New developments in POCT Prothrombin time determination

Gajdošík T., Mgr., Števlíková O., Alpha medical Laboratory Bratislava (Slovakia)
Müllerová D., Ing., Bio G Ltd. Bratislava (Slovakia)
POCT Prothrombin time determination

- Amperometric (elektrochemical) determination of Prothrombin time after activation of the coagulation with recombinant thromboplastin on test strip (sample - whole capillary blood)

- NEW:
  Photometrical detection of solid gel clot within a specified period of time:
  Eurolyser Smart instrument
  (sample - whole capillary blood)
Coagulation and Thrombosis Diagnostics
INR(PT)
D-Dimer
GP, Internist, Cardiologist

Diabetes - Monitoring
HbA1c
Microalbumin
Diabetologist, Internist

Cardiological Risk
Homocysteine, Lp(a)
hsCRP
Cardiologist, Anti Aging Doctor

Inflammation status
CRP, hsCRP
GP, Pediatrician, Intensive Care Unit

Iron deficiency disorders
Haemoglobin
Ferritin
Gynecologist, Internist

Faecal Occult Blood
GP, Internist

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POCT instrument  

**Single Method Automated Reading Technology**

- Multiparameter POCT instrument
- It performs tests completely automatically in just a few minutes
- It reads type of test, the calibration curve, batch number and the expiration date from the RFID card
- Touch-screen display
- Maintenance-free
- Simple data transfer to printer or host
- Software in Slovak language

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Prothrombin time determination on Smart 700

Principle: Photometrical detection of a solid gel clot within a specified period of time
Measuring range: 1-6 INR
Sample: 20 µl fresh whole capillary blood
CV: < 5%

Content of kit (for 32 tests):

- RFID card
- R1 Dry chemistry coating (recombinant thromboplastin)
- R2 filled with buffer
**Processing of PT (INR) test on Smart 700**

1. Allow single test min. 30 minutes to warm to room temperature. Place cuvette and cap in smart test kit rack.

2. Insert RFID card.

3. Press this symbol on touch screen.


5. Aspirate 20 µl whole blood from fingertip.

6. By pressing the plunger immediately dispense sample into cuvette.

7. Apply cap firmly onto cuvette.

8. Insert cuvette in analyser, then press start button.

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Fig.: Example of PT (INR) determination on Smart 700

Left: patient (capillary blood)  Right: control (plasma)
Repeatibility and reproducibility of Smart PT (INR)

- **ST1800 Smart PT (INR)- Control Kit (2x1 ml) by Eurolyser Diagnostica GmbH**
  
  Control N (Lot: 0911-1) INR=1,00 (0,77-1,23)
  Control P (Lot: 0911-1) INR=2,90 (2,23-3,57)

- Repeat PT (INR) measurements were carried with this control material on Smart 700
  
  The content of vial was reconstituted in 1ml distilled water, then it was allowing to stand for 10 minutes at room temperature before use. The rest of reconstituted content of vial was aliquoted into several small Eppendorf tubes and frozen at -30°C. One tube of control was defrosted each day in period of 5 days and it was analysed 3-times.
### Table of results of Smart PT (INR)- Control N

<table>
<thead>
<tr>
<th>Day</th>
<th>1.</th>
<th>2.</th>
<th>3.</th>
<th>Ø</th>
<th>SD</th>
<th>CV%</th>
<th>MIN</th>
<th>MAX</th>
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<table>
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<tr>
<th>Statistics</th>
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<tr>
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</tbody>
</table>

Ø ... mean, SD...standard deviation, MIN ... minimal value, MAX ... maximal value, CV% ... coefficient of variation
Table of results of Smart PT (INR)- Control P

<table>
<thead>
<tr>
<th>Day</th>
<th>1.</th>
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<th>3.</th>
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<th>CV%</th>
<th>MIN</th>
<th>MAX</th>
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<tr>
<th>Statistics</th>
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<th>SD</th>
<th>CV%</th>
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</tbody>
</table>

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Comparative study
Eurolyser Smart 700 PT (INR) / Sysmex CA-1500

EACH PATIENT (n=69)

1. collection of venous blood
   (1 part of 0.109 M sodium citrate solution and 9 parts of venous blood)

2. centrifugation of collected sample

3. analysis of plasma on Sysmex CA-1500
   Reagents by Siemens
   OUHP 49 Thromborel S, Lot: 545425
   (own lab calibrated ISI with PT Multicalibrator)
   ORKE 41 Control Plasma N, Lot: 503167A
   OUPZ 17 Control Plasma P, Lot: 509942C

1. collection of capillary blood
   20 µl whole blood from fingertip

2. analysis of sample on Smart 700
   Reagents by Eurolyser Diagnostica GmbH
   ST0180 INR (PT) Test kit, Lot: 0911-1
   ST1800 INR (PT) Control kit, Lot: 0911-1

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Results:
Smart INR vs CA-1500 INR

n = 69

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Results: Smart INR vs CA-1500 INR

- Intercept: 0.299 [0.099 to 0.499]
- Slope: 0.880 [0.801 to 0.959]
- Unweighted linear regression N = 69
- $r = 0.938$
## Results: Smart INR vs CA-1500 INR

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<tr>
<th>Analyzer</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Min value</th>
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<table>
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<tr>
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Conclusions:
• Smart is the compact multiparameter analyzer
• its use is easy to learn and operation is simple
• INR (PT) Smart 700 tested against INR CA-1500 (as reference method) showed satisfactory acceptable correlation in this comparative study
• INR (PT) Smart determination is suitable for POCT monitoring of patients on oral coumarin anticoagulant therapy (GP, internist, cardiologist)