In theory, Medicare started reimbursing home monitoring of anticoagulation therapy for patients with heart valves over a year ago. But Dale Clendon, HemoSense executive vice president for business development, didn’t start celebrating until last month. That’s when Medicare changed its type-of-service classification of independent diagnostic testing facilities, or IDTFs, which distribute home anticoagulation meters to patients and provide reports on patient test results to physicians.

“The type of service was incorrect on the original codes,” Clendon says, “so the carriers that contracted with Medicare weren’t recognizing IDTFs—they were denying claims. But just as of July 1, Medicare has cleaned that up.”

Now that the ball’s rolling on reimbursement, HemoSense and other manufacturers of home coagulation monitoring devices are emphasizing their products’ accuracy and convenience. LifeScan, maker of the Harmony INR monitoring system, has “clinical data showing that Harmony is clinically accurate to the standard of care—the lab test,” says senior marketing manager Lawrence Chan. “Whether a health care professional runs a test or a patient does it, both consistently obtain accurate results.”

Test strips for the Harmony system don’t have to be refrigerated, Chan adds, which makes it convenient for patients who travel. Meanwhile, HemoSense’s INRatio meter has built-in quality controls to make the instrument simpler to use, a feature attractive to “the elderly population we’re primarily dealing with,” Clendon says.

Point-of-care anticoagulation monitor manufacturers, too, are showcasing their products’ accuracy and ease of use. Abbott product manager Joey Baugh says the i-Stat platform’s ubiquity makes using its prothrombin time cartridge simple. “The challenge a lot of POC programs have today is, they have multiple analyzers for different tests. You might have a blood gas machine, a hematology machine, a coagulation machine. But with the i-Stat you’ve got everything on just the one
platform,” he says. And on the accuracy front, he adds, the i-Stat prothrombin time cartridge uses a high-sensitivity tissue factor reagent with an International Sensitivity Index of 1.1.

With a new test strip, Roche plans to lighten the QC load for users of its CoaguChek S point-of-care analyzer. The strip, called the CoaguChek PT•S test, will be launched in early 2004. The PT•S will provide “a streamlined quality control process, so our customers won’t have to run as much QC,” POC coagulation marketing manager Kimberly Ward says. “It will be less time in their day, less work for them, and less cost.” She adds that the new test strip will have room-temperature stability, will not be sensitive to heparin, and will feature an ISI of 1.0.

Monitors from Medtronic and International Technidyne offer convenience to POC users by eliminating some of the calculation necessary to administer heparin. International Technidyne’s Hemochron Response v. 2.0 with RxDs dosing, says senior product manager Bill Fitzgerald, takes information from quantitative-heparin tests, “asks you the height, weight, and sex of a patient, and gives you the recommended dose. Prior to this you had to use a calculator or a pencil.” Like the Hemochron Response, Medtronic’s HMS Plus monitor can also calculate the amount of protamine needed to reverse the heparin, Medtronic representative Marsha Cusulos says.

Along with accuracy and expediency, another watchword is cropping up in the field—connectivity, says Jim Campbell, Helena Laboratories point-of-care division manager. Helena’s Actalyke monitors, he says, combine connectivity with convenience because they can be set to radio frequency output, so that operating room staff can move equipment quickly without unplugging and relogging the instrument.

The Rapidpoint Coag analyzer, distributed by Bayer, offers several connectivity options. “The Coag can transmit the data into many kinds of programs,” says Jan Price, senior marketing manager for near patient testing. “There is a program called the RapidLink Coag Reporter that resides on the computer. The Rapidpoint Coag also works with the Rals-Plus,” which is manufactured by Medical Automation Systems. Says she within approximately 60 days the Coag will have an interface to Telcor’s Quick-Multit-Link system as well.

Further down the road, fans of the former Avoco handheld coagulation monitor—originally offered by Avoco for both home and professional use—can look for it again in late 2004. Beckman Coulter, which acquired the monitor, plans to offer it for professional use only, says Michael Cote, tactical marketing manager for coagulation and microalbumin testing. “It’ll look a little bit different than when it was under the Avoco name, but it’s still going to be a fluorescent-based technology.”

CAP TODAY’s lineup of self-monitoring and point-of-care coagulation analyzers includes, in addition to those mentioned here, Abbott’s i-Stat 1, Bayer’s Rapidpoint Accenta, Instrumentation Laboratory’s Gem PCT Plus, International Technidyne’s Hemochron Jr. and ProTime microcoagulation system, Medtronic’s ACT II and ACT Plus, and Roche’s CoaguChek Pro DM. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm that it has the stated features and capabilities.
Coagulation Analyzers (Point-of-care or self-monitoring)

Part 2 of 6

Bayer Diagnostics
Jan Price - jan.price.b@bayer.com
511 Benedict Ave.
Tarrytown, NY 10591
845-333-9891
www.bayerdiag.com

Bayer Diagnostics
Jan Price - jan.price.b@bayer.com
511 Benedict Ave.
Tarrytown, NY 10591
845-333-9891
www.bayerdiag.com

Helena Point of Care
Jim Campbell - pointofcare@helena.com
1530 Lindbergh Drive
Buckhead, GA 30324
888-255-9003
www.helena.com

See accompanying article on page 34

Instrument name
First year sold
Reg(Point Coag
1998
Reg(Point Account
2001
Antikline XL
2002

No. of units sold in U.S.Outside U.S.
Country where analyzer designed/Manufactured
Is instrument POC or self-monitoring analyzer?
Specimen type
Model type
Dimensions in inches (H x W x D)/Weight
Specimen volume needs

• PT: Cost per sample for reagent rental
Cost per sample for:
Instrument list price
• Patient
Approx. No. of training hours needed for:
Training provided with instrument purchase
Onboard system for automatic error detection
• Reagent
Positive identification system (e.g. bar code) for:
Lab can control analyzer remotely
Commercially available systems for which interfaces are up and running in active user sites
How labs get LOINC codes for reagent kit
LOINC codes transmitted with results

• ACT:
• PT & PTT:
• PT:
• Other
• Integrated QC with each analysis
• Liquid
• MAX-ACT: maximum factor XII activation ACT test, celite, kaolin, glass

Clotting-based tests for which device has FDA-cleared applications
PT (deplorable range low 6 sec, high 150 sec; INR low 1.0, high 10.0; PT (deplorable range low 15 sec, high 300 sec); heparin management test (HMT) alternative to ACT (measures 1–10 units per mL of heparin); low heparin management test (LHMT), enox—low molecular weight heparin

Tests using other methodologies for which device has FDA-cleared applications
FDA-cleared tests but not yet clinically released
Tests submitted for 510(k) clearance
Tests in development but not yet submitted for clearance

Method of endpoint detection
Quality control methods
• Electronic
• Liquid
• Labeled/Identified
• Integrated QC with each analysis
• Automatic knockout for QC failure
• Other

Time (in minutes) to perform control plus specimen test
• PT
• PT & PTT:
• ACT:

Data management capability
Includes QC
System can automatically transfer data to information system
• Patient data
• QC data

Interface supported by instrument vendor
—

LOINC codes transmitted with results
How labs get LOINC codes for reagent kit
Commercially available systems for which interfaces are up and running in active user sites
Lab can control analyzer remotely

Real-time wireless linkage to LIS or HIS

Onboard system for automatic error detection

Training provided with instrument purchase
Approx. No. of training hours needed for:
• Medical staff
• Patient

Patient self-testing program is available

Instrument list price
Reasonable rental or lease only
Cost per sample for:
• PT:
• PTT:
• ACT:

Cost per sample if device purchased

CLIA ‘08 complexity rating

Unique advantages (provided by the vendor)

—

•well analyze/monitor citrated or recalcified samples
• menu of PT, APTT, INR (ACT), LIMIT, ENOX tests with expansion capability
• RapidPath Data Management system will allow connectivity to LIMIT; users can generate accession numbers for patient test results
• patient and operator ID, restricted analyzer access, 1,800 X-memory, QC tested, QC range assignment
• brings patients into safe coagulation range sooner
• reduces risk of post-op complications
• improves decision-making speed and accuracy
• ease-of-use (touchscreen)
• be-point electromechanical “soft-clot” detection principle
• MAX-ACT: maximum factor XII activity ACT test, 0.5 mL blood volume, linear up to 10 units of heparin, same plastic tube construction, for use on Actalyke and Hemochron instruments
• electronic clotting tube (ECD) that simulates and monitors actual blood coagulation form for accurate ECD challenges
• integrated printer
• 3.5-in diskette storage
Coagulation Analyzers (Point-of-care or self-monitoring)

**Part 3 of 6**

### Instrument name
- **ACL Lyte Mini**: n/a
- **INRatio**: n/a
- **Gem PCL Plus (Portable Coagulation) Lab System**: 2003

### First year sold
- **ACL Lyte Mini**: 2001
- **INRatio**: n/a
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

### No. of units sold in U.S./Outside U.S.
- **ACL Lyte Mini**: n/a
- **INRatio**: n/a
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

### Model type:
- **ACL Lyte Mini**: handheld/portable
- **INRatio**: handheld/portable
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

### Dimensions in (H x W x D)/Weight
- **ACL Lyte Mini**: 6.25 x 5 x 4.75/5 lb
- **INRatio**: 6.5 x 3 x 2.0/7 oz
- **Gem PCL Plus (Portable Coagulation) Lab System**: 5.5 x 3 x 2.0/75 lb

### Unique advantages (provided by the vendor)

#### Automate result
- **ACL Lyte Mini**: two-point electromechanical
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### Quality control methods
- **ACL Lyte Mini**: yes
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: no

#### Time (in minutes) to perform control plus specimen test
- **ACL Lyte Mini**: 1
- **INRatio**: 2
- **Gem PCL Plus (Portable Coagulation) Lab System**: 1–5

#### Method of endpoint detection
- **ACL Lyte Mini**: two-point electromechanical
- **INRatio**: change in impedance of the sample when clotting occurs
- **Gem PCL Plus (Portable Coagulation) Lab System**: mechanical endpoint clotting mechanism, monitored optically

#### Data management capability
- **ACL Lyte Mini**: no
- **INRatio**: onboard
- **Gem PCL Plus (Portable Coagulation) Lab System**: onboard

#### Includes QC
- **ACL Lyte Mini**: no
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: yes

#### System can automatically transfer data to information system
- **ACL Lyte Mini**: yes
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: yes

#### Interface supplied by instrument vendor
- **ACL Lyte Mini**: yes
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### LOINC codes transmitted with results
- **ACL Lyte Mini**: n/a
- **INRatio**: n/a
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### How labs get LOINC codes for reagent kit
- **ACL Lyte Mini**: n/a
- **INRatio**: no
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### Commercially available systems for which interfaces are up and running in active user sites
- **ACL Lyte Mini**: n/a
- **INRatio**: n/a
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### Lab can control analyzer remotely
- **ACL Lyte Mini**: no
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: no

#### Real-time wireless connectivity to LIS or HIS
- **ACL Lyte Mini**: yes
- **INRatio**: no
- **Gem PCL Plus (Portable Coagulation) Lab System**: no

#### Positive identification system (e.g. bar codes) for:
- **ACL Lyte Mini**: no
- **INRatio**: no
- **Gem PCL Plus (Portable Coagulation) Lab System**: no

#### Onboard system for automatic rejection detection
- **ACL Lyte Mini**: no
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: yes

#### Training provided with instrument purchase
- **ACL Lyte Mini**: yes
- **INRatio**: yes
- **Gem PCL Plus (Portable Coagulation) Lab System**: yes

#### Approx. No. of training hours needed for:
- **ACL Lyte Mini**: 1
- **INRatio**: 1
- **Gem PCL Plus (Portable Coagulation) Lab System**: 0.5

#### Instrument list price
- **ACL Lyte Mini**: $1,049–$1,149
- **INRatio**: $1,095
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### Reagent rental or lease only
- **ACL Lyte Mini**: no
- **INRatio**: no
- **Gem PCL Plus (Portable Coagulation) Lab System**: yes

#### Cost per sample for:
- **PT**: Cost per sample for reagent rental
- **PTT**: Cost per sample for reagent rental
- **ACT**: Cost per sample for reagent rental
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### CLIA '88 complexity rating
- **ACL Lyte Mini**: n/a
- **INRatio**: non-waived
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### Instrument features
- **ACL Lyte Mini**: one-step electromechanical "soft-clot" detection
- **INRatio**: no
- **Gem PCL Plus (Portable Coagulation) Lab System**: n/a

#### Unique advantages
- **Gem PCL Plus (Portable Coagulation) Lab System**:
  - Gem PCL Plus can be used in conjunction with the Gem Premier 3000, consolidating BG/Lytes/GIu/Lac/ Hemostasis testing.
  - Comprehensive POC coagulation menu that allows for POC coagulation analysis throughout an institution.
  - Fresh whole blood, citrated whole blood (fingerstick or PT), PT, APTT, ACT, and APTT range.

### Conclusion
Tabulation does not represent an endorsement by the College of American Pathologists.
### Coagulation Analyzers (Point-of-care or self-monitoring)

#### Part 4 of 6

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>First year sold</th>
<th>No. of units sold in U.S./Outside U.S.</th>
<th>Country where analyzer designed/Manufactured</th>
<th>No. to units sold in U.S.</th>
<th>No. to units sold outside U.S.</th>
<th>Is instrument POC or self-monitoring analyzer?</th>
</tr>
</thead>
<tbody>
<tr>
<td>ProTime Microa</td>
<td>1996</td>
<td>3 units</td>
<td>U.S.</td>
<td>3 units</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ProTime Microa</td>
<td>1996</td>
<td>3 units</td>
<td>U.S.</td>
<td>3 units</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Hemochron Jr.</td>
<td>1998</td>
<td>5 units</td>
<td>U.S.</td>
<td>5 units</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### Tabulation

- **ACT:** Cost per sample for reagent rental
- **PTT:** Cost per sample for reagent rental
- **PT:** Cost per sample for reagent rental

#### Additional Information

- **Patient self-testing program is available**
  - **Patient**
  - **Medical staff**

#### Approx. No. of training hours needed for:

- **Training provided with instrument purchase**
  - **Patient**
  - **Patient self-testing program is available**
  - **Laboratory**

#### Onboard system for automatic error detection

- **Data management capability**
  - **Includes QC**
  - **System can automatically transfer data to information system**
  - **Interface supplied by instrument vendor**
  - **LOINC codes transmitted with results**

#### Method of endpoint detection

- **Quality control methods**
  - **Electronic**
  - **Liquid**
  - **Expiry**
  - **Integrated QC with each analysis**
  - **Other**

#### Time (in minutes) to perform control plus specimen test

- **Data management capability**
  - **Data storage and management**
  - **QC lockout**
  - **Connectivity options**
  - **Real-time wireless linkage to LIS or HIS**

#### Observations

- **Real-time wireless connectivity to LIS or HIS**
- **Positive identification system (e.g., bar code) for:**
  - **Patient specimen**
  - **Reagent**

#### Onboard system for automatic error detection

- **Instruments list price**
  - **Reagent rental or lease only**
  - **Cost per sample for:**
    - **PT**
    - **PTT**
    - **ACT**
    - **Clotting-based tests for which device has CLIA '88 complexity rating**
      - **Blood volume—15 µL**
      - **Nose of use**
      - **Data management software/printing**
      - **Connectivity options**
      - **Tablet system (e.g., iPad)**

#### Additional notes

- **Itemized list price**
  - **Reagent rental or lease only**
  - **Cost per sample for:**
    - **PT**
    - **PTT**
    - **ACT**
    - **Clotting-based tests for which device has CLIA '88 complexity rating**

---

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

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<table>
<thead>
<tr>
<th><strong>CLIA '99 complexity rating</strong></th>
<th><strong>Test in development but not yet clinically released</strong></th>
<th><strong>FDA-cleared tests but not yet clinically released</strong></th>
<th><strong>Tests using other methodologies for which device has CLIA '88 complexity rating</strong></th>
<th><strong>Tests using other methodologies for which device has CLIA '88 complexity rating</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blood volume—15 µL</strong></td>
<td><strong>Nose of use</strong></td>
<td><strong>Data management software/printing</strong></td>
<td><strong>Connectivity options</strong></td>
<td><strong>Tablet system (e.g., iPad)</strong></td>
</tr>
<tr>
<td><strong>Blood volume—15 µL</strong></td>
<td><strong>Nose of use</strong></td>
<td><strong>Data management software/printing</strong></td>
<td><strong>Connectivity options</strong></td>
<td><strong>Tablet system (e.g., iPad)</strong></td>
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<tr>
<td><strong>Blood volume—15 µL</strong></td>
<td><strong>Nose of use</strong></td>
<td><strong>Data management software/printing</strong></td>
<td><strong>Connectivity options</strong></td>
<td><strong>Tablet system (e.g., iPad)</strong></td>
</tr>
<tr>
<td><strong>Blood volume—15 µL</strong></td>
<td><strong>Nose of use</strong></td>
<td><strong>Data management software/printing</strong></td>
<td><strong>Connectivity options</strong></td>
<td><strong>Tablet system (e.g., iPad)</strong></td>
</tr>
</tbody>
</table>
**Coagulation Analyzers (Point-of-care or self-monitoring)**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>First year sold</th>
<th>CLIA '88 complexity rating</th>
<th>ACT: Cost per sample for reagent rental</th>
<th>PT: Cost per sample for reagent rental</th>
<th>Cost per sample if device purchased</th>
<th>ACT: Cost per sample for reagent rental</th>
<th>CLIA '98 complexity rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmony BB Monitoring System</td>
<td>2003</td>
<td>n/a</td>
<td>$24.75 for patient self-testing</td>
<td>$2,950 for patient self-testing</td>
<td>$2,900</td>
<td>up to 12 (depending on patient sample)</td>
<td>n/a</td>
</tr>
<tr>
<td>ACT II</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>HMS Plus</td>
<td>1999</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>n/a</td>
</tr>
<tr>
<td>PT (INR: low, 0.8; high, 0.3)</td>
<td>n/a</td>
<td>n/a</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>n/a</td>
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<tr>
<td>Data management capability</td>
<td></td>
<td></td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>n/a</td>
</tr>
<tr>
<td>Includes QC</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
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<tr>
<td>System can automatically transfer data to information system</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
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<tr>
<td>QC data</td>
<td>yes</td>
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<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
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<tr>
<td>Instrument list price</td>
<td>$2,260 for patient self-testing</td>
<td>$2,600</td>
<td>$26,000</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
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<td>Specification</td>
<td></td>
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<tr>
<td>Method of endpoint detection</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Quality control methods</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Electronic</td>
<td>no (not required, onboard QC integrated into test strip)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
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<tr>
<td>• Liquid</td>
<td>no (not required, onboard QC integrated into test strip)</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>• Lyophilized</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
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<td>yes</td>
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<tr>
<td>• Integrated QC with analysis</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
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<tr>
<td>• Automatic lockout for QC failure</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
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<tr>
<td>• Other</td>
<td>two levels of onboard QC integrated into test strip</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Clogging-based tests for which device has FDA-cleared applications</td>
<td>PT (INR: low, 0.8; high, 0.3)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
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<td>Data management capability</td>
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<td>Includes QC</td>
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<td>QC data</td>
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<td>yes</td>
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<td>Specification</td>
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<tr>
<td>Method of endpoint detection</td>
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<tr>
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<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Liquid</td>
<td>no (not required, onboard QC integrated into test strip)</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>• Lyophilized</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>• Integrated QC with analysis</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>• Automatic lockout for QC failure</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>• Other</td>
<td>two levels of onboard QC integrated into test strip</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Clogging-based tests for which device has FDA-cleared applications</td>
<td>PT (INR: low, 0.8; high, 0.3)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>ACT (high range, low range, reactivated, and heparin test)</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Tabulation does not represent an endorsement by the College of American Pathologists.
### Coagulation Analyzers (Point-of-care or self-monitoring)

**Part 6 of 6**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>ACT Plus</th>
<th>CoaguChek Pro-DW System</th>
<th>CoaguChek S System for Prothrombin Time Testing (Professional Use)</th>
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<tbody>
<tr>
<td>First year sold</td>
<td>2003</td>
<td>1999</td>
<td>2001</td>
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#### No. of units sold in U.S./Outside U.S.

<table>
<thead>
<tr>
<th>Country where analyzer designed/Manufactured</th>
<th>Instrument POC or self-monitoring analyzer?</th>
<th>Specimen type</th>
<th>Model type</th>
<th>Dimensions in inches (H x W x D)/Weight</th>
<th>Specimen volume needs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Unique advantages (provided by the vendor)

- **Data management capability**
  - **entire**
  - **entire**
  - **entire**

- **Quality control methods**
  - **yes**
  - **yes**
  - **yes**

- **Method of endpoint detection**
  - **ACT**
  - **PT**
  - **PT & APTT**

- **Patient control analyzer remotely**
  - **yes**
  - **yes**
  - **yes**

- **Training provided with instrument purchase**
  - **yes**
  - **yes**
  - **yes**

- **Instrument list price**
  - **$4,200**
  - **$3,795**
  - **$1,295**

#### CLIA '88 complexity rating

- **data management software application**
- **duplicate test results**
- **optional bar-code scanner**
- **user-defined QC lockout, new lot lockout, and operator lockouts**
- **use of specific key only**
- **contact Roche Diagnostics sales**
- **contact Roche Diagnostics sales**
- **contact Roche Diagnostics sales**
- **data management software and with hospital LIS via **

#### Customer contacts

- **Medtronic Cardiac Surgery**
  - 7611 Northland Drive North
  - Minneapolis, MN 55428
  - 800-359-4363
  - www.medtronic.com

- **Roche Diagnostics Corp.**
  - 1915 Hagan Rd., Bldg. H
  - Indianapolis, IN 46250
  - 800-359-4363
  - www.roche.com

**Appendix**

- **Table 10 of 10**
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- **Survey of INstruMENTS**

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