<table>
<thead>
<tr>
<th>Instrument Name/Fist year sold</th>
<th>Bio/Data Corp.</th>
<th>Chrono-log Corp.</th>
<th>Chrono-log Corp.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bio/Data Corp.</td>
<td>Kathy Jacobs</td>
<td>Kathy Jacobs</td>
</tr>
<tr>
<td></td>
<td>Horsham, PA</td>
<td>Havertown, PA</td>
<td>Havertown, PA</td>
</tr>
<tr>
<td></td>
<td>215-441-4000</td>
<td>800-247-6665</td>
<td>800-853-1130</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>List/Price/Model type</th>
<th>$21,990/benchtop</th>
<th>$10,192–$24,575/benchtop</th>
<th>$19,587–$37,645/benchtop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (H × W × D)/Weight/Instrument footprint</td>
<td>$21.5–25.5 × 19.0 × 24.0 in./40 lbs./8 sq. ft.</td>
<td>$5.9–6.0 × 5.9–6.0 × 40 in./3.75 lbs./1 sq. ft.</td>
<td>$5.9–6.0 × 5.9–6.0 × 40 in./3.75 lbs./1 sq. ft.</td>
</tr>
<tr>
<td>Instrument footprint</td>
<td>85%10%5% (unspecifed)</td>
<td>1.0 1.0 1.0</td>
<td>1.0 1.0 1.0</td>
</tr>
<tr>
<td>Targeted daily, monthly, annual test volume</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Operational type</td>
<td>batch, random access</td>
<td>discrete</td>
<td>discrete</td>
</tr>
<tr>
<td>Company manufactures instrument</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

| FDA-approved clotting-based tests | — | — | — |
| FDA-approved chromogenic tests | — | — | — |
| Other FDA-approved tests | — | — | — |

| Tests in development or awaiting FDA 510(k) clearance | — | — | — |

<table>
<thead>
<tr>
<th>Methodologies supported</th>
<th>ristocetin cofactor assay, rIPA, agglutination; open system for other Ab-Ag tests; turbidimetric, immunologic (agglutination)</th>
<th>turbidimetric for measuring platelet aggregation in PRP and ristocetin cofactor assay</th>
<th>turbidimetric for measuring platelet aggregation in PRP and ristocetin cofactor assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of different measured assays onboard simultaneously</td>
<td>99</td>
<td>4–8</td>
<td>2–4</td>
</tr>
<tr>
<td>Number of different assays programmed and calib. at one time</td>
<td>99</td>
<td>4–8</td>
<td>2–4</td>
</tr>
<tr>
<td>No. of user-definable (open) channels/No. active simultaneously</td>
<td>8/8</td>
<td>4/4–8</td>
<td>2–4/4–8</td>
</tr>
<tr>
<td>Factor assays require manual manipulation or dilutions</td>
<td>yes (manual manipulation and dilutions)</td>
<td>yes (manual dilutions)</td>
<td>yes (manual dilutions)</td>
</tr>
<tr>
<td>Test throughput per hour/Assay run time</td>
<td>6 (up to 8 tests in throughput)/up to 8 hours</td>
<td>6 (24–48 tests in throughput)/5 min. minimum manual up to 8 hours</td>
<td>6 (24–48 tests in throughput)/5 min. minimum manual up to 8 hours</td>
</tr>
<tr>
<td>Design of sample-handling system</td>
<td>spin plasma</td>
<td>spin plasma</td>
<td>spin plasma</td>
</tr>
<tr>
<td>Operates on whole blood or spun plasma</td>
<td>self-contained multislide vessels; open reagent system (liquid, lyophilized [reconstituted manually])</td>
<td>self-contained multislide vessels; open reagent system (liquid, lyophilized [reconstituted manually])</td>
<td>self-contained multislide vessels; open reagent system (liquid, lyophilized [reconstituted manually])</td>
</tr>
<tr>
<td>Reagent type</td>
<td>yes (all tests)</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Reagent</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Reagent barcode-reading capability</td>
<td>yes/no —</td>
<td>yes/no —</td>
<td>yes/no —</td>
</tr>
<tr>
<td>No. of reagent containers held onboard/Reagents ready to use</td>
<td>yes/no 2, with inserts for various sizes/requires operator prehandling</td>
<td>yes/no 2, with inserts for various sizes/requires operator prehandling</td>
<td>yes/no 2, with inserts for various sizes/requires operator prehandling</td>
</tr>
<tr>
<td>Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard</td>
<td>yes/no yes/no no</td>
<td>yes/no yes/no no</td>
<td>yes/no yes/no no</td>
</tr>
<tr>
<td>Reagents, consumables loaded without interrupting testing</td>
<td>no</td>
<td>yes (consumables)</td>
<td>yes (consumables)</td>
</tr>
<tr>
<td>Instrument uses proprietary or third-party reagents</td>
<td>—</td>
<td>yes (proprietary reagents)</td>
<td>yes (proprietary reagents)</td>
</tr>
<tr>
<td>Maximum time same lot number of reagents can be used onboard</td>
<td>2 years</td>
<td>18 months–3 years</td>
<td>18 months–3 years</td>
</tr>
<tr>
<td>Walkaway capability/Walkaway duration</td>
<td>yes/5 specimens or 9 tests</td>
<td>yes/6 specimens or 4–8 tests</td>
<td>yes/6 specimens or 4–8 tests</td>
</tr>
<tr>
<td>Min. max. specimen volume that can be aspirated at one time</td>
<td>25–50 mL minimum</td>
<td>250–500 mL</td>
<td>250–500 mL</td>
</tr>
<tr>
<td>Min. sample volume required for PT/PTT/Factor VIII activity</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Types of disposables used</td>
<td>siliconized micro test tubes, plastic coated stir bars, pipette tips, MagnaTubes</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Primary tube sampling supported/Pierces caps on primary tubes</td>
<td>no/no</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Accommodates most standard tube sizes/Nonstandard sizes</td>
<td>no/no</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Sample barcode-reading capability/Auto/discrimination</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Auto tracks product/volume/Measures number of tests remaining</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Short sample detection</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Test throughput per hour/Assay run time</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Auto detects as preanalytical variable in plasma sample</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Auto detects adequate reagents for aspiration or analysis</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Detection or quantification of hemolysis, turbidity, clots, etc.</td>
<td>detection and quantification for hemolysis, turbidity, clots, etc.</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Dilutes patient samples onboard</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Automatic rerun capability/Auto/reflex testing capability</td>
<td>no/no yes/no —</td>
<td>yes/no —</td>
<td>yes/no —</td>
</tr>
<tr>
<td>Lag time during which hypercoagulable sample not detected</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>User can adjust reagent volumes/Sample volumes</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>User can adjust No. of reagents/Sources of reagents</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>User can adjust incubation times/Reading times</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>Read time extended for prolonged clotting times</td>
<td>yes (selectable on menus)</td>
<td>yes (selectable on menus)</td>
<td>yes (selectable on menus)</td>
</tr>
<tr>
<td>Autocalibration/Calibrants stored onboard</td>
<td>yes/no —</td>
<td>yes/no —</td>
<td>yes/no —</td>
</tr>
<tr>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Multipoint calibration supported/Recommended frequency</td>
<td>yes/variable</td>
<td>yes/annually</td>
<td>yes/annually</td>
</tr>
</tbody>
</table>

**COAGULATION ANALYZERS**

**Chrono-log Corp.**

**Kathy Jacobs**

**Havertown, PA**

**800-247-6665**

**www.chronolog.com**

**Bio/Data Corp.**

**Robert F. Wheaton III**

**rob.wheaton@biodatacorp.com**

**Horsham, PA**

**215-441-4000**

**www.biodatacorp.com**

**All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.**
Diagnostic Stage
Nichole Howard
2013
Parsippany, NJ
800-222-2624
www.stago-us.com

Diagnostic Stage
Nichole Howard
2014
Parsippany, NJ
800-222-2624
www.stago-us.com

Diagnostic Stage
John G. Chromczak
2015
Parsippany, NJ
800-222-2624
www.stago-us.com

FDA-approved clotting-based tests
- PT, APTT, TT, fibrinogen, reptilase, factors, proteins C and S, lupus anticoagulant, DRVVT (screen and confirm)
- anti-Fxα (FV and LMWH), antithrombin, protein C, alpha-2-antiplasmin, plasminogen, FVII; chromogenic

FDA-approved chromogenic tests
- anti-Fxα (FV and LMWH), antithrombin

FDA-approved immunologic tests
- D-dimer, antithrombin antigen, free protein S, total protein S, VWF antigen (all micromoles)

Other FDA-approved tests
- PT, APTT, fibrinogen

User-defined tests in clinical use
- APCR, other clotting, chromogenic, and immunological tests with user-defined applications

Tests in development or awaiting FDA 510(k) clearance
- STA Neo/Final prospective reagent with ISI ~1.0, VWF/FIST

Methods supported
- continuous loading sample drawer with continuous random access

Design of sample-handling system
- self-contained single-use and mutiwave units; open reagent system (liquid, lyophilized [reconstituted manually])

Operates on whole blood or spun plasma
- yes

Reagent type
- no

Reagent barcode-reading capability
- no

Reagents, consumables loaded without interrupting testing
- no

Instrument uses proprietary or third-party reagents
- yes

Maximum time same lot number of reagents can be used
- 18 months

Walkway capability/Walkaway duration
- yes (60 specimens or 12 tests)

Min.-max. specimen volume that can be aspirated at one time
- 5–100 µL

Min. sample volume required for PTT/Factor VIII activity
- 50 µL

Types of disposables used
- cuvettes, stir bars, cleaner solution

Primary tube sampling supports/Froces caps on primary tubes
- yes

Accommodates most standard tube sizes/Nonstandard sizes
- no

Sample barcode-reading capability/Autodiscrimination
- no

Auto tracks product volume/Measures number of tests remaining
- no

Short sample detection
- yes

Clot detection as preanalytical variable in plasma sample
- no

Auto detects adequate reagents for aspiration or analysis
- yes

Detection or quantification for hemolysis, turbidity, clots, lipemia
- yes

Dilutes patients sample onto
- yes

Automatic rerun capability/Auto reflex testing capability
- yes

Lag time during which hypercoagulable may not detected
- 15 seconds

Can User adjust reagent amount/Sample volumes
- yes

Can User adjust No. of reagents/Sources of reagents
- yes

User can adjust incubation times/Read times
- yes

Read time extended for prolonged clotting time
- yes

Autocalibration/Calibrants stored onboard
- yes

Multipoint calibration supported/Recommended frequency
- yes

Stat time to complete all analytes/Throughput per hour for:
- yes

Part 6 of 2
See capitadayonline.com/productguides
for an interactive version of guide

Instrument name/First year sold
- Nichole Howard
- 2013

List price/Model type
- $150,000/Compact

Dimensions (H × W × D)/Weight/Instrument footprint
- 27.75 × 36.18 × 28.73 in./309 lbs./sq. ft.
- 1,600 × 1,500 × 1,600 mm/360 lbs./sq. ft.

Compatibility of instruments/Manual/Reference lab/Other
- yes

Targeted daily, monthly, annual test volume
- continuous random access

Operational type
- France/France

Country where analyzer designed/Manufactured
- Company manufactures instrument

Distinguishing features (supplied by company)
- viscosity-based, mechanical clot detection; precalibrated D-dimer and fibrinogen reagents, full complement of lupus anticoagulant testing, STA Coag Expert data manager delivers full automation, reflex/revalidation, broadcast upload of 64-bit software

Note: a dash in lieu of an answer means company did not answer question or question is not applicable
<table>
<thead>
<tr>
<th>Instrument name/First year sold</th>
<th>Diagnosticas</th>
<th>Instrumentation Laboratory</th>
<th>Instrumentation Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Year/Supplier/Website</td>
<td>StArt Hemostasis Analyzer/1998</td>
<td>ACL ACOsStar/2010</td>
<td>ACL TOP 350/300 CTS/2012</td>
</tr>
<tr>
<td>List price/Model type</td>
<td>$13,079/benchtop</td>
<td>— benchtop</td>
<td>— benchtop</td>
</tr>
<tr>
<td>Dimensions (H × W × D)</td>
<td>4.7 × 16.1 × 16.5 in./12.5 lbs./18 sq. ft.</td>
<td>21 × 34 × 24 in./[170 lbs./10 sq. ft.</td>
<td>29 × 32 × 33 in./250 lbs./8 sq. ft.</td>
</tr>
<tr>
<td>Number of units in clinical use</td>
<td>&lt;850—900 (France, Spain, UK, Germany, Denmark others)</td>
<td>100—1/0</td>
<td>250—250</td>
</tr>
<tr>
<td>Country where analyzer designed/Manufactured</td>
<td>France/yes</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Company manufactures instrument</td>
<td>yes</td>
<td>no</td>
<td>—</td>
</tr>
<tr>
<td>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

### Distinguishing Features (supplied by company)

- Viscoisty-based, mechanical clot detection; unique ball dispenser and pipette included; small foot print ideal as an alternate methodology for photo-optical systems.
- On-demand HIT IgG testing with results available in 30 minutes; uses sensitive chemiluminescent technology, improving sensitivity; reagents are ready to use with onboard stability up to 12 weeks.
- FDA 510k approved; improves patient care, lab efficiencies, and costs; supports label’s policy on sample acceptance with quantitative HL, sample filter detection, aspiration errors (detection); fast-4<1 minutes; rapid format for PT/PTT (10-day onboard stability), high specificity D-dimer, on-demand HIT testing.
**Instrumentation Laboratory**

**ACL TOP 550 CTS**

- Instrument name: ACL TOP 550 CTS
- First year sold: 2016

**ACL TOP 750 Series/2016**

- Instrument name: ACL TOP 750 Series
- First year sold: 2016

**LABITec BioMedical Technologies GmbH**

- Instrumentation Laboratory
- LABITec
- Biomedical Technologies GmbH

**V. Shirley**

- Product Guide
- www.ilww.com

**LABITec**

- Product Guide
- www.labitec.com

**CoaDATA**

- Product Guide
- www.coadata.com

**CAP**

- Product Guide
- www.cap.org

**FDA 510(k) approved**

- Product Guide
- www.fda.gov

**Note:** All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP.
<table>
<thead>
<tr>
<th>Methodology supported</th>
<th>clot detection, mechanical and optical; photometric with mechanical stirring, turbidometric; chromogenic; immunologic (photometric)</th>
<th>clot detection, optical; chromogenic; immunologic</th>
<th>clot detection, mechanical and optical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of different measured assays onboard simultaneously</td>
<td>15</td>
<td>&gt;100</td>
<td>1</td>
</tr>
<tr>
<td>Number of different assays programmed and called at one time</td>
<td>50</td>
<td>99</td>
<td>3</td>
</tr>
<tr>
<td>No. of user-definable (open) channels/No. active simultaneously</td>
<td>50/15</td>
<td>7,999&gt;100</td>
<td>—</td>
</tr>
<tr>
<td>Test duration per throughput per assay run time</td>
<td>120 PT tests/—</td>
<td>380 (1 test in throughput)/7–3 min. (avg. 5 min.)</td>
<td>—</td>
</tr>
<tr>
<td>Design of sample-handling system</td>
<td>cuvette ring, sample cups</td>
<td>—</td>
<td>manual</td>
</tr>
<tr>
<td>Operates on whole blood or spun plasma</td>
<td>spun plasma</td>
<td>spun plasma</td>
<td>spun plasma</td>
</tr>
<tr>
<td>Reagent type</td>
<td>yes, for some tests</td>
<td>yes, for all tests</td>
<td>no</td>
</tr>
<tr>
<td>Reagent barcode-reading capability</td>
<td>15/yes/no</td>
<td>yes/yes/yes (15°C ≥ 2°C)</td>
<td>no</td>
</tr>
<tr>
<td>No. of reagent carriers held onboard/Reagents ready to use</td>
<td>yes (reagents)</td>
<td>yes (reagents and consumables)</td>
<td>yes (reagents and consumables)</td>
</tr>
<tr>
<td>Reagent lot tracking/Reagent inventory/Reagents refrigerated onboard</td>
<td>yes/yes/no</td>
<td>yes/yes/yes (cost dependent on contract)</td>
<td>yes/yes/yes (proprietary reagents, third-party reagents, user’s option)</td>
</tr>
<tr>
<td>Maximum time same lot number of reagents can be used</td>
<td>—</td>
<td>1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>Walkaway capability/Walkaway duration</td>
<td>yes/22 samples plus 3 stat (reagent dependent)</td>
<td>yes/100 specimens or up to 400 tests</td>
<td>no</td>
</tr>
<tr>
<td>Min.–max. specimen volume that can be aspirated at one time</td>
<td>2–275 µL</td>
<td>3 µL minimum</td>
<td>—</td>
</tr>
<tr>
<td>Min. specimen volume required for PT/PTT/Factor VIII activity</td>
<td>50 µL/50 µL/assay dependent</td>
<td>50 µL/50 µL/50 µL (standard)</td>
<td>—</td>
</tr>
<tr>
<td>Types of disposables used</td>
<td>rotors and wash solution</td>
<td>cuvettes</td>
<td>cuvettes</td>
</tr>
<tr>
<td>Primary tubular sampling supported/Plastic cups on primary tubes</td>
<td>yes/no</td>
<td>yes/yes/no</td>
<td>no/no</td>
</tr>
<tr>
<td>Accommodates most standard tube sizes/Nonstandard sizes</td>
<td>yes/no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Sample barcode-reading capability/Auto/discrimination</td>
<td>yes/yes/yes (reconstituted manually)</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Auto track product volume/Measures number of tests remaining</td>
<td>yes/yes/no</td>
<td>yes/yes/yes (reconstituted manually)</td>
<td>no</td>
</tr>
<tr>
<td>Short sample detection</td>
<td>yes</td>
<td>yes/yes/yes (15°C ≥ 2°C)</td>
<td>no</td>
</tr>
<tr>
<td>Clot detection as preanalytical variable in plasma sample</td>
<td>yes</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Auto detects adequate reagents for aspiration or analysis</td>
<td>no</td>
<td>aspiration and analysis</td>
<td>aspiration and analysis</td>
</tr>
<tr>
<td>Detection or quantitation for hemolysis, turbidity, clotted, lipemia</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Dilutes patient samples onboard</td>
<td>yes/no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Automatic reversibility/Auto reflex testing capability</td>
<td>yes</td>
<td>yes/yes/yes (reconstituted manually)</td>
<td>no/no</td>
</tr>
<tr>
<td>Lag time during which hypercoagulable sample not detected</td>
<td>no</td>
<td>yes (PT and PTT: 7 seconds)</td>
<td>no</td>
</tr>
<tr>
<td>User can adjust reagent volumes/Sample volumes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>User can adjust No. of reagents/Sources of reagents</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>User can adjust incubation times/Reading times</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Read time extended for prolonged clotting times</td>
<td>yes (detectable on menus)</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Autocalibration/Calibrators stored onboard</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Multipoint calibration supported/Recommended frequency</td>
<td>yes/with kit change</td>
<td>yes/6 months, per regulatory guidelines</td>
<td>yes/6 months, per regulatory guidelines</td>
</tr>
<tr>
<td>Stat time to complete all analytes/Throughput per hour for:</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>• PT alone</td>
<td>&lt;2 minutes/120 specimens</td>
<td>5 minutes/380 specimens</td>
<td>1 minute/specimen</td>
</tr>
<tr>
<td>• PT, PTT</td>
<td>&lt;5 minutes/71 specimens</td>
<td>5 minutes/325 specimens</td>
<td>—</td>
</tr>
<tr>
<td>• Fibrogen</td>
<td>&lt;5 minutes/50 specimens</td>
<td>5 minutes/315 specimens</td>
<td>1 minute/specimen</td>
</tr>
<tr>
<td>• Factor VIII assay</td>
<td>&lt;6 minutes/—</td>
<td>5 minutes/280 specimens</td>
<td>—</td>
</tr>
<tr>
<td>• D-dimer</td>
<td>&lt;8 minutes/—</td>
<td>5 minutes—</td>
<td>—</td>
</tr>
<tr>
<td>• Time delay from ordering stat to aspiration of sample</td>
<td>3 minutes</td>
<td>1 minute</td>
<td>—</td>
</tr>
<tr>
<td>How labs get long codes for results</td>
<td>—</td>
<td>website</td>
<td>—</td>
</tr>
<tr>
<td>Onboard real-time QC/Onboard software capability to review QC Information that can be barcode-scanned on instrument</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Compatible with laboratory automation systems</td>
<td>no</td>
<td>operator identifier, specimen identifier, reagent lot No.</td>
<td>no</td>
</tr>
<tr>
<td>Data-management capability/LIS or EHR systems interfaced onboard</td>
<td>no</td>
<td>onboard/most major vendors</td>
<td>no/no</td>
</tr>
<tr>
<td>Interface supplied by instrument vendor</td>
<td>yes</td>
<td>contract dependent</td>
<td>no</td>
</tr>
<tr>
<td>Results transferred to LIS as soon as test time complete</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Bidirectional interface capability</td>
<td>yes (host query)</td>
<td>yes (host query)</td>
<td>yes</td>
</tr>
<tr>
<td>Remote servicing provided/DSIS backup power supply</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Instrument connections to transfer information</td>
<td>no</td>
<td>data-management system, which in turn connects to LIS or EHR, directly to LIS or EHR, directly to lab automation system; commercial middleware (most major companies)</td>
<td>commercial middleware (most major companies)</td>
</tr>
<tr>
<td>Interface standards supported</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Information transferred to data-management software</td>
<td>LAN connection provides FTP result file transfer device unique identifier, patient ID, specimen ID, result</td>
<td>device unique identifier, operator ID, patient ID, specimen ID, result</td>
<td>Siemens Picture archiving and communication system (PACS) Siemens FPD connect; online daily; 1:15 minutes</td>
</tr>
<tr>
<td>Avg. time for basic user training</td>
<td>3 days (at customer and vendor offices) per shift: 1 minute; daily: 3 minutes; weekly: 5 minutes; monthly: 15 minutes</td>
<td>yes</td>
<td>Siemens FPD connect online daily; 1:15 minutes</td>
</tr>
<tr>
<td>Maintenance records kept onboard</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Warranty purchase/Average service contract cost (24/7)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Distinguishing features (supplied by company)</td>
<td>easy-to-use, standalone device with small footprint; onboard user and service software, no external PC required; optimized for small to mid-sized labs</td>
<td>user-definable calibration curve expiration and prewarning alerts; user-definable barcode utility enables customizable reagent protocols; user-friendly Windows 7 software</td>
<td>2-channel micro reagent volume clot-based technology; optical/mechanical detection accurate on Ioric, Ieric samples; automatic INR calculation, curve storage, built-in thermal printer; effective for low-volume testing, backup to larger systems</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Methodologies supported</th>
<th>clot detection, optical; chromogenic; immunologic</th>
<th>clot detection, optical; chromogenic; immunologic</th>
<th>clot detection, optical; chromogenic; immunologic</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of different measured assays onboard simultaneously</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>No. of assays programmed and calibrated at one time</td>
<td>1/2/3</td>
<td>1/2/3</td>
<td>1/2/3</td>
</tr>
<tr>
<td>Continuous loading capped and uncapped primary sample tubes</td>
<td>yes/no (15°C ± 2°C)</td>
<td>yes/no (15°C ± 2°C)</td>
<td>yes/no (15°C ± 2°C)</td>
</tr>
<tr>
<td>Continuous loading capped and uncapped primary sample tubes and cups in same rack</td>
<td>180 (2 tests in throughput)/1–10 min. (avg. min.)</td>
<td>180 (2 tests in throughput)/1–10 min. (avg. min.)</td>
<td>180 (2 tests in throughput)/1–10 min. (avg. min.)</td>
</tr>
<tr>
<td>Continuous loading capped and uncapped primary sample tubes and cups in same rack; 10-tube position sample rack</td>
<td>5 spu plasma</td>
<td>5 spu plasma</td>
<td>5 spu plasma</td>
</tr>
<tr>
<td>Instrument connections to transfer information</td>
<td>data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies)</td>
<td>data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies)</td>
<td>data-management system, which in turn connects to LIS or EHR; directly to LIS or EHR; directly to lab automation system; commercial middleware (most major companies)</td>
</tr>
<tr>
<td>Data-management capability/LIS or EHR systems interfaced onboard</td>
<td>yes (reagents and consumables)</td>
<td>yes (reagents and consumables)</td>
<td>yes (reagents and consumables)</td>
</tr>
<tr>
<td>Information that can be barcode-scanned on instrument</td>
<td>specimen identifier, reagent lot No.</td>
<td>specimen identifier, operator identifier, specimen identifier, reagent lot No.</td>
<td>specimen identifier, operator identifier, specimen identifier, reagent lot No.</td>
</tr>
<tr>
<td>How labs get LOINC codes for results</td>
<td>website</td>
<td>website</td>
<td>website</td>
</tr>
<tr>
<td>Time delay from ordering stat to aspiration of sample</td>
<td>1 minute</td>
<td>1 minute</td>
<td>1 minute</td>
</tr>
<tr>
<td>• Factor VIII activity assay</td>
<td>5 minutes/—</td>
<td>5 minutes/—</td>
<td>5 minutes/—</td>
</tr>
<tr>
<td>• Fibrinogen</td>
<td>7 minutes/60 specimens</td>
<td>5 minutes/180 specimens</td>
<td>5 minutes/180 specimens</td>
</tr>
<tr>
<td>• Prothrombin time</td>
<td>7 minutes/60 specimens</td>
<td>5 minutes/90 specimens</td>
<td>5 minutes/90 specimens</td>
</tr>
<tr>
<td>• APTT</td>
<td>5 minutes/12 specimens</td>
<td>5 minutes/50 specimens</td>
<td>5 minutes/50 specimens</td>
</tr>
<tr>
<td>• PT</td>
<td>1 minute</td>
<td>1 minute</td>
<td>1 minute</td>
</tr>
<tr>
<td>Remote testing provided/UPS backup power supply</td>
<td>yes (reagents and consumables)</td>
<td>yes (reagents and consumables)</td>
<td>yes (reagents and consumables)</td>
</tr>
<tr>
<td>Instrument name/First year sold</td>
<td>Sysmex CA-600 Series Systems/2012</td>
<td>Sysmex CS-2500 System/2016</td>
<td>Sysmex CS-5100 System/2016</td>
</tr>
<tr>
<td>List price/Model type</td>
<td>CA-600: $42,000; CA-660: $55,000/22.5 x (195 x 19.5 x 94.8 x 31.8 sq. ft. /3,600,000 (worldwide) daily continuously random access no/yes</td>
<td>$155,000/benchtop 27 x 30.6 x 35.2 x 242.5 sq. ft./7.5 sq. ft./&gt;50,000,000 (worldwide) daily continuously random access no/yes</td>
<td>$205,000/benchtop 50 x 40.6 x 45.3 x 912.8 x 712.8 sq. ft./&gt;100,000,000 (worldwide) daily continuously random access no/yes</td>
</tr>
<tr>
<td>Operational type</td>
<td>Continuous loading capped and uncapped primary sample tubes and cups in same rack, 10-tube position sample rack</td>
<td>Continuous loading capped and uncapped primary sample tubes and cups in same rack, 10-tube position sample rack</td>
<td>Continuous loading capped and uncapped primary sample tubes and cups in same rack, 10-tube position sample rack</td>
</tr>
<tr>
<td>Country where analyzer designed/Manufactured</td>
<td>Japan</td>
<td>Japan</td>
<td>Japan</td>
</tr>
<tr>
<td>Company manufactures instrument</td>
<td>no (manufactured by Sysmex)</td>
<td>no (manufactured by Sysmex)</td>
<td>no (manufactured by Sysmex)</td>
</tr>
<tr>
<td>FDA-approved immunologic tests</td>
<td>— — Innovance D-dimer</td>
<td>— — Innovance D-dimer</td>
<td>— — Innovance D-dimer</td>
</tr>
<tr>
<td>Other FDA-approved tests</td>
<td>— — platelet aggregation von Willebrand factor</td>
<td>— — platelet aggregation von Willebrand factor</td>
<td>— — platelet aggregation von Willebrand factor</td>
</tr>
<tr>
<td>No. of reagent containers held onboard/Reagents ready to use</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>Reagent lot tracking/Reagent information/Reagent refrigerated onboard</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Reagents, consumable loaded without interrupting testing</td>
<td>no</td>
<td>yes (residents and consumables)</td>
<td>yes (residents and consumables)</td>
</tr>
<tr>
<td>Instrument uses proprietary or third-party reagents</td>
<td>user’s option (same capabilities when third-party reagents used) 1 year</td>
<td>user’s option (same capabilities when third-party reagents used) 1 year</td>
<td>user’s option (same capabilities when third-party reagents used) 1 year</td>
</tr>
<tr>
<td>Maximum time same lot number of reagents can be used</td>
<td>1 year</td>
<td>1 year</td>
<td>1 year</td>
</tr>
<tr>
<td>Walkaway capability/Walkaway duration</td>
<td>yes/10 specimens or up to 50 tests yes/50 specimens or up to 500 tests yes/100 specimens or up to 1,000 tests</td>
<td>yes/10 specimens or up to 50 tests yes/50 specimens or up to 500 tests yes/100 specimens or up to 1,000 tests</td>
<td>yes/10 specimens or up to 50 tests yes/50 specimens or up to 500 tests yes/100 specimens or up to 1,000 tests</td>
</tr>
<tr>
<td>Min.–max. specimen volume that can be aspirated at one time</td>
<td>5 µL minimum</td>
<td>5 µL minimum</td>
<td>5 µL minimum</td>
</tr>
<tr>
<td>Min. sample volume required for PT/PTT/Factor VIII activity</td>
<td>50 µL/50 µL/50 µL (standard) reaction tubes, CA clean I and II</td>
<td>50 µL/50 µL/50 µL (standard) reaction tubes, CA clean I and II</td>
<td>50 µL/50 µL/50 µL (standard) reaction tubes, CA clean I and II</td>
</tr>
<tr>
<td>Primary tube sampling supported/Fires caps on primary tubes</td>
<td>yes/no</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>Accommodates most standard tube sizes/Nonstandard sizes</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>Sample barcode-reading capability/Barcode discrimination</td>
<td>no</td>
<td>no/yes (selectable on menus) no</td>
<td>no/yes (selectable on menus) no</td>
</tr>
<tr>
<td>Auto track product volume/Measures number of tests remaining</td>
<td>yes</td>
<td>yes/yes (selectable on menus) no</td>
<td>yes/yes (selectable on menus) no</td>
</tr>
<tr>
<td>Short sample detection</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Dot detection as preanalytical variable in plasma sample</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Auto detects adequate reagents for aspiration or analysis</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Detection or quantitation for hemolysis, turbidity, icterus, lipemia</td>
<td>detection and quantification for hemolysis, turbidity, icterus, lipemia detection and quantification for hemolysis, turbidity, icterus, lipemia detection and quantification for hemolysis, turbidity, icterus, lipemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dilutes patient samples onboard</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Automatic rebus capability/Reus tray testing capability</td>
<td>no/no</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Lag time during which hypercoagulable sample not detected</td>
<td>yes (PT; 7 seconds; PTT; 15 seconds) yes (PT; 7 seconds; PTT; 15 seconds) yes (PT; 7 seconds; PTT; 15 seconds)</td>
<td>yes (PT; 7 seconds; PTT; 15 seconds) yes (PT; 7 seconds; PTT; 15 seconds) yes (PT; 7 seconds; PTT; 15 seconds)</td>
<td>yes (PT; 7 seconds; PTT; 15 seconds) yes (PT; 7 seconds; PTT; 15 seconds) yes (PT; 7 seconds; PTT; 15 seconds)</td>
</tr>
<tr>
<td>User can adjust reagent volumes/Sample volumes</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>User can adjust No. of reagents/Size of reagents</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>User can adjust incubation times/Reading times</td>
<td>yes/yes</td>
<td>yes/yes</td>
<td>yes/yes</td>
</tr>
<tr>
<td>Read time extended for prolonged clotting times</td>
<td>yes (selectable on menus) yes (selectable on menus) yes (selectable on menus)</td>
<td>yes (selectable on menus) yes (selectable on menus) yes (selectable on menus)</td>
<td>yes (selectable on menus) yes (selectable on menus) yes (selectable on menus)</td>
</tr>
<tr>
<td>Autocalibration/Calibrators stored onboard</td>
<td>no/no</td>
<td>yes/yes (selectable on menus) yes/yes (selectable on menus) yes/yes (selectable on menus)</td>
<td>yes/yes (selectable on menus) yes/yes (selectable on menus) yes/yes (selectable on menus)</td>
</tr>
<tr>
<td>Multipoint calibration supported/Recommended frequency</td>
<td>yes/6/months, regulatory guidelines yes/6/months, regulatory guidelines yes/6/months, regulatory guidelines</td>
<td>yes/6/months, regulatory guidelines yes/6/months, regulatory guidelines yes/6/months, regulatory guidelines</td>
<td>yes/6/months, regulatory guidelines yes/6/months, regulatory guidelines yes/6/months, regulatory guidelines</td>
</tr>
</tbody>
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