Implementing eGFR

Implementing eGFR

Coagulation Analyzers
(Point of care, self-monitoring)

Part 1 of 5

Dr. Radensky

See accompanying article on page 18

Table of Instruments

Coagulation Analyzers
(Point of care, self-monitoring)

Sue Parham is a writer in Edgewater, Md.

Implementing eGFR

Dr. Radensky

Quality control methods

• Electronic

• Liquid

• Lyophilized

• Integrated QC with each analysis

• Automatic lockout for QC failure

• Other

Time (in minutes) to perform control plus specimen test

• PT: 2 min

• PT & PTT: —

• ACT: 2 min+

Data management capability

• Unbound & optional add-on (HW ref: 1-0741)

System can automatically transfer data to information system

• Patient data

• QC data

• Interface supplied by instrument vendor

• Yes (additional cost)

LDMS codes transmitted with results

• Yes

How labs get LDMS codes for reagent kit

• Package insert

Commercially available systems for which interfaces are up and running in active user sites

Lab can control analyzer remotely

• Yes (phone)

Real-time wireless linkage to LIS or HIS

Positive identification system (e.g. bar code) for:

• Patient specimen

• Reagent

Onboard system for automatic error detection

• Yes, for sample (volume), reagent/cartridge error

Training provided with instrument purchase

Approx. No. of training hours needed for:

• Medical staff

• 1 hr

• Patient

• Yes

Patient self-testing program is available

• Yes (on-site)

Instrument list price

$6,000

Reagent rental or lease only

Yes

Cost per sample for:

• PT: Cost per sample for reagent rental

Cost per sample if device purchased

Yes

• PTT: Cost per sample for reagent rental

Cost per sample if device purchased

No

• ACT: Cost per sample for reagent rental

Cost per sample if device purchased

Yes

CLIA ’88 complexity rating

Call for pricing

Unique advantages (provided by the vendor)

• Handheld portable device

• Gooselock/thermometer lockout

• External blood gas, chemistry, electrolytes, coagulation, immunosassay

• Bar-code scanner

• Electric battery charger

Abbott Point of Care

9700 Amber Ridge Drive

Aliso Viejo, CA 92656

See accompanying article on page 18
### Coagulation Analyzers (Point of care, self-monitoring)

#### Part 2 of 5

**See accompanying article on page 18**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>i-STAT 1000</th>
<th>Actalyte XL</th>
<th>Actalyte Mini II</th>
</tr>
</thead>
</table>

**No. of units sold in U.S./Outside U.S.**
- Country where analyzer designed/Manufactured:
  - U.S.A.
  - POC
- Instrument POC or self-monitoring analyzer?
- cardboard/pouch:
  - Portable
- Dimensions in inches (H x W x D): 10.25 x 2.25 x 13.64 in
- Weight: 2.15 lb
- Accuracy volume required (ill ill line or cartridge):
  - Portable
- Accuracy volume required (ill line on cuvette):
  - Portable

**Clotting-based tests for which device has FDA-cleared applications**
- PT/INR, Coag ACT, Kaolin ACT
- Activated clotting time (ACT)–whole blood
- MAX-ACT: maximum factor XII activation ACT, coag, kaolin, glass

**Tests using other methodologies for which device has FDA-cleared applications**
- Blood gases, electrolytes
- Chemical analysis
- Urinalysis

**Tests that were not yet clinically released**
- None

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

**Tests in development but not yet submitted for clearance**
- APTT
- AP rt (whole blood), PT (whole blood), haptoglobin, proteins assay, therapeutic assessment kit (TMA), LMM

**Method of endpoint detection**
- Electromagnetic
- Two-point electromechanical

**Quality control methods**
- Electronic
- Yes
- Liquid
- Yes
- Lyophilized
- Yes
- Integrated QC with each analysis
- Yes
- Automated control for QC failure
- Yes
- Other
- N/A

**Time (in minutes) to perform control plus specimen test**
- PT: 2 min
- PT & APTT: 5 min
- ACT: 5 min

**Data management capability**
- Onboard
- Yes
- Optional add-on (for: i-STAT): Yes
- System can automatically transfer data to information system
- Patient data
- Yes
- QC data
- Yes
- Interface supplied by instrument vendor
- Yes
- LOINC codes transmitted with results
- Yes
- How labs get LOINC codes for reagent kit
- N/A
- Commercially available systems for which interfaces are up and running in active user sites
- None

**Real-time wireless linkages to LIS or HIS**
- Patient specimen
- Yes
- Reagent
- Yes
- Onboard system for automatic error detection
- Yes
- Yes

**Training provided with instrument purchase**
- Approx. No. of training hours needed for:
- Medical staff
- 1-2 hr
- Patient
- N/A
- Patient self-testing program is available
- Yes

**Instrument list price**
- Reagent rental or lease only
- $6,000
- PT: Cost per sample for reagent rental
- N/A
- PTT: Cost per sample for reagent rental
- N/A
- ACT: Cost per sample for reagent rental
- Call for pricing
- CLIA 181 complexity rating
- Moderate

**Unique advantages (provided by the vendor)**
- Hardened
- QC locked/operated locked
- Magnetic detection—electronic QC/monitoring
- Magnetic detection device—electronic QC/monitoring
- Via electronic clotting tube (ECC) that simulates and records actual blood clot formation for accurate ECC challenges
- Integrated printer
- 3–5 in diode storage

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

### Part 3 of 5

**See accompanying article on page 18**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>First year sold</th>
<th>Manufacturer</th>
<th>Address</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>HomeSonic Inc.</td>
<td>501 River Oaks Parkway</td>
<td>Instrumentation Laboratory</td>
<td>17177</td>
<td>D. Walsh</td>
</tr>
<tr>
<td>651 River Oaks Parkway</td>
<td>501 River Oaks Parkway</td>
<td>International Technigene Corp.</td>
<td>651 River Oaks Parkway</td>
<td>D. Walsh</td>
</tr>
</tbody>
</table>

### Instrument Details

**No. of units sold in U.S./Outside U.S.**
- Country where analyzer designed/Manufactured: none
- Instrument OPO or self-monitoring analyzer: none
- Specimen type: fingerstick
- Mode of use: hand-held/portable
- Dimensions in inches: 6.2 x 3 x 2.25 in
- Weight: 7 lbs
- Specimen volume needs: 2 ml

**Clotting-based tests for which device has FDA-cleared applications**
- PT
- PT and citrate PT (reportable range: 10–150 sec; INR: 1.5–2.0)
- APTT (reportable range: 16–50 sec), ACT (95–1,800 sec), APTT–act (low–400 sec)

**Tests using other methodologies for which device has FDA-cleared applications**
- None

**Tests submitted for TOE clearance**
- PT (reportable range: low 1 sec, high 75 sec; INR: low 0.7, high 2.5)

**Tests in development but not yet submitted for clearance**
- Planned tests: APTT, ACT

### Method of endpoint detection

- Change in impedance of the sample when clotting occurs
- Mechanical endpoint clotting mechanism, monitored optically
- Mechanical clot detection

**Quality control methods**
- Electronic:
  - No (not required, built-in QC on test strip)
  - Liquid:
    - No (not required, built-in QC on test strip)
    - Yes (calibrated whole blood)
- Lysophilized:
  - Yes
- Integrated QC with each analysis:
  - Yes (automatic self-check diagnosis)
  - No
- Automatic (notch for QC failure):
  - Yes
  - No
- Interference check
  - Impedance check strip:
    - Yes
    - No
- Time (in minutes) to perform control plus specimen test:
  - PT: 2
  - APTT & PTTH:
    - n/a
  - ACT:
    - 1–5

**Data management capability**
- Onboard:
  - Yes
  - No
- Offboard:
  - Onboard (via Gem Premier 3000)
  - No

**Includes QC**
- Yes
- No

**System can automatically transfer data to information system**
- Yes
- No

**QC data**
- Yes
- No

**Interface supplied by instrument vendor**
- Yes
- No

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

### Relevant wireless communications

**Real-time wireless links to LIS or HIS**
- Patient
  - Yes
- Reagent
  - No

**Onboard system for automatic error detection**
- Yes, for sample (volume), reagent stability
- Yes, for sample (volume) and instrument
- No

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

**Reagent management**
- Cost per sample for:
  - PT: $1.00
  - APTT: $1.00
- Cost per reagent:
  - PT: $1.00
  - APTT: $1.00

**Unique advantages (provided by the vendor)**
- Gem PCL Plus can be used in conjunction with the Gem Premier 3000; consolidating biochemistry assay
- Test results can be stored at room temperature for 12 months
- Gem PCL Plus can be used in conjunction with the Gem Premier 3000; consolidating biochemistry assay
- Easy to use
- Fast results
- Rarely requires reagent
- Low maintenance

**References**
- All information is derived from the manufacturer's literature.
### Coagulation Analyzers (Point of care, self-monitoring)

#### Part 4 of 5

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Homecheir Jr—Signature/Signature+</th>
<th>Homecheir Response</th>
<th>HER Plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>First year sold</td>
<td>1990</td>
<td>1990</td>
<td>1999</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Country where analyzer designed/Manufactured</th>
<th>In 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>U.S./U.S.</td>
<td>Fingerstick, venipuncture (white blood)</td>
<td>Venipuncture (white blood, anticoagulated whole blood)</td>
<td>Handwritten/porable</td>
<td>6.7 x 16.5 x 7.5/6.4 B</td>
<td>Accurate volume not necessary (drop)</td>
</tr>
</tbody>
</table>

#### Clotting-based tests for which device has FDA-cleared applications

<table>
<thead>
<tr>
<th>Tests using other methodologies for which device has FDA-cleared applications</th>
<th>FDA-cleared tests but not yet clinically released</th>
<th>Tests submitted for 510(k) clearance</th>
<th>Tests in development but not yet submitted for clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT (prothrombin time: low 11.4 sec, high 129 sec)</td>
<td>PT (prothrombin time: low 50 sec, high 346 sec)</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>INR (low 0.8, high 13.0, PT (calculated), PTT (prothrombin time: low 20 sec, high 400 sec (plasma cephalin), APTT (citrated), ACT low-range, ACT+)</td>
<td>APTT (citrated), ACT, STTDACG, ACT, PT, INR, FIX, K, PT, APTT, PSSG, PTOP</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>

#### Method of endpoint detection

<table>
<thead>
<tr>
<th>Quality control methods</th>
<th>Data management capability</th>
<th>Interface supplied by instrument vendor</th>
<th>How labs get DINIC codes for reagent kit</th>
<th>Commercially available systems for which interfaces are up and running in active user sites</th>
<th>Lab care control analyzer remotely</th>
<th>Real-time wireless linkage to LIS or HIS</th>
<th>Positive identification system (e.g. bar code)</th>
<th>Onboard system for automatic error detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗ Electronic</td>
<td>In-house</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

#### Data management capability

<table>
<thead>
<tr>
<th>Onboard system for automatic error detection</th>
<th>Training provided with instrument purchase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, for sample (volume)</td>
<td>Yes (on site)</td>
</tr>
<tr>
<td>Yes, for sample and reagent/expiration data</td>
<td>Yes (on site)</td>
</tr>
</tbody>
</table>

#### Injection list price

<table>
<thead>
<tr>
<th>Instrument list price</th>
<th>Reagent rental or lease only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature, $1,000</td>
<td>$4,806</td>
</tr>
<tr>
<td>Signature+, $1,100</td>
<td>$4,806</td>
</tr>
</tbody>
</table>

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

- ✗ Blood volume—15 µL
- ✗ Size of one
- ✗ Data management storing/printing
- ✗ Connectivity options
- ✗ Configurable QS and operator lockout for Signature+
- ✗ QC lockout
- ✗ Data storage and management
- ✗ Connectivity options
- ✗ HEP/Heparin/Pontamine dosing system
- ✗ Automated sample dispensing
- ✗ Constant temperature control
- ✗ Multiple testing capability
- ✗ HER: heparin dose response
- ✗ HPT: heparin potassium titration
- ✗ High range ACT
- ✗ Optional bar-code scanner
- ✗ Optional data management software

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### Coagulation Analyzers (Point of care, self-monitoring)

**Part 5 of 5**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Roche Diagnostics Corp.</th>
<th>Roche Diagnostics Corp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td>Point of Care</td>
<td>Point of Care</td>
</tr>
<tr>
<td></td>
<td>911 E Hagadorn Rd, Blq 2</td>
<td>911 E Hagadorn Rd, Blq 2</td>
</tr>
<tr>
<td></td>
<td>Indianapolis, IN 46250</td>
<td>Indianapolis, IN 46250</td>
</tr>
<tr>
<td></td>
<td>800-452-8766</td>
<td>800-452-8766</td>
</tr>
<tr>
<td></td>
<td><a href="http://www.roche.com">www.roche.com</a></td>
<td><a href="http://www.roche.com">www.roche.com</a></td>
</tr>
</tbody>
</table>

**First year sold**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>2003</th>
<th>1999</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Roche Diagnostics Corp.</td>
<td>Roche Diagnostics Corp.</td>
</tr>
<tr>
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</tr>
<tr>
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<td>800-452-8766</td>
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</tr>
<tr>
<td></td>
<td><a href="http://www.roche.com">www.roche.com</a></td>
<td><a href="http://www.roche.com">www.roche.com</a></td>
</tr>
</tbody>
</table>

**No. of units sold in U.S./Outside U.S.**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Germany/Germany</th>
<th>U.S./U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td>10,800/15,000</td>
<td>2,800/5,400</td>
</tr>
</tbody>
</table>

**Country where analyzer designed/Manufactured**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Germany/Germany</th>
<th>U.S./U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td>10,800/15,000</td>
<td>2,800/5,400</td>
</tr>
</tbody>
</table>

**Specimen type**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Venipuncture (whole blood)</th>
<th>Fresh whole blood (venous, arterial, or fingerstick capillary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Model type**

- hand-held portable
- hand-held portable

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

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>11 x 8 x 13/15 lb</th>
<th>6.1 x 4.5 x 21/5 lb</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Specimen volume needs**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>60 µl</th>
<th>45 µl</th>
<th>10 µl</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Method of endpoint detection

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Mechanical citrate</th>
<th>Laser photometry detects change in blood flow when citrate forms</th>
<th>True particles mixed with the sample move in magnetically fluid; reflection photometry detects change in particle movement with citrate formation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Quality control methods**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Electronic</th>
<th>Liquid</th>
<th>Lysophilized</th>
<th>Integrated QC with analysis</th>
<th>Automatic lockout for QC failure</th>
<th>Optional (user-defined)</th>
<th>Other</th>
<th>Performed protected QC lockouts by time of day, shift, or QC level</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
<td>n/a</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>PT:</th>
<th>PT &amp; PTT:</th>
<th>ACT:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Quality control methods**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Data management capability**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Lab control analyzer remotely</th>
<th>Inbound</th>
<th>yes, with Coag Clinic from Standing Stone Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>No</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Positive identification system (e.g., bar code)**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Data management capability**

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<tr>
<td>ACT Plus</td>
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**Real-time wireless linkage to LIS or HIS**

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<th>Yes</th>
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**Positive identification system (e.g., bar code)**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Training provided with instrument purchase**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Yes (on site)</th>
<th>Yes (on site)</th>
<th>Yes (on site)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Medical staff</th>
<th>Patient</th>
<th>Patient self-testing program available</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td>1 hr</td>
<td></td>
<td></td>
</tr>
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</table>

**Instrument list price**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>$4,000</th>
<th>$3,795</th>
<th>$1,295</th>
</tr>
</thead>
</table>

**Reagent rental or lease only**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Rental and purchase available</th>
<th>contact Roche Diagnostics sales</th>
<th>contact Roche Diagnostics sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Cost per sample for:**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cost per sample for reagent rental</td>
<td>Cost per sample if device purchased</td>
<td>Cost per sample for reagent rental</td>
<td>Cost per sample if device purchased</td>
<td>Cost per sample for reagent rental</td>
<td>Cost per sample if device purchased</td>
<td>Cost per sample if device purchased</td>
<td>Cost per sample if device purchased</td>
<td>Cost per sample if device purchased</td>
<td>Cost per sample if device purchased</td>
<td>Cost per sample if device purchased</td>
</tr>
</tbody>
</table>

**CLIA ‘88 compliance rating**

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Moderate (non-waived)</th>
<th>Moderate</th>
<th>CLIA waived for professional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Data management software application</th>
<th>Data management software application</th>
<th>Fast results in 45 sec</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACT Plus</td>
<td>Duplication of tests</td>
<td>Duplicate test results</td>
<td>Small sample: 10 µl from fingerstick</td>
</tr>
</tbody>
</table>

### Tabulation data

- not represented an endorsement by the College of American Pathologists

- source: www.roche.com