For home or POC use, a variety of options

Anne Ford

Something about springtime impels everyone to clean, organize, and consolidate. To wit: Hormone Serase’s redesigned, streamlined test strip package for its INRatio PT/INR monitoring system. “A new packaging design will be introduced mid-2006,” says David Phillips, vice president of marketing. “The reduced test strip box size will allow easier storage, handling, and convenience.” Another change in the name of efficiency is the system’s recently modified test strip dosing area, which, Phillips says, “provides increased visibility for users applying the test sample.”

Many of the other vendors in this month’s instrumentation survey, which features point-of-care and self-monitoring coagulation analyzers, echo these sentiments of efficiency. Roche’s CoagChek System family of analyzers, says Randy Pritchard, manager of segment marketing for near-patient testing, “offers the fastest test time and lowest sample size available to the patient and professional markets.” Recently added to the CoaguChek ranks in Europe is the CoaguChek XS; “we are actively working to make it available to the U.S. market,” Pritchard says.

International Technidyne Corp. has scheduled the release of a new ProTime instrument for this spring. The product “has a new design along with several key software enhancements,” says marketing manager Kathy Kornafel. “Several of these new features benefit the professional as well as the patient self-tester.” Features include the ability to auto-send results to a printer or computer; the new ProTime also accepts and stores patient and operator IDs. Kornafel says that the new ProTime is designed to enhance user ease and convenience, increase results-reporting efficiency, and reduce transcription errors.

She adds that the patient self-testing market is trending toward small instruments that are easy to use, requiring a small sample size, and providing quick results. “Not to forget low cost!” she adds. “I believe the glucose monitors have set the standard, and people expect Counoedin monitors to follow.”

Meanwhile, Instrumentation Laboratory continues to offer its Gem PCL Plus Coagulation Laboratory, a portable, whole-blood system that can be used in point-of-care settings and in tandem with the company’s Gem Premier 3000 analyzer in the laboratory. The company calls the PCL Plus easy to use and maintenance-free, adding that the system offers fully automated sample measuring and mixing and is designed to handle fresh or citrated whole-blood samples.

CAP TODAY’s survey of point-of-care and self-monitoring coagulation analyzers includes products from the manufacturers cited above and from Abbott Point of Care, Helena Point of Care, and Medtronic Cardiac Surgery. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.

Anne Ford is a writer in Chicago.
## Coagulation analyzers (point of care, self-monitoring)

### Table of Specifications

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>i-STAT</th>
<th>Actalyke XL</th>
<th>Actalyke Mini II</th>
</tr>
</thead>
<tbody>
<tr>
<td>First year sold</td>
<td>1992</td>
<td>2000</td>
<td>2004</td>
</tr>
<tr>
<td>No. of units sold in U.S./Outside U.S.</td>
<td>— / —</td>
<td>2000+ / 1000+</td>
<td>750+ / 900+</td>
</tr>
<tr>
<td>No. of units sold in 2005</td>
<td>— / —</td>
<td>1500+</td>
<td>2000+</td>
</tr>
<tr>
<td>Country where analyzer designed/Manufactured</td>
<td>— / —</td>
<td>U.S. / ILS</td>
<td>U.S. / ILS</td>
</tr>
<tr>
<td>Is instrument POC or self-monitoring analyzer?</td>
<td>— / —</td>
<td>POC / POC</td>
<td>POC</td>
</tr>
<tr>
<td>Specimen type</td>
<td>Fingerstick, venipuncture (whole blood, anticoagulated whole blood)</td>
<td>Venipuncture (whole blood)</td>
<td>Venipuncture (whole blood)</td>
</tr>
<tr>
<td>Model type</td>
<td>Handheld/portable</td>
<td>Portable</td>
<td>Benchtop</td>
</tr>
<tr>
<td>Dimensions (H x W x D)/Weight</td>
<td>8.25 x 2.52 x 2.06/18.34 oz</td>
<td>5.6 x 10.7 x 10.3/15 lb</td>
<td>6.25 x 6 x 5/6.3 lb</td>
</tr>
</tbody>
</table>

- **Clotting-based tests for which device has FDA-cleared applications**
  - PT/INR, HcG ACT, Kaolin ACT
  - activated clotting time (ACT)—whole blood, MAX-ACT: maximum factor XII activation ACT, cor ties, kaolin, glass
  - ACT—MAX-ACT, C-ACT, H-ACT, 6-ACT

- **Tests using other methodologies for which device has FDA-cleared applications**
  - Blood gases, electrolytes, chemistry
  - None

- **FDA-cleared tests but not yet clinically released**
  - None

- **Tests submitted for 510(k)/clearance**
  - None

- **Tests in development but not yet submitted for clearance**
  - PT, PT & PTT

<table>
<thead>
<tr>
<th>Method of endpoint detection</th>
<th>Electrostatic</th>
<th>Two-point electromechanical soft-clot detection</th>
<th>Two-point electromechanical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality control methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Electronic</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>• Liquid</td>
<td>Yes</td>
<td>Yes (simulated whole blood)</td>
<td>Yes (simulated whole blood)</td>
</tr>
<tr>
<td>• Lyophilized</td>
<td>Yes</td>
<td>Yes (simulated whole blood)</td>
<td>Yes (simulated whole blood)</td>
</tr>
<tr>
<td>• Integrated QC with each analysis</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>• Automatic lockout for QC failure</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>• Other</td>
<td>N/A</td>
<td>Data management for entering heparin dose, L-J chart generation for all controls</td>
<td>—</td>
</tr>
</tbody>
</table>

- **Time (in minutes) to perform control plus specimen test**
  - PT: 2 min
  - PT & PTT: 2 min
  - ACT: 2 min

- **Data management capability**
  - Excluded & optional add-on (SW mfr: i-STAT)
  - Yes (L-J plots)
  - Yes
  - Yes (L-J charts by level/well)

- **System can automatically transfer data to information system**
  - Includes QC
  - No

- **Interface supplied by instrument vendor**
  - Yes (additional cost)
  - Interface specifications supplied, PCTTA compliant

- **LOINC codes transmitted with results**
  - No

- **How labs get LOINC codes for reagent kit**
  - None

- **Commercially available systems for which interfaces are up and running in active user sites**
  - Cerber, Micros, McKesson, CitiCation, Medtech, others

- **Lab can control analyzer remotely**
  - Yes

- **Real-time wireless linking to LIS or HIS**
  - Yes (infrared)

- **Positive identification system (e.g. bar code) for:**
  - Patient specimen
  - Yes, any disposable bar code for identification with use on any Actalyke model
  - Reagent
  - Yes

- **Onboard system for automatic error detection**
  - Yes, for sample (volume), reagent/cartridge error
  - Yes, stuck magnet, no tube; mechanical instrument parameter only: well rotation, temperature, and detection settings

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

- **Instrument list price**
  - $8,000
  - $8,295
  - $8,495

- **Reagent rental or lease only**
  - Yes

- **Cost per sample for reagent rental**
  - PT: $0.74–$1.76
  - PT: $0.74–$1.76
  - ACT: $0.74–$1.76

- **Cost per sample if device purchased**
  - $1,059 (battery only)–$1,249 (with printer and battery)

- **Unique advantages (provided by the vendor)**
  - Handheld
  - QC lockout/operator lockout

Tabulation does not represent an endorsement by the College of American Pathologists.
## Coagulation analyzers (point of care, self-monitoring)

**Part 3 of 5**

### Instrument name
- **HemoSense Inc.**
  - David Phillips
  - 681 River Oaks Parkway
  - San Jose, CA 95134
  - 408-719-1393
  - www.hemosense.com

- **Gem PCG Plus (Portable Coagulation Laboratory)**
  - Elizabeth Walsh
  - ewalsh@ilww.com
  - 101 Hartwell Ave.
  - Lexington, MA 02421
  - 781-861-4165
  - www.ilww.com

- **ProTime Microaspiration System**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Gem PCG Plus (Portable Coagulation Laboratory)</th>
<th>ProTime Microaspiration System</th>
</tr>
</thead>
<tbody>
<tr>
<td>First year sold</td>
<td>2003</td>
<td>2009</td>
</tr>
</tbody>
</table>

| No. of units sold in U.S. | 30,000 |
| No. of units sold in 2005 | 5,000  |
| Country where analyzer designed/Manufactured | U.S. |
| Onboard system for automatic error detection | yes |
| Specimen type | POC & self-monitoring analyzer |
| Model type | hand-held/portable |
| Dimensions (W x H x D) | 6.125 x 3 x 2.2 in/1.1 oz |
| Specimen volume needs | accurate volume not necessary (drop): ~15 µL |

### Clotting-based tests for which device has FDA-cleared applications
- **PT** (reportable range: low 7 sec, high 75 sec; INR: low 0.7, high 7.5)
- **APTT** (reportable range: 30–200 sec, ACT: low 150 sec, ACT: low 7–400 sec)

| Tests using other methodologies for which device has FDA-cleared applications | none |
| Clauss method | none |
| Tests submitted for 510(k) clearance | none |
| Tests in development but not yet submitted for clearance | none |

### Method of endpoint detection
- Electrochemical detection, change in impedance as sample clot
- Mechanical endpoint clotting mechanism, monitored optically

### Quality control methods
- **Electronic**
  - no (not required, built-in 2-level QC on each strip)
  - yes (simulated whole blood)
- **Liquid**
  - no (not required, onboard QC)
  - yes (available as an option but not required due to onboard controls)
- **Lyo phosphorylated**
  - no
  - yes
- **Integrated QC with each analysis**
  - no
  - yes
- **Automatic lockout for QC failure**
  - no
  - yes
- **Other**
  - no
  - n/a
  - 2 levels of onboard QC integrated into each cuvette

### Time (in minutes) to perform control plus specimen test
- **PT**
  - <2
  - 1–5
- **PT & APTT**
  - <5
  - <5
- **ACT**
  - 1 hr

### Data management capability
- Includes QC system
- Can automatically transfer data to information system
- Patient data
  - yes
- QC data
  - yes
- Communication cable available
  - yes
- LOINC codes transmitted with results
  - no
- Communication cable available
  - no
- Commercially available systems for which interfaces are up and running in active user sites
  - no
  - n/a
- Lab control analyzer required
  - no

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

### Positive identification system (e.g. bar code) for:
- **Patient specimen**
  - no
  - yes
- **Reagent**
  - no
  - yes

### Onboard system for automatic error detection
- yes, for sample (volume), reagent, and instrument
- yes, for sample (volume), reagent, and instrument
- yes, for sample (volume) and reagent/cuvette expiration date

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

### Instrument test price
- **Reagent rental or lease only**
  - no
  - n/a
  - yes
- **Cost per sample for reagent rental**
  - $1.05/prf; $1.95/self-test
  - varies with volume
  - varies with volume
- **Cost per sample if device purchased**
  - $5.50/prf/self-test
  - varies with volume
  - varies with volume
- **PTT**
  - $3.50/prf/self-test
  - varies with volume
  - varies with volume
- **ACT**
  - $3.50/prf/self-test
  - varies with volume
  - varies with volume
- **Cost per sample if device purchased**
  - $5.50/prf/self-test
  - varies with volume
  - varies with volume

### Unique advantages (provided by the vendor)
- onboard QC—2 levels of quantitative controls with results
- very simple test procedure
- human recombinant thromboplastin (B1.8)
- non-refrigerated test strips
- Gem PCL Plus can be used in conjunction with the Gem Premier 3000, consolidating ISTH/ISU/GluAc
- Hct testing
- comprehensive POC coagulation menu that allows for POC coagulation analysis throughout an institution, whole blood PT, citrate PT, APTT, ACT, and ACT low range
- onboard data management
- mandatory operator ID and patient ID options
- 2 levels of integral reagent control automatically run with each patient
- Instrument control checks verify optical, electrical, and mechanical functions—no further calibration required
- sensitive thromboplastin reagent (B1.8), as recommended by AHA, CAP, and NHQ
- results in less than 5 min
- 10-hour room temperature open pouch stability of cuvette
- bar-coded cuvette—no coding necessary
- accepts and stores patient ID/operator ID
- automatically sends test results to printer, computer, LIS
- both onboard and external controls available

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## Coagulation analyzers (point of care, self-monitoring)

### Part 4 of 5

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>HEMOCHEL Jr.—Signature/Signature+</th>
<th>HEMOCHEL Response</th>
<th>HEMOCHEL Signature Elite</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of units sold in U.S./Outside U.S.</td>
<td>—/—</td>
<td>—/—</td>
<td>—/—</td>
</tr>
<tr>
<td>No. of units sold in 2005</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>• units sold to:</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>• Specimen type POC</td>
<td>POC</td>
<td>POC</td>
<td>POC</td>
</tr>
<tr>
<td>• Dimensions in inches (H x W x D)/Weight 2 x 7.5 x 3.75/12 oz</td>
<td>8.7 x 16.5 x 7.96.4 lb</td>
<td>2 x 15.5 x 3.75/2 lb</td>
<td></td>
</tr>
<tr>
<td>• Specimen volume needed accurate volume needed (fill line in cuvette sample well)</td>
<td>accurate volume required (fill line on tubes)</td>
<td>accurate volume needed (fill line in cuvette sample well)</td>
<td></td>
</tr>
<tr>
<td>• Clotting-based tests for which device has FDA-cleared applications PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR</td>
<td>ACT, (FTCA610, KACT, PZ14), HITT, TT, Th, KBT, K2E, KSP, PAOK, PDOK, PT, APTT, citrated</td>
<td>PT, APTT, PT citrate, APTT citrate, ACT+, ACT-LR</td>
<td></td>
</tr>
<tr>
<td>• Tests using other methodologies for which device has FDA-cleared applications none</td>
<td>none</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>• FDA-cleared tests but not yet clinically released none</td>
<td>none</td>
<td>none</td>
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<tr>
<td>• Tests submitted for 510(k) clearance none</td>
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<tr>
<td>• Tests in development but not yet submitted for clearance none</td>
<td>none</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>• Method of endpoint detection optical detection of clot</td>
<td>mechanical clot detection</td>
<td>optical detection of clot</td>
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</tr>
<tr>
<td>• Quality control methods</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Electronic yes</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• Liquid yes (simulated whole blood)</td>
<td>yes (simulated whole blood)</td>
<td>yes (simulated whole blood)</td>
<td></td>
</tr>
<tr>
<td>• Lyophilized yes (simulated whole blood)</td>
<td>yes (simulated whole blood)</td>
<td>yes (simulated whole blood)</td>
<td></td>
</tr>
<tr>
<td>• Integrated QC with each analysis no</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• Automatic lockout for QC failure</td>
<td>Signature, etc, Signature+, yes</td>
<td>operator lockout</td>
<td>operator lockout</td>
</tr>
<tr>
<td>• Other</td>
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<td>• Time (in minutes) to perform control specimen test</td>
<td>2</td>
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</tr>
<tr>
<td>• PT: 2</td>
<td>2</td>
<td>2</td>
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</tr>
<tr>
<td>• PT &amp; PTT: 2</td>
<td>2</td>
<td>2</td>
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</tr>
<tr>
<td>• ACT: 1-5</td>
<td>1-5</td>
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</tr>
<tr>
<td>• Data management capability</td>
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<tr>
<td>• System can automatically transfer data to information system yes</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• Patient data yes</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• QC data yes</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• Interface supplied by instrument vendor yes</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• LOINC codes transmitted with results</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>• How labs get LOINC codes for reagent kit</td>
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<td>• Commercially available systems for which interfaces are up and running in active user sites yes</td>
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<td>yes</td>
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<tr>
<td>• Lab can control analyzer remotely no</td>
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<td>no</td>
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<tr>
<td>• Real-time wireless links to LIS or HIS no</td>
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<td>no</td>
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<tr>
<td>• Positive identification system (e.g. bar code) for:</td>
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</tr>
<tr>
<td>• Patient specimen no</td>
<td>no</td>
<td>no</td>
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</tr>
<tr>
<td>• Reagent yes</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• Onboard system for automatic error detection yes, for sample (volume)</td>
<td>yes, for sample (volume) and reagent/expiration date</td>
<td>yes, for sample (volume) and reagent/expiration date</td>
<td></td>
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<tr>
<td>• Training provided with instrument purchase yes (on site)</td>
<td>yes (on site)</td>
<td>yes (on site)</td>
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<tr>
<td>• Approx. No. of training hours needed for:</td>
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<td></td>
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</tr>
<tr>
<td>• Medical staff 1 hr</td>
<td>1-2 hr</td>
<td>1 hr</td>
<td></td>
</tr>
<tr>
<td>• Patient n/a</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>• Patient self-testing program is available yes</td>
<td>yes</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>• Instrument list price Signature, $3,005; Signature+, $5,100</td>
<td>$4,095</td>
<td>$7,990</td>
<td></td>
</tr>
<tr>
<td>• Reagent rental or lease only no</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>• Reagent Cost per sample for:</td>
<td>Cost per sample for:</td>
<td>Cost per sample for:</td>
<td>Cost per sample for:</td>
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<tr>
<td>• PT: Cost per sample for rent</td>
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<td>• PTT: Cost per sample for rent</td>
<td>$/100</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>• ACT: Cost per sample for rent</td>
<td>$/100</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>• Cost per sample if device purchased no</td>
<td>no</td>
<td>no</td>
<td></td>
</tr>
<tr>
<td>• CLIA ‘98 complexity rating moderate</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>• Unique advantages (provided by the vendor)</td>
<td>• blood volume—15 µL</td>
<td>• QC lockout</td>
<td>• new compliance technology</td>
</tr>
<tr>
<td></td>
<td>• ease of use</td>
<td>• data storage and management</td>
<td>• QC lockout</td>
</tr>
<tr>
<td></td>
<td>• data management storage and printing</td>
<td>• connectivity options</td>
<td>• data management storage and printing</td>
</tr>
</tbody>
</table>
| | • connectivity options | • adaptation to apheresis 
| | • configure QC and operator lockout for Signature+ | • connectivity options | • blood volume—15 µL |
| | • new completeness technology | | • ease of use |
| | • configurable QC and operator lockout | | |

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### Coagulation analyzers (point of care, self-monitoring)

#### Medtronic Cardiac Surgery
- **Instruments**
  - HXS Plus
  - ACT Plus

#### Roche Diagnostics Corp.
- **Instruments**
  - CoaguChek S System for Prothrombin Time Testing (professional use)

### Instrument Name
- **HXS Plus**
- **ACT Plus**

#### First Year Sold
- 1999
- 2003

### No. of units sold in U.S.
- 89
- 336

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

#### What is is instrument POC or self-monitoring analyzer?
- POC
- POC

#### Specimen type
- venipuncture (white blood)
- venipuncture (white blood)

#### Model type
- benchtop
- benchtop

#### Dimensions in inches (H x W x D)/Weight
- 15.7 x 15 x 13/4 lb
- 11 x 6 x 13/4 lb

#### Required training
- 1 hr
- 1 hr

### Cost per Sample
- ACT: Cost per sample for reagent rental
- PT: Cost per sample for reagent rental

#### Cost per Sample for:
- Reagent rental or lease only
- Instrument list price
- Patient self-testing program is available

### Method of endpoint detection
- mechanical clot detection
- mechanical clot detection

#### Quality control methods
- Yes
- Yes

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

#### Interface supplied by instrument vendor
- Yes
- Yes

#### LOINC codes transmitted with results
- Yes
- Yes

#### Lab can control analyzer remotely
- No
- Yes

### Data management capability
- Yes
- Yes

#### Lab to control analyzer remotely
- No
- No

### Time (in minutes) to perform control plus specimen test
- PT: 1 hr
- PT & PTT: 1 hr

#### Tests submitted for 510(k) clearance
- None
- None

### QC data
- Yes
- Yes

#### CLIA waived for professional use
- Yes
- Yes

### Positive identification system (e.g. bar code) for:
- Reagent
- Patient specimen

#### Sample type
- Venipuncture
- Venipuncture

### Method of endpoint detection
- None
- None

#### Method of endpoint detection
- Particle movement with clot formation
- Particle movement with clot formation

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

### Positive identification system (e.g. bar code) for:
- Patient specimen
- Reagent

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

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

#### Instrument list price
- $26,000
- $4,200

#### Contact Roche Diagnostics sales
- 800-328-3320
- 800-328-3320

### Unique advantages (provided by the vendor)
- Optional easy filling accessory
- Optional bar-code scanner

#### Data management software application
- Yes
- Yes