### COAGULATION ANALYZERS

#### POINT OF CARE, SELF-MONITORING

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>First year sold</th>
<th>CoaguSense PT/INR Monitoring System 2010</th>
<th>Cascade Abraão 2014 (EU/CE; 510(k) submitted to FDA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>i-STAT 1</td>
<td>2000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| No. of units sold in U.S./Outside U.S. | —                |                                        |                                                  |
| No. of units sold in 2017              | —                |                                        |                                                  |
| Country where analyzer designed/Manufactured | U.S./Canada           |                                      | U.S./A.I.S.                                      |
| Is instrument POC or self-monitoring analyzer? | POC                |                                      | POC                                             |
| Specimen type                        | fresh whole blood from arterial, venous, or skin puncture | fingerstick                        | fingerstick, venipuncture (whole blood, anticoagulated whole blood, plasma) |
| Model type                           | handheld/ portable |                                               | handheld/ portable                             |
| Dimensions in (H × W × D)/Weight     | 9.25 × 3.03 × 2.85/22.56 oz |                                               | 3 × 6.5 × 5.75/1.2 lb (with 4 AA 1.5V alkaline batteries) |
| Specimen volume needs                | 17 µL–95 µL       |                                               | 10 µL via cap sample transfer tube              |
| Clotting-based tests for which device has FDA-cleared applications | PT-INR, ACT kaolin, ACT celite |                                               | PT (reportable range—low: 7 seconds; high: 180 seconds; INR—low: 0.8 seconds; high: 8.0 seconds) |
| Tests using other methodologies for which device has FDA-cleared applications | chemistries/electrolytes (sodium, potassium, chloride, TC02, anion gap, ionized calcium, glucose, urea nitrogen, creatinine, lactate); hematology (hematocrit, hemoglobin); blood gases (pH, PC02, P02, TC02, HCO3, base excess, so2); cardiac markers (cTnl, CK-MB, BNP), β-hCG |                                               |                                               |
| FDA-cleared tests but not yet clinically released | —                |                                        | PT-G, APTT, c-APT, c-APT-LR, direct thrombin inhibitors, LMWH, fibrinogen, heparin titration, protamine titration, direct oral anticoagulants (DOACs) |
| Tests submitted for 510(k) clearance | —                |                                        |                                                 |
| Tests in development but not yet submitted for clearance | —                |                                        |                                                 |

#### Method of endpoint detection

- **Quality control methods**
  - Electronic: yes
  - Liquid: yes
  - Lyophilized: yes (plasma)
  - Integrated QC with each analysis: yes
  - Automatic lockout for QC failure: —
  - Other: —

- **Time (in minutes) to perform control plus specimen test**
  - PT: >3
  - PT and PTT: —
  - ACT: >3

- **Data-management capability**
  - Includes QC: yes
  - System can automatically transfer data to information system: yes
  - Patient data: yes
  - QC data: yes
  - Interface supplied by instrument vendor: yes
  - Commercially available systems for which interfaces are up and running in active user sites: Sunquest, Cerner, SCC Soft Computer, McKesson, Meditech, GE, Siemens, Vista, more
  - LOINC codes transmitted with results: no
  - How labs get LOINC codes for reagent kit: package insert
  - Lab can control analyzer remotely: yes

- **Real-time wireless linkage to LIS or HIS**
  - yes

- **Positive identification system (e.g. barcode) for:**
  - Patient specimen: yes
  - Reagent: yes

- **Onboard system for automatic error detection**
  - yes

- **Training provided with instrument purchase**
  - yes (on site)

- **Approximate number of training hours needed for:**
  - Medical staff: 1
  - Patient: 1
  - Patient self-testing program is available: yes, available through IDTF

- **Instrument list price**
  - Reagent rental or lease only: no
  - Cost per sample:
    - PT: for reagent rental: —
    - PT: for reagent rental: —
    - ACT: for reagent rental: —
  - CLIA ’88 complexity rating: moderate

- **Distinguishing features (supplied by company)**

  - broad testing menu; many data-management and interfacing options; easy to use; integrated wireless capability for real-time transmission to EMR
  - directly detects clot formation; emulates WHO reference tilt-tube method using micromechanical means of clot detection; system not affected by low hemoglobin or hematocrit levels; % CVs of 2.5%; runs true plasma controls with the actual thromboplastin and plasma of known INR; two levels of controls included with each box of strips; individually wrapped, nonrefrigerated, barcoded test strips with 24-month dating and IS of 1.0
  - uses a card-based technology that affords a smaller reagent storage footprint; true smart-card type technology by using a 2D barcode labeling system; incorporates enabling technology in an ergonomic package; running a test is user friendly, requiring only 3 steps: scan the reagent card barcode, insert the reagent card, present the sample via hanging drop; digital device offers versatility and features unique to its class, such as a color touchscreen monitor and connectivity via USB configuration or wireless (such as Wi-Fi and Bluetooth)

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**Note:** a dash in lieu of an answer means company did not answer question or question is not applicable.
### Instrument name
- **Actalyke Mini II**
- **Actalyke XL**
- **Hemochron Signature Elite**

### First year sold
- 2004
- 2002
- 2005

### No. of units sold in U.S./Outside U.S.
- >450–5,000
- >300–400
- 10,000/5,000

### No. of units sold in 2017
- —
- —
- 2,000

### Country where analyzer designed/Manufactured
- U.S./U.S.
- U.S./U.S.
- U.S./U.S.

### Is instrument POC or self-monitoring analyzer?
- POC
- POC
- POC

### Specimen type
- venipuncture (whole blood)
- venipuncture (whole blood)
- —

### Model type
- portable
- portable
- handheld/portable

### Dimensions in inches (H × W × D)/Weight
- 4.8 × 6.1 × 6.3/5.3 lb
- 8 × 10.7 × 12/15 lb
- 2 × 7.5 × 3.7/1.2 lb

### Clotting-based tests for which device has FDA-cleared applications
- activated clotting time (whole blood), MAX-ACT, celite, kaolin, glass
- activated clotting time (whole blood), MAX-ACT, celite, kaolin, glass
- PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR

### Tests using other methodologies for which device has FDA-cleared applications
- —
- —
- —

### Tests FDA-cleared but not yet clinically released
- —
- —
- —

### Tests submitted for 510(k) clearance
- —
- —
- —

### Tests in development but not yet submitted for clearance
- —
- —
- —

### Method of endpoint detection
- two-point electromechanical soft-clot detection principle
- two-point electromechanical soft-clot detection principle
- optical mechanical true endpoint clot detection

### Quality control methods
- Electronic: yes
- Liquid: yes
- Lyophilized: yes
- Integrated QC with each analysis: yes
- Automatic lockout for QC failure: yes
- Other: data management for enterine heparin dose, L-J chart generation for all controls

### Time (in minutes) to perform control plus specimen test
- PT: 5
- PT and APTT: 2
- ACT: 4.5

### Data-management capability
- Includes QC: yes
- Patient data: yes
- QC data: yes
- Interface specifications supplied, POCT1-A compliant: yes
- Commercially available systems for which interfaces are up and running in active user sites: Telcor OML, Alere RALS-Web 3, Aegis POC, Corworks UnPQC
- LOINC codes transmitted with results: no
- How labs get LOINC codes for reagent kit: email query
- QC data: yes
- Patient data: yes
- System can automatically transfer data to information system: yes
- Onboard: yes

### Positive identification system (e.g. barcode) for:
- Patient specimen: yes
- Reagent: yes
- Onboard: yes, for stuck magnet, printer problems

### Onboard system for automatic error detection
- yes

### Training provided with instrument purchase
- yes (on site)
- yes (on site)
- yes (on site)

### Approximate number of training hours needed for:
- Medical staff: 1
- Patient: 1–2
- Patient self-testing program is available: <1

### Instrument list price
- $1,107–$1,442
- $4,114
- inquire

### Reagent rental or lease only
- purchase, lease, or reagent rental
- purchase, lease, or reagent rental
- purchase and usage agreement available (reagent rental)

### Cost per sample:
- PT: for reagent rental if device purchased
- PTT: for reagent rental if device purchased
- ACT: for reagent rental if device purchased
- $0.74–$1.76

### CLIA '88 complexity rating
- nonwaived
- moderate
- moderate

### Distinguishing features (supplied by company)
- two-point electromechanical soft-clot detection; magnetic detection device—electronic QC/revolution; MAX-ACT tubes, 0.5 mL volume and linear to 6 U/mL; linear to upper 10 units of heparin; safer plastic tube construction, for use on Actalyke and Hemochron instruments; electronic clotting tube that simulates and mimics actual blood-clot formation for accurate ECT challenges; integrated printer; 3.5-inch diskette storage
- two-point electromechanical soft-clot detection principle; MAX-ACT test, 0.5 mL blood volume, linear to upper 10 units of heparin; safer plastic tube construction, for use on Actalyke and Hemochron instruments; electronic clotting tube that simulates and mimics actual blood-clot formation for accurate ECT challenges; integrated printer; 3.5-inch diskette storage

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All information is supplied by the companies listed. The tabulation does not represent an endorsement by the CAP. See captodayonline.com/productguides for an interactive version of guide.
### COAGULATION ANALYZERS

#### POINT OF CARE, SELF-MONITORING

| Instrument name          | First year sold | No. of units sold in U.S./Outside U.S. | Country where analyzer designed/Manufactured | Is instrument POC or self-monitoring analyzer? | Dimension in inches (H × W × D)/Weight | Is instrument POC or self-monitoring analyzer? | No. of units sold in 2017 | Tests submitted for 510(k) clearance | Tests in development but not yet submitted for clearance | Method of endpoint detection | Data-management capability | System can automatically transfer data to information system | Interface supplied by instrument vendor | Commercially available systems for which interfaces are up and running in active user sites | LOINC codes transmitted with results | How labs get LOINC codes for reagent kit | Lab can control analyzer remotely | Real-time wireless linkage to LIS or HIS | Positive identification system (e.g. barcode) for: | Onboard system for automatic error detection | Training provided with instrument purchase | Approximate number of training hours needed for: | Instrument list price | Reagent rental or lease only | Cost per sample | Distinguishing features (supplied by company) |
|-------------------------|-----------------|---------------------------------------|---------------------------------------------|-----------------------------------------------|---------------------------------------|---------------------------------------------|--------------------------|-------------------------------|-------------------------------------------------|-----------------------------|---------------------------------|---------------------------------------------|----------------------------------------|-------------------------------------------------|---------------------------------|-------------------------------------------|------------------------------------------|---------------------------------|---------------------------------|-------------------------------------------|
| Hemochron Response      | 2000            | 1,000/2,000                           | U.S./U.S.                                  | POC                                           | 8.7 × 10.5 × 7.5/6.4 lb               | POC                                         | 400                      |                                |                                  | mechanical clot detection          | onboard                         | yes                             | yes                          | Telcor QML, Alere RALS-Web 3, Aegis POC, Conworks UniPOC | no                          | email query                        | no                                      | no                          | no                                      | no                                      | no                          | no                                      | yes (on site)                  | 1–2                              | inquire purchase and usage agreement available (reagent rental) | $4,400 purchase and rental available | $20,000 purchase and rental available | QC lockout; data-management storage; connectivity options; RoXa heparin/protamine dosing system | data-management software application; duplicate test results; optional barcode scanner; optional easy filling accessory; ACT Plus Education Program CD | automated sample dispensing; constant temperature control; multiple testing capability; heparin dose response; heparin protamine titration; high-range ACT; optional barcode scanner; optional data-management software; HMS Plus Education Program CD |
### COAGULATION ANALYZERS

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### POINT OF CARE, SELF-MONITORING

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>First year sold</th>
<th>CoaguChek Vantus System 2018</th>
<th>CoaguChek XS Pro PT Test System 2010</th>
<th>CoaguChek XS Plus PT Test System 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche Diagnostics</td>
<td>Chris Grams</td>
<td><a href="mailto:Christopher.grams@roche.com">Christopher.grams@roche.com</a></td>
<td>Indianapolis, IN</td>
<td>317-521-2000</td>
</tr>
<tr>
<td>Roche Diagnostics</td>
<td>Chris Grams</td>
<td><a href="mailto:Christopher.grams@roche.com">Christopher.grams@roche.com</a></td>
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<td>Indianapolis, IN</td>
<td>317-521-2000</td>
</tr>
</tbody>
</table>

#### No. of units sold in U.S./Outside U.S.
- No. of units sold in 2017
  - No.

#### Country where analyzer designed/Manufactured
- Germany/Germany

#### Is instrument POC or self-monitoring analyzer?
- POC

#### Specimen type
- fresh whole blood (fingerstick capillary)

#### Model type
- handheld/porable

#### Dimensions in inches (H × W × D)/Weight
- 5.7 × 2.95 × 1.135 g / 135 g
- 9.09 × 3.89 × 1.65/12.35 oz
- 7.28 × 3.89 × 1.65/12.35 oz

#### Clotting-based tests for which device has FDA-cleared applications
- INR (0.8–6.0)
- INR (0.8–8.0), PT seconds, % quick
- INR (0.8–8.0), PT seconds, % quick

#### Tests using other methodologies for which device has FDA-cleared applications
- no

#### FDA-cleared tests but not yet clinically released
- no

#### Tests submitted for 510(k) clearance
- no

#### Tests in development but not yet submitted for clearance
- no

#### Method of endpoint detection
- amperometric detection
- amperometric detection
- amperometric detection

#### Quality control methods
- **Electronic**
  - no (not required, onboard QC)
  - yes (not required, onboard QC)
  - yes (not required, onboard QC)

#### System can automatically transfer data to information system
- yes

#### Data-management capability
- no

#### Interface supplied by instrument vendor
- yes

#### Commercially available systems for which interfaces are up and running in active user sites
- Roche cobas IT 1000, Alere RALS-Plus, Telcor OML

#### LOINC codes transmitted with results
- no

#### How labs get LOINC codes for reagent kit
- no

#### Lab can control analyzer remotely
- no

#### Real-time wireless linkage to LIS or HIS
- no

#### Positive identification system (e.g. barcode) for:
- no

#### Onboard system for automatic error detection
- yes

#### Training provided with instrument purchase
- no

#### Approximate number of training hours needed for:
- no

#### Patient self-testing program is available
- no

#### Instrument list price
- no

#### Reagent rental or lease only
- no

#### Cost per sample:
- no

#### CLIA ‘88 complexity rating
- CLIA waived

#### Distinguishing features (supplied by company)
- designed specifically for patient self-testing: transmit test results wirelessly via compatible smartphone or tablet application; program customizable INR target range, set test reminders; performs onboard QC and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; top or side dosing; results in 1 minute or less; icon-driven color screen interface, memory of 2,000 patient and 500 optional liquid QC tests, ability to add comments with each patient and liquid quality control test; integrated barcode scanner able to scan operator and patient IDs

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

#### Instrument name
- CoaguChek XS PT Test System 2006 (outside U.S./2007/0.5)
- Xprecia Stride Coagulation Analyzer 2015 (outside U.S.)

#### First year sold

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>First year sold</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>2006 (outside U.S./2007/0.5)</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>2015 (outside U.S.)</td>
</tr>
</tbody>
</table>

#### Country where analyzer designed/Manufactured

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<thead>
<tr>
<th>Instrument name</th>
<th>Country where analyzer designed/Manufactured</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>Germany/Germany</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>Australia/Malaysia</td>
</tr>
</tbody>
</table>

#### Tests using other methodologies for which device has FDA-cleared applications

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Tests using other methodologies for which device has FDA-cleared applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>鲜 whole blood (venous or fingerstick capillary)</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>Fingerstick handheld/portable</td>
</tr>
</tbody>
</table>

#### Dimensions in inches (H x W x D)/Weight

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Dimensions in inches (H x W x D)/Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>5.43 x 3.07 x 1.10/4.8 oz</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>6.7 x 2.8 x 1.6/10.8 oz (with batteries)</td>
</tr>
</tbody>
</table>

#### Clotting-based tests for which device has

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<thead>
<tr>
<th>Instrument name</th>
<th>Clotting-based tests for which device has</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>INR (0.8-8.0), PT seconds, % quick</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>PT (INR 0.8-4.5)</td>
</tr>
</tbody>
</table>

#### Method of endpoint detection

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Method of endpoint detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>amperometric detection</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>electrochemical technology with amperometric (electric current) detection of thrombin activity</td>
</tr>
</tbody>
</table>

#### Positive patient identification products

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Positive patient identification products</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>Innovin reagent and liquid QC, barcode scanner offers fast, accurate patient and operator ID entry with optional manual entry on touchscreen</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>Detects test-strip degradation due to exposure to environmental conditions; electronic, signal, software, and memory integrity checks; performs various checks along the entire testing procedure to ensure process integrity</td>
</tr>
</tbody>
</table>

#### Training provided with instrument purchase

<table>
<thead>
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<th>Training provided with instrument purchase</th>
</tr>
</thead>
<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>Medical staff: 1</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>Patient self-testing program is available: yes</td>
</tr>
</tbody>
</table>

#### Distinguishing features (supplied by company)

<table>
<thead>
<tr>
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<th>Distinguishing features (supplied by company)</th>
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<tbody>
<tr>
<td>CoaguChek XS PT Test System</td>
<td>Performs onboard quality control and determines patient results in a single test chamber; neutralizes therapeutic levels of heparin and LMWH; INR corrected for hematocrit within specified range; top or side dosing; results in 1 minute or less</td>
</tr>
<tr>
<td>Xprecia Stride Coagulation Analyzer</td>
<td>Moderately complex usability; touchscreen features include bright-color interface with step-by-step instructions, display shows clear, easy-to-read results, lot calibration is simple using integrated barcode scanner; safety: test-strip eject button, operator lockout feature, data transfer occurs seamlessly and securely via USB connection; accuracy: Xprecia PT/INR test strips and Siemens’ central lab analyzers use same Dade Innovin reagent and liquid QC, barcode scanner offers fast, accurate patient and operator ID entry with optional manual entry on touchscreen</td>
</tr>
</tbody>
</table>

#### Notes
- A dash in lieu of an answer means company did not answer question or question is not applicable.