Analytical validation of the new plasma calibrated Accu-Chek Test Strips (Roche Diagnostics®)

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C.H.U. Liège, Belgium
CHU Liège: 3 sites

The site of the CHU consists of three establishments:

• CHU Sart-Tilman
• CHU Notre-Dame des Bruyères
• CHU Ourthe-Amblève
CHU Liège: 3 sites

± 1000 beds

- 635 beds CHU S-T
- 226 beds CHU NDB
- 94 beds CHU OA

Wards: medicine, surgery, paediatrics, maternity, geriatrics, dialysis, emergencies, intensive care, center of the burned, haematology, sterile unity, metabolic unity…
8 blood gas analyzers.

Before December 2004

- 2 PCx (Abbott) in the metabolic unity under the control of the laboratory. Recovery of the fees.

- A lot of Accu-Chek Sensors (Roche) distributed in the other services without control of the laboratory.
Point of Care in CHU Liège: Accu-Chek Inform.

- Since December 2004
  - 65 Accu-Chek Informs distributed in all the departments of the 3 sites.

Recovery of the results and invoicing via the software DataCarePOC (Roche).
Accu-Chek Inform: Why?

**In Belgium: new legislation for the laboratories.**

POC analyzes charged if:

- Traçability: operator’s identification, patient’s identification.
- Daily quality controls.
- Maintenances, QC, calibrations under the responsibility of the laboratory.
- Recording of the lots of used tigettes.
- Documented training of the staff.
- External QC 4×/year.
Training of the staff

Nurses = Qualified technicians under the responsibility of the clinical biologist.

➢ Importance of the training of the staff.

Sessions of training organized in every ward by the biologists and the responsible technicians.

Printing of an identification bar code on the badge of the users of the Accu-Chek Inform.

Every user is registered to work only on the devices of his own ward.
Validation of the Accu-Chek Informs

Each device was validated before its first use:

• Repeatability
• Reproducibility
• Linearity

Any device presenting a total error > 14%: rejected.
March 2005: Accu-Chek Informs effective in the wards.

27000 glycaemias realized from March 05 to this day.

By extrapolating: ± 120000 glycaemias / year.

The most consumer wards:
metabolic unity (7362), cardiology (2122), pneumology (2087).
Point of Care in CHU Liège: Accu-Chek Inform
Plasma calibrated test strips

- May 2005: New plasma calibrated test strips.

Test strips calibrated to deliver results of glycaemia comparable to those obtained on plasma by an analyzer.
Plasma calibrated test strips

**Validation:**

- Repeatability
- Reproducibility
- Linearity
- Plasma strips VS Whole blood strips
- Plasma strips VS Analyzer (on plasma)
- Plasma strips VS Blood gas analyzer
- Capillary whole blood VS Venous whole blood with the plasma test strips.
## Repeatability

10-fold-repeated measure of controls low and high level (mg/dl):

<table>
<thead>
<tr>
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<th>Level 1</th>
<th>Level 2</th>
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<tbody>
<tr>
<td>Labo mean</td>
<td>54,4</td>
<td>327</td>
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<tr>
<td>Standard deviation</td>
<td>1,65</td>
<td>10,52</td>
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<tr>
<td>CV</td>
<td>3,03</td>
<td>3,22</td>
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</tbody>
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56 342  
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54 330  
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57 321  
54 331  
51 317  
53 316  
55 343
## Reproducibility

Daily measure of controls low and high level during 10 days (mg/dl):

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<th>Level 1</th>
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<tr>
<td><strong>CV</strong></td>
<td>5,26</td>
<td>2,99</td>
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Linearity

Linearity test kit (Roche) mg/dl

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<th>Level</th>
<th>Reference</th>
<th>Labo</th>
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</thead>
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<td>537</td>
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<td>6</td>
<td>510</td>
<td>HA</td>
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</table>

Linear regression:

\[ Y = -12.4095 + 1.1345 \times X \]

Level 6 not considered because out of the range accepted by the Accu-Chek Inform.
Plasma strips VS WB strips

Material

60 venous whole blood (EDTA):
• 20 with normal glucose concentration: 60-100 mg/dl
• 20 with low glucose concentration: < 60 mg/dl
• 20 with high glucose concentration: > 200 mg/dl

10 samples of capillary whole blood drawn in premature babies (high haematocrit level).
Plasma strips VS WB strips

Method
Measure of the glycaemia of each of the samples with the plasma and then the WB test strips.

Results
Considering the 70 samples together:
- Correlation: $r = 0.9965$
- Regression: New strips $= 0.2090 + 1.0726 \times$ Former strips
- Wilcoxon test: $p < 0.0001$
Plasma strips VS WB strips

- Linear regression
Plasma strips VS WB strips

- Bland-Altman plot
Plasma strips VS WB strips

The same statistical tests were realized on every group of samples taken separately.

Conclusions

**Significant difference** between the results obtained with the plasma and the WB strips:

• considering the 70 samples together

• considering each group separately except for the low concentration samples.

Results of plasma strips on average 7% **superior** to those given by the WB strips.

**Excellent correlation** in every case.
Material
54 patients
Simultaneous puncture of a drop of capillary whole blood and a tube of venous whole blood.

Method
Capillary whole blood directly analyzed by Accu-Chek Inform with plasma calibrated test strips.
Centrifugation of the tubes and measure of glycaemia on plasma (hexokinase method). Delay: < 2 hours.
Analyzer: Integra 700 (Roche).
Plasma strips VS Analyzer

Results

Plasma strips VS Integra

- Correlation: \( r = 0.9780 \)
- Regression: New test strips = \(-6.1860 + 1.1766 \times \) Integra
- Mann-Whitney test: \( p = 0.0351 \)
Plasma strips VS Analyzer

- Bland-Altman plot:
Plasma strips VS Analyzer

- Clark error grid
New strips VS Analyzer

Conclusions

Results of the Accu-Chek Inform about 10% higher than results of the Integra.

Statistically significant difference.

Underestimation of plasma glucose concentration might be explained by the delay in separating plasma from blood. (A.Y.W. Chan, Clin. Chem. 35/2, 315-317 (1989)).

But no clinically significant difference.

Good correlation.
Plasma strips VS Blood gas analyzer

Material

20 syringes of whole blood (11 arterial et 9 venous) drawn in ICU.

Method

Determination of the glycaemia by the electrode of glucose of the blood gas analyzer (Rapidlab 865, Bayer: glucose oxydase method, amperometric detection) on the syringe.

Right after that, measure of the glycaemia from a drop of blood of this syringe with Accu-Chek Inform and plasma calibrated test strips.
Plasma strips VS Blood gas analyzer

Results

For all the 20 samples:

- Correlation: $p = 0.9778$
- Regression: New strips = $-2.7847 + 1.0409 \times \text{Bayer 865}$
- Wilcoxon test: $p = 0.2579$
Plasma strips vs Blood gas analyzer

- Bland-Altman plot
Plasma strips VS Blood gas analyzer

Conclusions
No significant difference between the results given by the blood gas analyzer and those given by the Accu-Chek Inform, whatever arterial or venous sample was used.

Good correlation.
Capillary VS Venous

Material
20 patients
Simultaneous puncture of a drop of capillary whole blood and an EDTA tube of venous whole blood.

Method
Capillary whole blood analyzed directly by Accu-Chek Inform with plasma calibrated test strips.
Simultaneous determination of the glycaemia on a drop of venous whole blood.
Capillary VS Venous

Results

- Correlation: \( r = 0.9615 \)
- Regression: Capill blood = 3.4657 + 0.9633 \times \) Venous blood
- Mann-Whitney test: \( p = 0.7150 \)
Capillary VS Venous

- Bland-Altman plot
Capillary VS Venous

Conclusions

No significant difference between a glycaemia measured on capillary whole blood or venous whole blood with the plasma calibrated Accu-Chek test strips.

Good correlation.
Conclusions

Global difference between the plasma and WB test strips of 7.3 %.

Not influenced by:

✓ the glucose concentration in the sample
✓ the haematocrit rate
Conclusions

Comparable values of glycaemia obtained with:

- Plasma calibrated strips on capillary whole blood
- Plasma calibrated strips on venous whole blood
- Blood gas analyzer with venous or arterial blood.