<br>continuous specimen access-primary tube<br>floor-standing<br>44.7 x 36.6 x 25.8 in/551 lbs/23.5 sq ft  | 669/3,619<br>France/France<br>continuous random access<br>open reagent system (lyoph., reconst. manually)<br>spun plasma<br>continuous specimen access-primary tube<br>benchtop<br>25.2 x 38.8 x 25.8 in/351 lbs/25.6 sq ft   |
| <b>FDA-cleared clotting-based tests</b><br><br><b>FDA-cleared chromogenic tests</b><br><br><b>FDA-cleared immunologic tests</b><br><br><b>Other FDA-cleared tests</b><br><b>User-defined tests in clinical use</b><br><br><b>Tests submitted for 510(k) clearance</b><br><b>Tests in development but not yet submitted</b>   | PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.<br>unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin<br>D-dimer, vWF, protein S antigen & AT III antigen (microlatex agglut.)<br>none<br>all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVVT screen. & confirm. assays & activated protein C resistance<br>none<br>none | PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.<br>unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin<br>D-dimer, vWF, protein S antigen & AT III antigen (microlatex agglut.)<br>none<br>all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVVT screen. & confirm. assays & activated protein C resistance<br>none<br>none | PT, APTT, TT, fib., reptilase, intr. & extr. factors, proteins C & S, lupus anticoag. screen & confirm.<br>unfrac. hep., LMWH, protein C, AT III, plasminogen & antiplasmin<br>D-dimer, vWF antigen, protein S antigen & AT III antigen (microlatex agglut.)<br>none<br>all clotting-based, chrom., & immunol. tests can have user-def. applications in addition to dRVVT screen. & confirm. assay & activated protein C resistance<br>none<br>none |
| <b>Methodologies supported</b><br><b>Oper. must load sep. reag. pack for ea. specimen/test run</b><br><b>No. of different measured assays onboard simultaneously</b><br><b>No. of different assays programmed and calibrated at one time</b><br><b>No. of user-definable (open) channels</b><br><b>Of those defined, No. active simultaneously</b><br><b>Factor assays require manual manipulation or dilutions</b><br><b>No. of reag. containers onboard at one time/tests per container</b><br><b>Reagents refrigerated onboard</b><br><b>Multiple reag. configurations supported</b><br><b>Reag., consumables loaded without interrupting testing</b><br><b>Same capabilities when 3rd-party reag. used</b><br><b>Max. time same lot number of reag. can be used</b><br><b>Walkaway capacity: No. of specimens/No. of tests</b><br><b>Min. sample vol. aspirated precisely at one time</b><br><b>Standard specimen vol. required to run PT or PTT/factor VIII activity</b><br><b>Disposables used/price of each</b>   | clotting, chromogenic, & immunological assays<br>no/no<br>up to 200<br>up to 200<br>200<br>200<br>no<br>70/up to 83<br>yes (15-19°C)<br>yes<br>yes<br>yes<br>18 mos<br>215/32 per specimen<br>5 µL<br>50 µL, min. 50 µL/50 µL, min. 50 µL<br>cuvettes, wash-cleaner solution/—   | clotting, chromogenic, & immunological assays<br>no/no<br>up to 80<br>up to 80<br>70<br>70<br>no<br>45/varies, up to 83<br>yes (15-19°C)<br>yes<br>yes<br>yes<br>18 mos<br>192/12 per specimen<br>5 µL<br>50 µL, min. 50 µL/50 µL, min. 50 µL<br>cuvettes, wash-cleaner solution/—   | clotting, chromogenic, & immunological assays<br>no/no<br>up to 80<br>up to 80<br>70<br>70<br>no<br>45/varies, up to 83<br>yes (15-19°C)<br>yes<br>yes<br>yes<br>18 mos<br>96/12 per sample<br>5 µL<br>50 µL, min. 50 µL/50 µL, min. 50 µL<br>cuvettes, glycol, wash-cleaner solution/—   |
| <b>Supports direct-from-track sampling</b><br><b>Primary tube sampling supported/pierces caps on primary tubes</b><br><b>Sample bar-code reading capability</b><br><b>Reagent bar-code reading capability</b><br><b>Onboard test automatic inventory</b><br><b>Measures No. of tests remaining</b><br><b>Short sample detection</b><br><b>Clot detection as preanalytical variable in plasma sample</b><br><b>Auto. detection of adequate reag. for aspir. &amp; anal.</b><br><b>Hemolysis/turbidity detection-quantitation</b><br><b>Dilution of patient samples onboard</b><br><b>Automatic rerun capability/auto reflex testing capability</b><br><b>Lag time during which hypercoagulable samples will not be detected</b><br><b>Read time extended for prolonged clotting times</b><br><b>User can set different-than-standard:</b><br>• Reag. volumes/sample volumes<br>• No. and sources of reag.<br>• Incub. times/reading times<br><b>Autocalibration or autocallib. alert/multipoint calibration supported</b><br><b>Auto shutdown/auto startup programmable</b> | yes<br>yes/optional<br>yes<br>yes (not for user-defined tests)<br>yes<br>yes<br>yes<br>no<br>yes<br>no/no<br>yes<br>yes/yes<br>no<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>yes/yes<br>no/no (not needed)   | no<br>yes/no<br>yes<br>yes (not for user-defined tests)<br>yes<br>yes<br>yes<br>no<br>yes<br>no/no<br>yes<br>yes/no<br>no<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>yes/yes<br>no/no (not needed)   | no<br>yes (5 & 2.5 mL tube sizes)/optional<br>yes<br>yes (not for user-defined tests)<br>yes<br>yes<br>yes<br>no<br>yes<br>no/no<br>yes<br>yes/no<br>no<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>yes/yes<br>no/no (not needed)  |
| <b>Stat time to completion of all analytes and throughput per hour for:</b><br>• PT alone<br>• PT, PTT<br>• Fibrinogen<br>• Factor VIII activity assay<br><b>Time delay from ordering stat to aspir. of sample</b><br><b>Auto. transfer of QC results to LIS</b><br><b>Data management capability</b><br><b>Interface supplied by instrument vendor</b><br><b>Interfaces in active user sites for:</b><br>Bidirectional interface capability<br>Results transferred to LIS as soon as test time complete<br>LOINC codes transmitted with all results<br>How labs get LOINC codes for reagent kits<br>Electronic interface available (or will be) to automated (or robotic) specimen handling system  | <6 min/300 specimens<br>7 min/150 specimens<br>7 min/180 specimens<br>7 min/180 specimens<br><15 sec<br>yes<br>onboard (incl. QC: L-J)<br>no<br>contact marketing for updated list<br>yes (host query)<br>yes<br>no<br>n/a<br>yes (contact marketing for list of systems)  | <6 min/300 specimens<br>7 min/150 specimens<br>7 min/180 specimens<br>7 min/180 specimens<br><15 sec<br>yes<br>onboard (incl. QC: L-J)<br>no<br>contact marketing for updated list<br>yes (host query)<br>yes<br>no<br>n/a<br>no   | <6 min/150 specimens<br>7 min/75 specimens<br>7 min/75 specimens<br>7 min/70 specimens<br><15 sec<br>yes<br>onboard (incl. QC: L-J)<br>no<br>contact marketing for updated list<br>yes (host query)<br>yes<br>no<br>n/a<br>no   |
| <b>Modem servicing</b><br><b>Time required for maintenance by lab personnel</b><br><b>Onboard maintenance records</b><br><b>Training provided with purchase</b><br><b>Approx. No. of training hours needed per tech</b>  | yes<br>daily: none; weekly: <30 min; monthly: <30 min<br>yes<br>varies on site, 3 days at vendor offices<br>2 h basic, 24 h system training at training center   | no<br>daily: none; weekly: <30 min; monthly: <30 min<br>yes<br>varies on site, 3 days at vendor offices<br>2 h basic, 24 h system training at training center  | no<br>daily: none; weekly: <30 min; monthly: <30 min<br>yes<br>varies on site, 3 days at vendor offices<br>2 h basic, 24 h system training at training center   |
| <b>List price</b><br><b>Ann. svc. contract cost (24 h/7 d)/warranty with purchase</b>  | \$149,995<br>prices available on request/1 yr  | \$99,845<br>prices available on request/1 yr   | \$75,000<br>prices available on request/1 yr  |
| <b>Unique advantages</b>   | • walkaway testing with robotics-capable interface to automated lines for high-volume testing, with touch-screen software & cap piercing option<br>• continuous random access for up to 200 test selections with no carryover<br>• able to standardize with other STA family of analyzers<br>• unique viscosity-based detection system   | • walkaway testing for routine & specialty hemostasis assays with 45 reag. positions, 192 sample pos., up to 1,000 dispos. cuvettes<br>• continuous random access for up to 80 test selections with no carryover<br>• able to standardize with other STA family of analyzers<br>• unique viscosity-based detection system  | • walkaway testing for routine & specialty hemostasis assays with 45 reag. positions, 96 sample pos., up to 1,000 dispos. cuvettes<br>• continuous random access for up to 80 test selections with no carryover<br>• able to standardize with other STA analyzers<br>• unique viscosity-based detection system  |

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



## Coagulation Analyzers

|  |  |   |   |
|--|--|---|---|
| <b>Part 6 of 11</b>  | <p>Diagnostica Stago Inc.<br/>Pascal Boulanger pascal.boulanger@stago-us.com<br/>5 Century Dr., Parsippany, NJ 07054<br/>800-222-COAG<br/>www.stago-us.com</p>   | <p>Diagnostica Stago Inc.<br/>Pascal Boulanger pascal.boulanger@stago-us.com<br/>5 Century Dr., Parsippany, NJ 07054<br/>800-222-COAG<br/>www.stago-us.com</p>  | <p>Helena Laboratories<br/>Joe Gollas helena@helena.com<br/>1530 Lindbergh Dr., Beaumont, TX 77704<br/>800-231-5663<br/>www.helena.com</p>  |
| See accompanying article, page 18  |  |   |   |
| Instrument name/first year sold  | Start 4/1998   | Start 8/1999  | Thor/1997   |
| No. of units installed in U.S./outside U.S.<br>Country where analyzer designed/manufactured<br>Operational type<br>Reagent type<br>Operates on whole blood or spun plasma<br>Sample handling system<br>Model type<br>Dimensions (H x W x D)/weight/instrument footprint  | <p>615/7,159<br/>France/France<br/>batch<br/>open reagent system (lyoph., reconst. manually)<br/>spun plasma<br/>manual<br/>benchtop<br/>4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft</p>   | <p>&gt;20/599<br/>France/France<br/>batch<br/>open reagent system (lyoph., reconst. manually)<br/>spun plasma<br/>manual<br/>benchtop<br/>4.7 x 16.1 x 16.5 in/12.5 lbs/1.8 sq ft</p>   | <p>&gt;15/0<br/>U.S./U.S.<br/>random access<br/>open reagent system<br/>spun plasma<br/>6 racks, 10 positions each<br/>benchtop<br/>23 x 44 x 28 in/252 lbs/8.5 sq ft</p>   |
| FDA-cleared clotting-based tests<br><br>FDA-cleared chromogenic tests<br>FDA-cleared immunologic tests<br>Other FDA-cleared tests<br>User-defined tests in clinical use<br><br>Tests submitted for 510(k) clearance<br>Tests in development but not yet submitted  | <p>PT, APTT, TT, fib., reptilase, intr. &amp; extr. factors, proteins C &amp; S, lupus anticoag. screen &amp; confirm.<br/>none<br/>none<br/>none<br/>same as clotting-based tests above &amp; dRVVT screen. &amp; confirm. assays &amp; activated protein C resistance<br/>none<br/>none</p>  | <p>PT, APTT, TT, fib., reptilase, intr. &amp; extr. factors, proteins C &amp; S, lupus anticoag. screen &amp; confirm.<br/>none<br/>none<br/>none<br/>same as clotting-based tests above &amp; dRVVT screen. &amp; confirm. assays &amp; activated protein C resistance<br/>none<br/>none</p>   | <p>PT, APTT, fib., thromb. clotting time, factor assays II, V, VII–XII with 8 user-definable tests<br/>none<br/>none<br/>none<br/>PT, APTT, fib., TCT, factors II, V, VII–XII<br/>none<br/>dRVVT</p>  |
| Methodologies supported<br>Oper. must load sep. reag. pack for ea. specimen/test run<br>No. of different measured assays onboard simultaneously<br>No. of different assays programmed and calibrated at one time<br>No. of user-definable (open) channels<br>Of those defined, No. active simultaneously<br>Factor assays require manual manipulation or dils<br>No. of reag. containers onboard at one time/tests per container<br>Reagents refrigerated onboard<br>Multiple reag. configurations supported<br>Reag., consumables loaded without interrupting testing<br>Same capabilities when 3rd-party reag. used<br>Max. time same lot number of reag. can be used<br>Walkaway capacity: No. of specimens/No. of tests<br>Min. sample vol. aspirated precisely at one time<br>Standard specimen vol. required to run PT or PTT/factor VIII activity<br>Disposables used/price of each   | <p>clotting tests<br/>no/no<br/>1<br/>20<br/>4<br/>1<br/>yes<br/>4/varies, up to 100<br/>no<br/>yes<br/>no<br/>yes<br/>18 mos<br/>4/1<br/>25 µL<br/>50 µL, min. 50 µL/50 µL, min. 50 µL<br/>cuvettes, beads, ball/—</p>  | <p>clotting tests<br/>no/no<br/>1<br/>20<br/>4<br/>1<br/>yes<br/>4/varies, up to 100<br/>no<br/>yes<br/>no<br/>yes<br/>18 mos<br/>4/1<br/>25 µL<br/>50 µL, min. 50 µL/50 µL, min. 50 µL<br/>cuvettes, beads, ball/—</p>   | <p>clot detection, optical, turbidimetric<br/>no/no<br/>12<br/>1<br/>8<br/>12<br/>no<br/>11/200<br/>yes (5°C)<br/>yes<br/>yes<br/>yes<br/>12 mos<br/>60/12 per sample<br/>50 µL<br/>200 µL, min. 100 µL/200 µL, min. 100 µL<br/>reagent reservoirs &amp; tubing (5 sets) 5 pumps/\$187.75 per set; cuvettes (4 tests/500)/\$173–11.56 per test; biohazard trays/5/\$16.25</p> |
| Supports direct-from-track sampling<br>Primary tube sampling supported/pierces caps on primary tubes<br>Sample bar-code reading capability<br>Reagent bar-code reading capability<br>Onboard test automatic inventory<br>Measures No. of tests remaining<br>Short sample detection<br>Clot detection as preanalytic variable in plasma sample<br>Auto. detection of adequate reag. for aspir. & anal.<br>Hemolysis/turbidity detection-quantitation<br>Dilution of patient samples onboard<br>Automatic rerun capability/auto reflex testing capability<br>Lag time during which hypercoagulable samples will not be detected<br>Read time extended for prolonged clotting times<br>User can set different-than-standard:<br>• Reag. volumes/sample volumes<br>• No. and sources of reag.<br>• Incub. times/reading times<br>Autocalibration or autocalib. alert/multipoint calibration supported<br>Auto shutdown/auto startup programmable | <p>no<br/>no/no (n/a)<br/>no<br/>no<br/>no<br/>no<br/>no<br/>no<br/>no<br/>no/no<br/>no<br/>no/no<br/>no<br/>yes (selectable on menus)<br/>yes/yes<br/>yes<br/>yes/yes<br/>no/yes<br/>no</p>   | <p>no<br/>no/no (n/a)<br/>no<br/>no<br/>no<br/>no<br/>no<br/>no<br/>no<br/>no/no<br/>no<br/>yes (selectable on menus)<br/>yes/yes<br/>yes<br/>yes/yes<br/>no/yes<br/>no</p>   | <p>no<br/>yes (tube sizes 5 mL and lower)/yes<br/>yes<br/>yes (not for user-defined tests)<br/>yes<br/>yes<br/>yes<br/>—<br/>yes<br/>yes/yes<br/>yes<br/>yes/yes<br/>yes (PT: 4 sec, PTT: 14 sec)<br/>yes (selectable on menus)<br/>yes/yes<br/>yes<br/>yes/yes<br/>no/yes<br/>no/no</p>  |
| Stat time to completion of all analytes and throughput per hour for:<br>• PT alone<br>• PT, PTT<br>• Fibrinogen<br>• Factor VIII activity assay<br>Time delay from ordering stat to aspir. of sample<br>Auto. transfer of QC results to LIS<br>Data management capability<br>Interface supplied by instrument vendor<br>Interfaces in active user sites for:<br>Bidirectional interface capability<br>Results transferred to LIS as soon as test time complete<br>LOINC codes transmitted with all results<br>How labs get LOINC codes for reagent kits<br>Electronic interface available (or will be) to automated (or robotic) specimen handling system  | <p>&lt;1 min/up to 120 specimens<br/>n/a/n/a<br/>&lt;1 min/up to 120 specimens<br/>varies/varies<br/>n/a<br/>no<br/>no<br/>no<br/>n/a<br/>no<br/>yes<br/>no<br/>n/a<br/>no</p>   | <p>&lt;1 min/up to 120 specimens<br/>n/a/n/a<br/>&lt;1 min/up to 120 specimens<br/>varies/varies<br/>n/a<br/>no<br/>no<br/>no<br/>n/a<br/>no<br/>yes<br/>no<br/>n/a<br/>no</p>  | <p>8 min/ 240 specimens<br/>10 min/144 specimens<br/>5 min/360 specimens<br/>10 min/144 specimens<br/>30 sec–1 min<br/>yes<br/>onboard (incl. QC: L–J, Westgard)<br/>no<br/>Mediatech, Cerner<br/>yes (broadcast download &amp; host query)<br/>yes<br/>no<br/>—<br/>no</p>   |
| Modem servicing<br>Time required for maintenance by lab personnel<br>Onboard maintenance records<br>Training provided with purchase<br>Approx. No. of training hrs needed per tech   | <p>no<br/>daily: &lt;5 min; weekly: &lt;5 min; monthly: &lt;5 min<br/>no<br/>1 day on site<br/>1 h</p>   | <p>no<br/>daily: &lt;5 min; weekly: &lt;5 min; monthly: &lt;5 min<br/>no<br/>1 day on site<br/>1 h</p>  | <p>TBD<br/>daily: 15 min; weekly: 30 min; monthly: 1 h<br/>yes<br/>3–5 days at vendor offices<br/>8 h</p>   |
| List price<br>Ann. svc. contract cost (24 hr/7 d)/warranty with purchase   | <p>\$9,600<br/>prices available on request/1 yr</p>  | <p>\$12,500<br/>prices available on request/1 yr</p>  | <p>\$67,600<br/>\$7,900/1 yr</p>  |
| Unique advantages  | <ul style="list-style-type: none"> <li>• excellent for low-volume testing or as backup to optical system</li> <li>• programmable and preprogrammed assays with curve storage, 4 independently timed incubation stations, electronically linked multiple pipettor, 40-character display and internal thermal printer</li> <li>• lightweight and compact</li> <li>• unique viscosity-based detection system</li> </ul> | <ul style="list-style-type: none"> <li>• excellent for low- &amp; mid-volume testing or backup</li> <li>• 32 incubation positions for samples, 8 measurement channels, 4 independent built-in timers for incubation; results in seconds and in various units (% ratio, INR, g/L, mg/dL, IU/mL), RS-232 interface</li> <li>• lightweight and compact</li> <li>• unique viscosity-based detection system</li> </ul> | <ul style="list-style-type: none"> <li>• primary tube sampling with cap piercing</li> <li>• integral bar-code reader to ensure positive patient ID</li> <li>• truly a walkaway coag analyzer</li> </ul>   |

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

## Coagulation Analyzers

|   |   |   |  |
|---|---|---|--|
| <b>Part 7 of 11</b>   | Helena Laboratories<br>Joe Gollas helena@helena.com<br>1530 Lindbergh Dr., Beaumont, TX 77704<br>800-231-5663<br>www.helena.com | Helena Laboratories<br>Joe Gollas helena@helena.com<br>1530 Lindbergh Dr., Beaumont, TX 77704<br>800-231-5663<br>www.helena.com | Helena Laboratories<br>Joe Gollas helena@helena.com<br>1530 Lindbergh Dr., Beaumont, TX 77704<br>800-231-5663<br>www.helena.com  |
| <i>See accompanying article, page 18</i>  |   |   |  |
| <b>Instrument name/first year sold</b>  | Cascade M/1991  | Cascade M-4/1992  | Packs-4/1991   |
| <b>No. of units installed in U.S./outside U.S.</b>  | >150/—  | >100/—  | 150/180  |
| <b>Country where analyzer designed/manufactured</b>   | U.S./U.S.   | U.S./U.S.   | U.S./U.S.  |
| <b>Operational type</b>   | batch   | random access   | random access  |
| <b>Reagent type</b>   | open reagent system   | open reagent system   | open reagent system  |
| <b>Operates on whole blood or spun plasma</b>   | spun plasma   | spun plasma   | spun plasma  |
| <b>Sample handling system</b>   | manual  | manual  | manual   |
| <b>Model type</b>   | benchtop  | benchtop  | benchtop   |
| <b>Dimensions (H x W x D)/weight/instrument footprint</b>   | 8 x 15 x 13 in/25 lbs/1.4 sq ft   | 8 x 15 x 13 in/25 lbs/1.4 sq ft   | 10 x 22 x 23 in/70 lbs/3.5 sq ft   |
| <b>FDA-cleared clotting-based tests</b>   | PT, APTT, fib., TCT, factor assays II, V, VII–XII   | PT, APTT, fib., TCT, factor assays II, V, VII–XII   | none   |
| <b>FDA-cleared chromogenic tests</b>  | none  | none  | AT III, F-VIII-C, hep., plasminogen, protein C   |
| <b>FDA-cleared immunologic tests</b>  | none  | none  | none   |
| <b>Other FDA-cleared tests</b>  | none  | none  | ristocetin cofactor and platelet aggreg.   |
| <b>User-defined tests in clinical use</b>   | PT, APTT, fib., TCT, factor assays II, V, VII–XII   | PT, APTT, fib., TCT, factor assays II, V, VII–XII   | chrom: AT III, F-VIII-C, hep., plasmin., protein C, ristocetin cofactor, platelet aggreg.–ADP, EPI, COL, ristocetin, arach. acid |
| <b>Tests submitted for 510(k) clearance</b>   | none  | none  | none   |
| <b>Tests in development but not yet submitted</b>   | dRVVT   | dRVVT   | none   |
| <b>Methodologies supported</b>  | clot detection, optical, turbidimetric  | clot detection, optical, turbidimetric  | chromogenic, ristocetin cofactor, platelet aggreg.   |
| <b>Oper. must load sep. reag. pack for ea. specimen/test run</b>                                      | no/no   | no/no   | no/no  |
| <b>No. of different measured assays onboard simultaneously</b>  | 1   | 4   | 4  |
| <b>No. of different assays programmed and calibrated at one time</b>                                  | 1   | 4   | 4  |
| <b>No. of user-definable (open) channels</b>  | 2   | 4   | 12   |
| <b>Of those defined, No. active simultaneously</b>  | 1   | 2   | 4  |
| <b>Factor assays require manual manipulation or dilutions</b>   | yes   | yes   | yes  |
| <b>No. of reag. containers onboard at one time/tests per container</b>                                | —/—   | 0/n/a   | n/a/n/a  |
| <b>Reagents refrigerated onboard</b>  | n/a   | no  | no   |
| <b>Multiple reag. configurations supported</b>  | n/a   | no  | no   |
| <b>Reag., consumables loaded without interrupting testing</b>   | no  | no  | no   |
| <b>Same capabilities when 3rd-party reag. used</b>  | yes   | yes   | n/a  |
| <b>Max. time same lot number of reag. can be used</b>   | 12 mos  | 12 mos  | 12 mos   |
| <b>Walkaway capacity: No. of specimens/No. of tests</b>   | no  | no  | no   |
| <b>Min. sample vol. aspirated precisely at one time</b>   | manual–50 µL  | manual–50 µL  | n/a  |
| <b>Standard specimen vol. required to run PT or PTT/Factor VIII activity</b>                          | 100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)   | 100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)   | chromogenics: 75 µL, Pit. aggreg.: 225 µL PRP, Risto cofactor: 50 µL   |
| <b>Disposables used/price of each</b>   | cuvettes/500@\$54; pipette tips/1,000@\$82  | cuvettes/500@\$54; pipette tips/1,000@\$82  | cuvettes/200@\$55.65; pipette tips/1,000@\$82; stir bars/30@\$62.25  |
| <b>Supports direct-from-track sampling</b>  | no  | no  | no   |
| <b>Primary tube sampling supported/pierces caps on primary tubes</b>                                  | no  | no  | no   |
| <b>Sample bar-code reading capability</b>   | no  | no  | no   |
| <b>Reagent bar-code reading capability</b>  | no  | no  | no   |
| <b>Onboard test automatic inventory</b>   | no  | no  | no   |
| <b>Measures No. of tests remaining</b>  | no  | no  | no   |
| <b>Short sample detection</b>   | no  | no  | no   |
| <b>Clot detection as preanalytical variable in plasma sample</b>                                      | —   | —   | —  |
| <b>Auto. detection of adequate reag. for aspir. &amp; anal.</b>                                       | no  | no  | no   |
| <b>Hemolysis/turbidity detection-quantitation</b>   | no/no   | no/no   | no/no  |
| <b>Dilution of patient samples onboard</b>  | no  | no  | no   |
| <b>Automatic rerun capability/auto reflex testing capability</b>                                      | no/no   | no/no   | no/no  |
| <b>Lag time during which hypercoagulable samples will not be detected</b>                             | yes (PT: 4 sec, PTT: 14 sec)  | yes (PT: 4 sec, PTT: 14 sec)  | n/a  |
| <b>Read time extended for prolonged clotting times</b>  | yes (selectable on menus)   | yes (selectable on menus)   | n/a  |
| <b>User can set different-than-standard:</b>  |   |   |  |
| • Reag. volumes/sample volumes  | yes/yes   | yes/yes   | yes/yes  |
| • No. and sources of reag.  | yes   | yes   | yes  |
| • Incub. times/reading times  | yes/yes   | yes/yes   | yes/yes  |
| <b>Autocalibration or autocallib. alert/multipoint calibration supported</b>                          | no/yes  | no/yes  | no/yes   |
| <b>Auto shutdown/auto startup programmable</b>  | no/no   | no/no   | no/no  |
| <b>Stat time to completion of all analytes and throughput per hour for:</b>                           |   |   |  |
| • PT alone  | 3 min/120 specimens   | 3 min/140 specimens   | —  |
| • PT, PTT   | 7 min/50 specimens  | 7 min/80 specimens  | —  |
| • Fibrinogen  | 3 min/140 specimens   | 3 min/160 specimens   | —  |
| • Factor VIII activity assay  | 7 min/50 specimens  | 7 min/80 specimens  | 20–24 specimens for any test   |
| <b>Time delay from ordering stat to aspir. of sample</b>  | n/a   | n/a   | n/a  |
| <b>Auto. transfer of QC results to LIS</b>  | yes   | yes   | yes  |
| <b>Data management capability</b>   | no (incl. QC: L–J)  | no (incl. QC: L–J)  | onboard (incl. QC: L–J, Westgard)  |
| <b>Interface supplied by instrument vendor</b>  | no  | no  | no   |
| <b>Interfaces in active user sites for:</b>   | n/a   | —   | —  |
| <b>Bidirectional interface capability</b>   | no  | no  | no   |
| <b>Results transferred to LIS as soon as test time complete</b>                                       | no  | yes   | yes  |
| <b>LOINC codes transmitted with all results</b>   | no  | no  | no   |
| <b>How labs get LOINC codes for reagent kits</b>  | —   | —   | —  |
| <b>Electronic interface available (or will be) to automated (or robotic) specimen handling system</b> | —   | no  | no   |
| <b>Modem servicing</b>  | no  | no  | TBD  |
| <b>Time required for maintenance by lab personnel</b>   | daily: 10 min; weekly: 10 min; monthly: 20 min  | daily: 10 min; weekly: 10 min; monthly: 30 min  | daily: 15 min; weekly: 15 min; monthly: 1 h  |
| <b>Onboard maintenance records</b>  | no  | no  | yes  |
| <b>Training provided with purchase</b>  | 1 day on site   | 1 day on site   | 2 days on site   |
| <b>Approx. No. of training hours needed per tech</b>  | 2–4 h   | 2 h   | 4–8 h  |
| <b>List price</b>   | \$6,219   | \$8,403   | \$16,650   |
| <b>Ann. svc. contract cost (24 hr/7 d)/warranty with purchase</b>                                     | \$714/1 yr  | \$966/1 yr  | \$2,079/1 yr   |
| <b>Unique advantages</b>  | • QC program onboard<br>• curve storage<br>• suitable for office lab or as backup analyzer                                      | • 4-channel manual analyzer<br>• QC program onboard<br>• singles or duplicates  | • specialized coag instrument intended for platelet aggreg., ristocetin cofactor, & chromogenics                                 |

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

## Coagulation Analyzers

|   |   |   |   |
|---|---|---|---|
| <b>Part 8 of 11</b>   | Instrumentation Laboratory/Beckman Coulter Inc.<br>Katie Blount kblount@beckman.com<br>200 S. Kraemer Blvd., Brea, CA 92621<br>714-993-8749<br>www.beckmancoulter.com | Instrumentation Laboratory/Beckman Coulter Inc.<br>Katie Blount kblount@beckman.com<br>200 S. Kraemer Blvd., Brea, CA 92621<br>714-993-8749<br>www.beckmancoulter.com | Instrumentation Laboratory/Beckman Coulter Inc.<br>Katie Blount kblount@beckman.com<br>200 S. Kraemer Blvd., Brea, CA 92621<br>714-993-8749<br>www.beckmancoulter.com |
| <i>See accompanying article, page 18</i>  |   |   |   |
| <b>Instrument name/first year sold</b>  | Electra 1400C/1995  | Electra 1800C/1997  | ACL 100/1988  |
| <b>No. of units installed in U.S./outside U.S.</b>  | —/—   | —/—   | 4,000+ (all models combined)/8,000+ (all models combined)   |
| <b>Country where analyzer designed/manufactured</b>   | U.S./U.S.   | U.S./U.S.   | Italy/U.S.  |
| <b>Operational type</b>   | continuous random access  | continuous random access  | batch   |
| <b>Reagent type</b>   | open reagent system (reconst. manually)   | open reagent system (reconst. manually)   | open reagent system, guarantee only IL products   |
| <b>Operates on whole blood or spun plasma</b>   | spun plasma   | spun plasma   | spun plasma   |
| <b>Sample handling system</b>   | automatic pipetting from tray   | automatic pipetting, rack   | tray  |
| <b>Model type</b>   | benchtop  | benchtop  | benchtop  |
| <b>Dimensions (H x W x D)/weight/instrument footprint</b>   | 19.7 x 41 x 27.2 in/198 lbs/7.74 sq ft  | 25 x 48 x 30.4 in/283 lbs/10.13 sq ft   | 17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft   |
| <b>FDA-cleared clotting-based tests</b>   | PT, APTT, fib. (Claus), TT, factor assays, Pfib (PT assay-based fib.), protein S  | PT, APTT, fib. (Claus), TT, factor assays, Pfib (PT assay-based fib.), protein S  | PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR, Claus fib.                                   |
| <b>FDA-cleared chromogenic tests</b>  | plasminogen, factor VIII, antithrombin, protein C, heparin  | plasminogen, factor VIII, antithrombin, protein C, heparin  | none  |
| <b>FDA-cleared immunologic tests</b>  | none  | none  | none  |
| <b>Other FDA-cleared tests</b>  | none  | none  | none  |
| <b>User-defined tests in clinical use</b>   | none  | none  | none  |
| <b>Tests submitted for 510(k) clearance</b>   | none  | none  | none  |
| <b>Tests in development but not yet submitted</b>   | none  | none  | none  |
| <b>Methodologies supported</b>  | clot detection, optical, tungsten; chromogenic  | clot detection, optical, tungsten; chromogenic  | clot detection, optical, nephelometric  |
| <b>Oper. must load sep. reag. pack for ea. specimen/test run</b>                                      | no/no   | no/no   | no/no   |
| <b>No. of different measured assays onboard simultaneously</b>  | 11  | 12  | 3   |
| <b>No. of different assays programmed and calibrated at one time</b>                                  | 11  | 12  | 1   |
| <b>No. of user-definable (open) channels</b>  | 4   | 4   | 0   |
| <b>Of those defined, No. active simultaneously</b>  | 4   | 4   | 0   |
| <b>Factor assays require manual manipulation or dilutions</b>   | no  | no  | yes   |
| <b>No. of reag. containers onboard at one time/tests per container</b>                                | 4/variables   | 6/variables   | 3/variables by test   |
| <b>Reagents refrigerated onboard</b>  | yes (8°C ±4)  | yes (8°C ±4)  | yes (15°C)  |
| <b>Multiple reag. configurations supported</b>  | yes   | yes   | yes   |
| <b>Reag., consumables loaded without interrupting testing</b>   | yes   | yes   | no  |
| <b>Same capabilities when 3rd-party reag. used</b>  | yes   | yes   | yes   |
| <b>Max. time same lot number of reag. can be used</b>   | 12 mos recommended  | 12 mos recommended  | 18 mos  |
| <b>Walkaway capacity: No. of specimens/No. of tests</b>   | 35/4  | 100/4   | 18/36   |
| <b>Min. sample vol. aspirated precisely at one time</b>   | 10 µL   | 10 µL   | 10 µL   |
| <b>Standard specimen vol. required to run PT or PTT/factor VIII activity</b>                          | 100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)   | 100 µL, min. 50 µL/100 µL (dil.), min. 50 µL (dil.)   | 50 µL (PT), 53 µL (PTT)/40 µL   |
| <b>Disposables used/price of each</b>   | cuvette, dual well, 560 pk/price varies; heat exchanger, 10 pk/price varies   | cuvette, single well, 2,000 pk/price varies; heat exchanger, 10 pk/price varies   | sample cups/price varies; rotors/price varies   |
| <b>Supports direct-from-track sampling</b>  | no  | no  | no  |
| <b>Primary tube sampling supported/pierces caps on primary tubes</b>                                  | yes (13x75, 13x100, 10x85, 10x65, 12x91 mm Sarstedt)/no   | yes (13x75, 13x100 (closed & open tubes), 10x85, 10x65, 12x91 Sarstedt (open))/yes  | no/no   |
| <b>Sample bar-code reading capability</b>   | yes   | yes   | no  |
| <b>Reagent bar-code reading capability</b>  | no  | no  | no  |
| <b>Onboard test automatic inventory</b>   | yes   | yes   | no  |
| <b>Measures No. of tests remaining</b>  | yes   | yes   | no  |
| <b>Short sample detection</b>   | yes   | yes   | yes   |
| <b>Clot detection as preanalytical variable in plasma sample</b>                                      | no  | no  | no  |
| <b>Auto. detection of adequate reag. for aspir. &amp; anal.</b>                                       | yes   | yes   | yes   |
| <b>Hemolysis/turbidity detection-quantitation</b>   | no/no   | no/no   | no/no   |
| <b>Dilution of patient samples onboard</b>  | yes   | yes   | yes   |
| <b>Automatic rerun capability/auto reflex testing capability</b>                                      | yes/yes   | yes/yes   | no/no   |
| <b>Lag time during which hypercoagulable samples will not be detected</b>                             | yes (PT: 7 sec, PTT: 14 sec)  | yes (PT: 7 sec, PTT: 14 sec)  | yes (PT & PTT: 5.6 std, 6.7 ext)  |
| <b>Read time extended for prolonged clotting times</b>  | yes (selectable on menus)   | yes (selectable on menus)   | yes (selectable on menus)   |
| <b>User can set different-than-standard:</b>  |   |   |   |
| • Reag. volumes/sample volumes  | yes/yes   | yes/yes   | no/no   |
| • No. and sources of reag.  | yes   | yes   | no  |
| • Incub. times/reading times  | yes/yes   | yes/yes   | no/yes  |
| <b>Autocalibration or autocallib. alert/multipoint calibration supported</b>                          | yes/yes   | yes/yes   | no/yes  |
| <b>Auto shutdown/auto startup programmable</b>  | no/no   | no/no   | no/no   |
| <b>Stat time to completion of all analytes and throughput per hour for:</b>                           |   |   |   |
| • PT alone  | approx. 3 min/200 specimens   | approx. 3 min/228 specimens   | 5.5 min/110 specimens   |
| • PT, PTT   | approx. 7 min/136 specimens   | approx. 7 min/120 specimens   | 8.5 min/80 specimens  |
| • Fibrinogen  | approx. 3 min/160 specimens   | approx. 7 min/146 specimens   | 5.5 min/110 specimens   |
| • Factor VIII activity assay  | approx. 7 min/136 specimens   | approx. 7 min/120 specimens   | 9.5 min/80 specimens  |
| <b>Time delay from ordering stat to aspir. of sample</b>  | none  | none  | 15 sec  |
| <b>Auto. transfer of QC results to LIS</b>  | yes   | yes   | no  |
| <b>Data management capability</b>   | onboard (incl. QC: L-J, Westgard)   | onboard (incl. QC: L-J, Westgard)   | no  |
| <b>Interface supplied by instrument vendor</b>  | no  | no  | no  |
| <b>Interfaces in active user sites for:</b>   | Sunquest, Cerner, HBOC, Meditech, Dawning, Antrim, Soft Computer, others  | Sunquest, Cerner, HBOC, Meditech, Dawning, Antrim, Soft Computer, others  | most major LIS vendors  |
| <b>Bidirectional interface capability</b>   | yes (host query)  | yes (host query)  | no  |
| <b>Results transferred to LIS as soon as test time complete</b>                                       | yes   | yes   | yes   |
| <b>LOINC codes transmitted with all results</b>   | no  | no  | no  |
| <b>How labs get LOINC codes for reagent kits</b>  | in development  | in development  | in development  |
| <b>Electronic interface available (or will be) to automated (or robotic) specimen handling system</b> | no  | no  | no  |
| <b>Modem servicing</b>  | no  | no  | no  |
| <b>Time required for maintenance by lab personnel</b>   | daily: 5 min; weekly: 15 min; monthly: 15 min   | daily: 10 min; weekly: 25 min; monthly: 30 min  | daily: 10 min; weekly: 15 min; monthly: 10 min  |
| <b>Onboard maintenance records</b>  | no  | no  | yes   |
| <b>Training provided with purchase</b>  | up to 3 days on site  | up to 3 days on site  | 2 days on site  |
| <b>Approx. No. of training hours needed per tech</b>  | up to 24 h  | 24 h max.   | 2 h   |
| <b>List price</b>   | \$41,194  | \$73,645  | \$16,000  |
| <b>Ann. svc. contract cost (24 h/7 d)/warranty with purchase</b>                                      | variety of options available/1 yr   | variety of options available/1 yr   | variety of options available/1 yr   |
| <b>Unique advantages</b>  | • integral bar-code reader<br>• standardized test results   | • cap piercing<br>• standardized test results<br>• automatic sample predilution, including parallelism function   | • part of the ACL family, uses same consumables/reagents<br>• quantitative PT-based fib.<br>• positive displacement pipetting for low maintenance & high precision    |

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



## Coagulation Analyzers

|   |   |   |   |
|---|---|---|---|
| <b>Part 9 of 11</b>   | Instrumentation Laboratory/Beckman Coulter Inc.<br>Katie Blount kblount@beckman.com<br>200 S. Kraemer Blvd., Brea, CA 92621<br>714-993-8749<br>www.beckmancoulter.com | Instrumentation Laboratory/Beckman Coulter Inc.<br>Katie Blount kblount@beckman.com<br>200 S. Kraemer Blvd., Brea, CA 92621<br>714-993-8749<br>www.beckmancoulter.com | Instrumentation Laboratory/Beckman Coulter Inc.<br>Katie Blount kblount@beckman.com<br>200 S. Kraemer Blvd., Brea, CA 92621<br>714-993-8749<br>www.beckmancoulter.com                       |
| <i>See accompanying article, page 18</i>  |   |   |   |
| <b>Instrument name/first year sold</b>  | ACL 1000/1991   | ACL 7000/1997   | ACL 9000/2000   |
| <b>No. of units installed in U.S./outside U.S.</b>  | 4,000+ (all models combined)/8,000+ (all models combined)   | 4,000+ (all models combined)/8,000+ (all models combined)   | 300+/600+   |
| <b>Country where analyzer designed/manufactured</b>   | Italy/U.S.  | Italy/U.S.  | Italy/U.S.  |
| <b>Operational type</b>   | batch   | random programming  | random access   |
| <b>Reagent type</b>   | open reagent system, guarantee only IL products   | open reagent system, guarantee only IL products   | open reagent system   |
| <b>Operates on whole blood or spun plasma</b>   | spun plasma   | spun plasma   | spun plasma   |
| <b>Sample handling system</b>   | tray  | tray  | tray  |
| <b>Model type</b>   | benchtop  | benchtop  | benchtop  |
| <b>Dimensions (H x W x D)/weight/instrument footprint</b>   | 17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft   | 17.7 x 29.5 x 24.8 in/114 lbs/6 sq ft   | 23.6 x 36.2 x 23.6 in/138.6 lbs/6 sq ft   |
| <b>FDA-cleared clotting-based tests</b>   | PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.                                | PT, APTT, fib. (PT-based), factor assays (extrinsic & intrinsic), proteins C & S (clottable), TT, lupus anticoag., APCR-V, Clauss fib.                                | PT, APTT, PT-based fib., Clauss fib., TT, factor assays, protein C, protein S, LAC screen, LAC confirm, APCR-V  |
| <b>FDA-cleared chromogenic tests</b>  | none  | antithrombin, hep. Xa, plasminogen, antipiasmin, protein C  | antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin, factor VIII  |
| <b>FDA-cleared immunologic tests</b>  | none  | D-dimer (latex enhanced immunoassay), vWF   | D-dimer (latex enhanced immunoassay), vWF (latex enhanced immunoassay), free protein S  |
| <b>Other FDA-cleared tests</b>  | none  | none  | none  |
| <b>User-defined tests in clinical use</b>   | none  | none  | none  |
| <b>Tests submitted for 510(k) clearance</b>   | none  | none  | HS-CRP  |
| <b>Tests in development but not yet submitted</b>   | none  | none  | vWF activity  |
| <b>Methodologies supported</b>  | clot detection, optical, nephelometric  | clot detection, optical, nephelometric; chromogenic; immunologic (optical, latex enhanced immunoassay)  | clot detection, optical, nephelometric; chromogenic; immunologic  |
| <b>Oper. must load sep. reag. pack for ea. specimen/test run</b>                                      | no/no   | no/no   | no/no   |
| <b>No. of different measured assays onboard simultaneously</b>  | 3   | 4   | 18  |
| <b>No. of different assays programmed and calibrated at one time</b>                                  | 1   | 1   | 1   |
| <b>No. of user-definable (open) channels</b>  | 0   | 10 (requires optional research package)   | total test capacity: 300 (IL test channels 120+ open)   |
| <b>Of those defined, No. active simultaneously</b>  | 0   | 1   | varies with test-reagent combination  |
| <b>Factor assays require manual manipulation or dils</b>  | yes   | no  | no  |
| <b>No. of reag. containers onboard at one time/tests per container</b>                                | 3/varies by test  | 3/varies by test  | 18/varies by test   |
| <b>Reagents refrigerated onboard</b>  | yes (15°C)  | yes (15°C)  | yes (15°C)  |
| <b>Multiple reag. configurations supported</b>  | yes   | yes   | yes   |
| <b>Reag., consumables loaded without interrupting testing</b>   | no  | no  | no  |
| <b>Same capabilities when 3rd-party reag. used</b>  | yes   | yes   | yes   |
| <b>Max. time same lot number of reag. can be used</b>   | 18 mos  | 18 mos  | 18 mos  |
| <b>Walkaway capacity: No. of specimens/No. of tests</b>   | 18/36   | 18/36   | 40/260  |
| <b>Min. sample vol. aspirated precisely at one time</b>   | 10 µL   | 10 µL   | 5 µL  |
| <b>Standard specimen vol. required to run PT or PTT/factor VIII activity</b>                          | 50 µL (PT), 53 µL (PTT)/40 µL   | 50 µL (PT), 53 µL (PTT)/40 µL   | 50 µL/40 µL   |
| <b>Disposables used/price of each</b>   | rotors/price varies   | rotors/price varies   | rotors/price varies   |
| <b>Supports direct-from-track sampling</b>  | no  | no  | no  |
| <b>Primary tube sampling supported/pierces caps on primary tubes</b>                                  | yes (13 x 75 mm)/no   | yes (13 x 75 mm)/no   | yes (13 x 64, 75, 100 mm; 11.5 x 64, 92 mm)/no  |
| <b>Sample bar-code reading capability</b>   | yes (optional)  | yes   | yes   |
| <b>Reagent bar-code reading capability</b>  | no  | no  | no  |
| <b>Onboard test automatic inventory</b>   | no  | no  | yes   |
| <b>Measures No. of tests remaining</b>  | no  | no  | yes   |
| <b>Short sample detection</b>   | yes   | yes   | yes   |
| <b>Clot detection as preanalytical variable in plasma sample</b>                                      | no  | no  | no  |
| <b>Auto. detection of adequate reag. for aspir. &amp; anal.</b>                                       | yes   | yes   | yes   |
| <b>Hemolysis/turbidity detection-quantitation</b>   | no/no   | no/no   | no/no   |
| <b>Dilution of patient samples onboard</b>  | yes   | yes   | yes   |
| <b>Automatic rerun capability/auto reflex testing capability</b>                                      | no/no   | no/no   | yes/yes   |
| <b>Lag time during which hypercoagulable samples will not be detected</b>                             | yes (PT & PTT: 5.6 std, 6.7 ext)  | yes (PT & PTT: 5.6 std, 6.7 ext)  | yes (PT & PTT: 3 sec)   |
| <b>Read time extended for prolonged clotting times</b>  | yes (selectable on menus)   | yes (selectable on menus)   | yes (selectable on menus)   |
| <b>User can set different-than-standard:</b>  |   |   |   |
| • Reag. volumes/sample volumes  | no/no   | no/no   | yes/yes   |
| • No. and sources of reag.  | no  | no  | yes   |
| • Incub. times/reading times  | no/yes  | no/yes  | yes/yes   |
| <b>Autocalibration or autocallib. alert/multipoint calibration supported</b>                          | no/yes  | no/yes  | no/yes  |
| <b>Auto shutdown/auto startup programmable</b>  | no/no   | no/no   | no/no   |
| <b>Stat time to completion of all analytes and throughput per hour for:</b>                           |   |   |   |
| • PT alone  | 5.5 min/110 specimens   | 5.5 min/175 specimens   | 4 min/175 specimens   |
| • PT, PTT   | 8.5 min/80 specimens  | 8.5 min/110 specimens   | 8 min/110 specimens   |
| • Fibrinogen  | 5.5 min/110 specimens   | 5.5 min/175 specimens   | 4 min/175 specimens   |
| • Factor VIII activity assay  | 9.5 min/80 specimens  | 9.5 min/110 specimens   | varies/110 specimens  |
| <b>Time delay from ordering stat to aspir. of sample</b>  | 15 sec  | 15 sec  | 15 sec  |
| <b>Auto. transfer of QC results to LIS</b>  | no  | yes   | yes   |
| <b>Data management capability</b>   | no  | onboard (incl. QC: L-J)   | onboard (incl. QC: L-J)   |
| <b>Interface supplied by instrument vendor</b>  | no  | no  | no  |
| <b>Interfaces in active user sites for:</b>   | most major LIS vendors  | most major LIS vendors  | —   |
| <b>Bidirectional interface capability</b>   | no  | yes (host query)  | yes (broadcast download & host query)   |
| <b>Results transferred to LIS as soon as test time complete</b>                                       | yes   | yes   | yes   |
| <b>LOINC codes transmitted with all results</b>   | no  | no  | no  |
| <b>How labs get LOINC codes for reagent kits</b>  | in development  | in development  | in development  |
| <b>Electronic interface available (or will be) to automated (or robotic) specimen handling system</b> | no  | no  | no  |
| <b>Modem servicing</b>  | no  | no  | no  |
| <b>Time required for maintenance by lab personnel</b>   | daily: 10 min; weekly: 15 min; monthly: 10 min  | daily: 10 min; weekly: 15 min; monthly: 10 min  | daily: 0; weekly: 10 min; monthly: 5 min; biweekly: 5 min   |
| <b>Onboard maintenance records</b>  | yes   | yes   | yes   |
| <b>Training provided with purchase</b>  | 2 days on site  | 2 days on site  | 5 days at vendor offices in Miami   |
| <b>Approx. No. of training hrs needed per tech</b>  | 6 h   | 12 h  | varies  |
| <b>List price</b>   | \$21,500  | \$45,000  | \$61,950  |
| <b>Ann. svc. contract cost (24 h/7 d)/warranty with purchase</b>                                      | variety of options available/1 yr   | variety of options available/1 yr   | various options available/1 yr  |
| <b>Unique advantages</b>  | • part of ACL family, uses same consumables/reagents<br>• quantitative PT-based fib.<br>• positive displacement pipetting for low maintenance & high precision        | • part of ACL family, uses same consumables/reagents<br>• quantitative PT-based fib.<br>• positive displacement pipetting for low maintenance & high precision        | • robotic transport arm<br>• extensive menu of clotting, chromogenic, & immunological assays in a small footprint<br>• positive displacement pipetting for low maintenance & high precision |

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

## Coagulation Analyzers

|   |  |   |   |
|---|--|---|---|
| <b>Part 10 of 11</b>  | Instrumentation Laboratory/Beckman Coulter Inc.<br>Katie Blount kblount@beckman.com<br>200 S. Kraemer Blvd., Brea, CA 92621<br>714-993-8749<br>www.beckmancoulter.com              | Trinity Biotech<br>V. Eggerding hemostasisinfo@trinityusa.com<br>1930 Innerbelt Business Center Dr., St. Louis, MO 63114<br>800-325-3424<br>www.trinitybiotech.com                                  | Trinity Biotech<br>V. Eggerding hemostasisinfo@trinityusa.com<br>1930 Innerbelt Business Center Dr., St. Louis, MO 63114<br>800-325-3424<br>www.trinitybiotech.com  |
| <i>See accompanying article, page 18</i>  |  |   |   |
| Instrument name/first year sold   | ACL Advance/2000   | KC1A/2001   | KC4A/2001   |
| No. of units installed in U.S./outside U.S.<br>Country where analyzer designed/manufactured<br>Operational type<br>Reagent type<br>Operates on whole blood or spun plasma<br>Sample handling system<br>Model type<br>Dimensions (H x W x D)/weight/instrument footprint | 500+/1,000+<br>U.S./U.S.<br>random access<br>open reagent system, guarantee only IL products<br>spun plasma<br>racks, up to 12<br>benchtop<br>32.2 x 41 x 24.8 in/185 lbs/15 sq ft | <500/<500<br>Germany/Germany<br>semiautomatic, single channel<br>open reagent system<br>spun plasma<br>manual<br>benchtop<br>3.25 x 5.5 x 8.25 in/2.5 lbs/<1 sq ft                                  | <500/<500<br>Germany/Germany<br>semiautomatic, 4 channels<br>open reagent system<br>spun plasma<br>manual<br>benchtop<br>4.7 x 13.9 x 17.7 in/14 lbs/1.7 sq ft  |
| FDA-cleared clotting-based tests  | PT, APTT, PT-based fib., Clauss fib., TT, factor assays, protein C, LAC screen, LAC confirm, APCR-V  | PT, APTT, fib., TT, intrinsic & extrinsic factors   | PT, APTT, fib., TT, atroxin, intrinsic & extrinsic factors  |
| FDA-cleared chromogenic tests   | antithrombin, heparin, protein C, plasminogen, plasmin inhibitor, liquid antithrombin  | n/a   | n/a   |
| FDA-cleared immunologic tests   | D-dimer (latex enhanced immunoassay), vWF, free protein S  | n/a   | n/a   |
| Other FDA-cleared tests   | none   | n/a   | n/a   |
| User-defined tests in clinical use  | none   | n/a   | n/a   |
| Tests submitted for 510(k) clearance  | HS-CRP, protein S  | n/a   | n/a   |
| Tests in development but not yet submitted  | vWF activity   | n/a   | n/a   |
| Methodologies supported   | clot detection, optical; chromogenic; immunologic (optical, latex enhanced immunoassay)  | clot detection, mechanical  | clot detection, mechanical  |
| Oper. must load sep. reag. pack for ea. specimen/test run   | no/no  | no/no   | no/no   |
| No. of different measured assays onboard simultaneously   | varies with test-reagent combination, limited only by No. of reag. positions   | 1   | 5   |
| No. of different assays programmed and calibrated at one time   | 1  | manual  | 1/1   |
| No. of user-definable (open) channels   | total test capacity: 100 (IL test channels + open)   | n/a   | n/a   |
| Of those defined, No. active simultaneously   | varies with test-reag. combination   | n/a   | up to 4   |
| Factor assays require manual manipulation or dils   | no   | yes   | yes   |
| No. of reag. containers onboard at one time/tests per container   | 42/varies by test, container size  | 1/varies for each assay   | 5/varies for test kit   |
| Reagents refrigerated onboard   | yes (15°C)   | no  | no  |
| Multiple reag. configurations supported   | yes  | no  | no  |
| Reag., consumables loaded without interrupting testing  | yes  | n/a, manual   | n/a, manual   |
| Same capabilities when 3rd-party reag. used   | yes  | yes   | yes   |
| Max. time same lot number of reag. can be used  | 18 mos   | 12-18 mos   | 12-18 mos   |
| Walkaway capacity: No. of specimens/No. of tests  | 120/variable   | n/a, manual   | n/a, manual   |
| Min. sample vol. aspirated precisely at one time  | 10 µL  | n/a   | n/a   |
| Standard specimen vol. required to run PT or PTT/factor VIII activity   | 50 µL /10 µL   | 50 µL/50 µL   | 50 µL/50 µL   |
| Disposables used/price of each  | cuvettes/price varies  | cuvettes & ball dispenser/inquire   | cuvettes & ball dispenser/inquire   |
| Supports direct-from-track sampling   | no   | n/a   | n/a   |
| Primary tube sampling supported/pierces caps on primary tubes   | yes/no   | n/a   | n/a   |
| Sample bar-code reading capability  | yes  | n/a   | n/a   |
| Reagent bar-code reading capability   | no   | n/a   | n/a   |
| Onboard test automatic inventory  | no   | n/a   | n/a   |
| Measures No. of tests remaining   | no   | n/a   | n/a   |
| Short sample detection  | yes  | n/a   | n/a   |
| Clot detection as preanalytical variable in plasma sample   | no   | n/a   | n/a   |
| Auto. detection of adequate reag. for aspir. & anal.  | yes  | n/a   | n/a   |
| Hemolysis/turbidity detection-quantitation  | yes/yes  | n/a   | n/a   |
| Dilution of patient samples onboard   | yes  | n/a   | n/a   |
| Automatic rerun capability/auto reflex testing capability   | yes/no   | n/a   | n/a   |
| Lag time during which hypercoagulable samples will not be detected  | yes (PT: 7 sec., PTT: 10 sec)  | yes (PT & PTT: 4.5 sec)   | yes (PT & PTT: 4.5 sec)   |
| Read time extended for prolonged clotting times   | yes (selectable on menus)  | yes   | yes   |
| User can set different-than-standard:   |  |   |   |
| • Reag. volumes/sample volumes  | yes/yes  | yes/yes   | yes/yes   |
| • No. and sources of reag.  | yes  | yes   | yes   |
| • Incub. times/reading times  | yes/yes  | yes/yes   | yes/yes   |
| Autocalibration or autocallib. alert/multipoint calibration supported   | no/yes   | no/yes  | no/yes  |
| Auto shutdown/auto startup programmable   | no/no  | no/no   | no/no   |
| Stat time to completion of all analytes and throughput per hour for:  |  |   |   |
| • PT alone  | 2.5 min/240 specimens  | 75 sec/48   | 75 sec/48   |
| • PT, PTT   | 8 min/180 specimens  | 350 sec/10  | 350 sec/10  |
| • Fibrinogen  | 2.5 min/240 specimens  | 65 sec/55   | 65 sec/55   |
| • Factor VIII activity assay  | 2.5 min/180 specimens  | 275 sec/13  | 275 sec/13  |
| Time delay from ordering stat to aspir. of sample   | 20 sec   | n/a   | n/a   |
| Auto. transfer of QC results to LIS   | yes  | yes   | yes   |
| Data management capability  | onboard (incl. QC: L-J)  | yes   | yes   |
| Interface supplied by instrument vendor   | no   | no  | no  |
| Interfaces in active user sites for:  | most major LIS vendors   | —   | —   |
| Bidirectional interface capability  | yes (broadcast download)   | n/a   | n/a   |
| Results transferred to LIS as soon as test time complete  | yes  | yes   | yes   |
| LOINC codes transmitted with all results  | no   | —   | —   |
| How labs get LOINC codes for reagent kits   | in development   | —   | —   |
| Electronic interface available (or will be) to automated (or robotic) specimen handling system  | no   | n/a   | n/a   |
| Modem servicing   | no   | n/a   | n/a   |
| Time required for maintenance by lab personnel  | daily: 15 min; weekly: 15 min; monthly: 10 min   | none  | none  |
| Onboard maintenance records   | yes  | n/a   | n/a   |
| Training provided with purchase   | 5 days at vendor offices in Miami  | as needed on site   | as needed on site   |
| Approx. No. of training hrs needed per tech   | 24 h   | 2 h   | 2 h   |
| List price  | \$79,500   | \$2,100   | \$9,200   |
| Ann. svc. contract cost (24 h/7 d)/warranty with purchase   | various options available/1 yr   | \$350 (M-F, 8-5)/1 yr   | \$900 (M-F, 8-5)/1 yr   |
| Unique advantages   | • extensive menu of clotting, chromogenic, & immunologic assays<br>• high throughput<br>• positive displacement pipetting for low maintenance & high precision                     | • half volume PT & APTT testing for significant reagent savings<br>• patented ball technology for extremely reproducible & reliable results<br>• optional printer to ensure quality of test results | • single microcuvettes for all tests; uses half volume for PT & APTT, reduced volume for all other tests<br>• incub. area at 37°C; 12 samples, 5 reag., 2 pipettes<br>• 4 simultaneously usable test positions using patented ball method for extremely reproducible & reliable results<br>• optional printer to ensure quality of test results |

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

## Coagulation Analyzers

|  |   |  |  |
|--|---|--|--|
| <b>Part 11 of 11</b>   | Trinity Biotech<br>V. Eggerding hemostasisinfo@trinityusa.com<br>1930 Innerbelt Business Center Dr., St. Louis, MO 63114<br>800-325-3424<br>www.trinitybiotech.com  | Trinity Biotech<br>V. Eggerding hemostasisinfo@trinityusa.com<br>1930 Innerbelt Business Center Dr., St. Louis, MO 63114<br>800-325-3424<br>www.trinitybiotech.com   | Trinity Biotech<br>V. Eggerding hemostasisinfo@trinityusa.com<br>1930 Innerbelt Business Center Dr., St. Louis, MO 63114<br>800-325-3424<br>www.trinitybiotech.com   |
| <i>See accompanying article, page 18</i>   |   |  |  |
| <b>Instrument name/first year sold</b>   | Amax 200/2001   | Amax 400/1997  | Amax Destiny/2003  |
| <b>No. of units installed in U.S./outside U.S.</b><br><b>Country where analyzer designed/manufactured</b><br><b>Operational type</b><br><b>Reagent type</b><br><b>Operates on whole blood or spun plasma</b><br><b>Sample handling system</b><br><b>Model type</b><br><b>Dimensions (H x W x D)/weight/instrument footprint</b>  | <500/<500<br>Germany/Germany<br>random access<br>open reagent system<br>spun plasma<br>60-position continuous addition sample rack<br>benchtop or floor-standing<br>BT: 25 x 32.75 x 28.75 in/286 lbs/6.5 sq ft<br>FS: 53.25 x 32.75 x 28.75 in/451 lbs/6.5 sq ft   | <500/<500<br>Germany/Germany<br>random access<br>open reagent system<br>spun plasma<br>continuous feed sample chain<br>floor-standing<br>52 x 56 x 27 in/803 lbs/10.5 sq ft  | n/a/n/a<br>Germany & U.S./Germany<br>random access<br>open reagent system<br>spun plasma<br>rack<br>benchtop<br>22 x 33 x 27 in/165 lbs/150 sq ft  |
| <b>FDA-cleared clotting-based tests</b><br><br><b>FDA-cleared chromogenic tests</b><br><b>FDA-cleared immunologic tests</b><br><b>Other FDA-cleared tests</b><br><b>User-defined tests in clinical use</b><br><br><b>Tests submitted for 510(k) clearance</b><br><b>Tests in development but not yet submitted</b>   | APTT, atroxin, fib., PT, protein C, TT, protein S, intrinsic & extrinsic factors, dRVVT<br><br>antithrombin, plasminogen, hep-Xa, protein C<br>D-dimer<br>none<br>PT & APTT mixing studies, Ptt. neutralization, Kaolin clotting time, activated protein C resistance, protein S (immunol.), vWF assay (immunol.), thrombotest, hep. cofactor II, alpha-2 antiplasmin<br>none<br>activated protein C resistance | PT, APTT, fib., TT, intrinsic & extrinsic factors, protein C & S, dRVVT<br><br>hep-Xa, antithrombin, plasminogen, protein C<br>D-dimer<br>none<br>PT & APTT mixing studies, Ptt. neutralization, Kaolin clotting time, protein S (immunol.), vWF assay (immunol.), thrombo test, hep. cofactor II, alpha-2 antiplasmin<br>activated protein C resistance<br>none | PT, APTT, fib., TT, atroxin, factors II, V, VII, VIII, IX, X, XI, & XII<br><br>AT<br>D-dimer<br>—<br>—<br>—<br>—   |
| <b>Methodologies supported</b><br><br><b>Oper. must load sep. reag. pack for ea. specimen/test run</b><br><b>No. of different measured assays onboard simultaneously</b><br><b>No. of different assays programmed and calibrated at one time</b><br><b>No. of user-definable (open) channels</b><br><b>Of those defined, No. active simultaneously</b><br><b>Factor assays require manual manipulation or dilutions</b><br><b>No. of reag. containers onboard at one time/tests per container</b><br><b>Reagents refrigerated onboard</b><br><b>Multiple reag. configurations supported</b><br><b>Reag., consumables loaded without interrupting testing</b><br><b>Same capabilities when 3rd-party reag. used</b><br><b>Max. time same lot number of reag. can be used</b><br><b>Walkaway capacity: No. of specimens/No. of tests</b><br><b>Min. sample vol. aspirated precisely at one time</b><br><b>Standard specimen vol. required to run PT or PTT/factor VIII activity</b><br><b>Disposables used/price of each</b>   | clot detect, mechanical; clot detect, optical, tungsten, turbidimetric; chromogenic; immunologic (microparticles)<br>no/no<br>32<br>32<br>32<br>12<br>no<br>24/varies with kit & operational mode<br>yes (15°C)<br>yes<br>yes<br>yes<br>yes<br>12-18 mos<br>60/450<br>5 µL<br>50 µL/50 µL<br>cuvettes/—, probe decontaminate/—  | clot detect, mechanical; clot detect, optical, tungsten, turbidimetric; chromogenic; immunologic (microparticles)<br>no/no<br>40<br>40<br>40<br>40<br>no<br>24/varies with assay & operational mode<br>yes (15°C)<br>yes<br>yes<br>yes<br>yes<br>12-18 mos<br>1,250/450<br>3 µL<br>50 µL/50 µL<br>cuvettes/—, probe decontaminate/—, tubing/—                    | clot detect, mechanical; clot detect, optical, turbidimetric; chromogenic; immunologic<br>no/no<br>10<br>unlimited<br>unlimited<br>10<br>no<br>30/varies<br>yes (12-16°C)<br>yes<br>yes<br>yes<br>varies by reagent<br>50/10<br>5 µL<br>50 µL/5 µL<br>reaction trays, EnzyClean+/— |
| <b>Supports direct-from-track sampling</b><br><b>Primary tube sampling supported/pierces caps on primary tubes</b><br><b>Sample bar-code reading capability</b><br><b>Reagent bar-code reading capability</b><br><b>Onboard test automatic inventory</b><br><b>Measures No. of tests remaining</b><br><b>Short sample detection</b><br><b>Clot detection as preanalytical variable in plasma sample</b><br><b>Auto. detection of adequate reag. for aspir. &amp; anal.</b><br><b>Hemolysis/turbidity detection-quantitation</b><br><b>Dilution of patient samples onboard</b><br><b>Automatic rerun capability/auto reflex testing capability</b><br><b>Lag time during which hypercoagulable samples will not be detected</b><br><b>Read time extended for prolonged clotting times</b><br><b>User can set different-than-standard:</b><br>• Reag. volumes/sample volumes<br>• No. and sources of reag.<br>• Incub. times/reading times<br><b>Autocalibration or autocall. alert/multipoint calibration supported</b><br><b>Auto shutdown/auto startup programmable</b> | no<br>yes/no<br>yes<br>no<br>yes<br>yes<br>yes<br>n/a<br>yes<br>not necessary<br>yes<br>yes/no<br>yes (4.5 sec)<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>no/yes<br>yes/yes  | no<br>yes/no<br>yes<br>no<br>yes<br>yes<br>yes<br>n/a<br>yes<br>not necessary<br>yes<br>yes/yes<br>yes (4.5 sec)<br>yes (selectable on menus)<br>yes/yes<br>yes<br>yes/yes<br>no/yes<br>yes/yes  | no<br>yes (standard, pediatric, micro)/no<br>yes<br>no<br>yes<br>yes<br>yes<br>no<br>yes<br>n/a/n/a<br>yes<br>yes/no<br>no<br>yes<br>yes<br>yes/yes<br>no/yes<br>yes/yes   |
| <b>Stat time to completion of all analytes and throughput per hour for:</b><br>• PT alone<br>• PT, PTT<br>• Fibrinogen<br>• Factor VIII activity assay<br><b>Time delay from ordering stat to aspir. of sample</b><br><b>Auto. transfer of QC results to LIS</b><br><b>Data management capability</b><br><b>Interface supplied by instrument vendor</b><br><b>Interfaces in active user sites for:</b><br><b>Bidirectional interface capability</b><br><b>Results transferred to LIS as soon as test time complete</b><br><b>LOINC codes transmitted with all results</b><br><b>How labs get LOINC codes for reagent kits</b><br><b>Electronic interface available (or will be) to automated (or robotic) specimen handling system</b>   | 90 sec/190 tests<br>300 sec/120 tests<br>70 sec/115 tests<br>300 sec/120 tests<br>varies by test<br>yes<br>onboard (incl. QC: L-J, Westgard)<br>yes (included in instrument price)<br>all major LIS companies<br>yes (broadcast download & host query)<br>yes<br>—<br>—<br>no   | 90 sec/325 tests<br>300 sec/480 tests<br>70 sec/212 tests<br>300 sec/200 tests<br>varies by test<br>yes<br>onboard (incl. QC: L-J, Westgard)<br>yes (included in instrument price)<br>in development<br>yes (broadcast download & host query)<br>yes<br>—<br>—<br>yes  | <3 min/90 tests<br>—<br>—<br>—<br>—<br>yes<br>onboard (incl. QC: L-J, Westgard)<br>no<br>—<br>yes (broadcast download & host query)<br>yes<br>yes<br>—<br>no   |
| <b>Modem servicing</b><br><b>Time required for maintenance by lab personnel</b><br><b>Onboard maintenance records</b><br><b>Training provided with purchase</b><br><b>Approx. No. of training hours needed per tech</b>  | yes<br>daily: <2 min; weekly: <35 min; monthly: <1 h<br>no<br>5 days on site, 4 days at vendor office<br>16-24 h  | yes<br>daily: <10 min; weekly: <30 min; monthly: <1 h<br>yes<br>5 days on site, 5 days at vendor office<br>48-72 h   | no<br>per shift: <5 min; daily: <30 min; weekly: <30 min<br>yes<br>2 days on site<br>8 h   |
| <b>List price</b><br><b>Ann. svc. contract cost (24 hr/7 d)/warranty with purchase</b>   | \$81,000<br>\$8,000/1 yr  | \$132,000<br>\$14,000/1 yr   | \$49,000<br>\$6,000/1 yr   |
| <b>Unique advantages</b>   | • optical & mechanical testing for greatest reliability; can perform simultaneous chrom. & clotting tests<br>• quarter volume PT & APTT (half volume other tests)<br>• easy-to-use software monitors quality at all times   | • selective multichannel hemostasis testing offering true random access<br>• patented ball method technology<br>• parallel clotting & chromogenic testing  | • true clot detection<br>• IntuiTouch software<br>• expanded test menu (D-dimer)   |

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