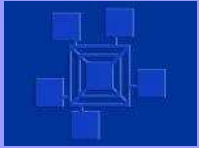# Analytical validation of the new plasma calibrated Accu-Chek Test Strips (Roche Diagnostics®)

Meex Cécile

Clinical Chemistry

C.H.U. Liège, Belgium

CHU Liège: 3 sites

The site of the CHU consists of three establishments:

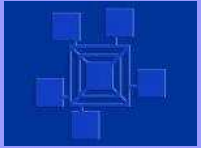- CHU Sart-Tilman
- CHU Notre-Dame des Bruyères
- CHU Ourthe-Amblève

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…

Point of Care in CHU Liège

- 8 blood gas analyzers.

❖ **Before December 2004**

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

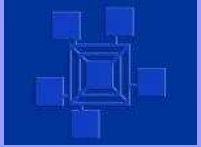- A lot of Accu-Chek Sensors (Roche) disributed in the other services **without control of the laboratory.**
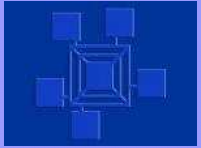
Point of Care in CHU Liège: Accu-Chek Inform.

❖ **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 responsability of the laboratory.

➢Recording of the lots of used tigettes.

➢ Documented training of the staff.

➢ External QC 4×/year.

Training of the staff

Nurses = Qualificated technicians under the responsability 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.

Point of Care in CHU Liège:
Accu-Chek Inform

Validation of the Accu-Chek Informs

Each devices was validated before its first use:

• Repeatability

• Reproducibility

• Linearity

Any device presenting a total error > 14 % : **rejected**.
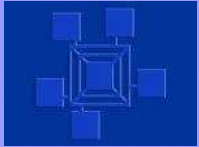
Point of Care in CHU Liège: Accu-Chek Inform

❖March 2005: Accu-Chek Informs effective in the wards.
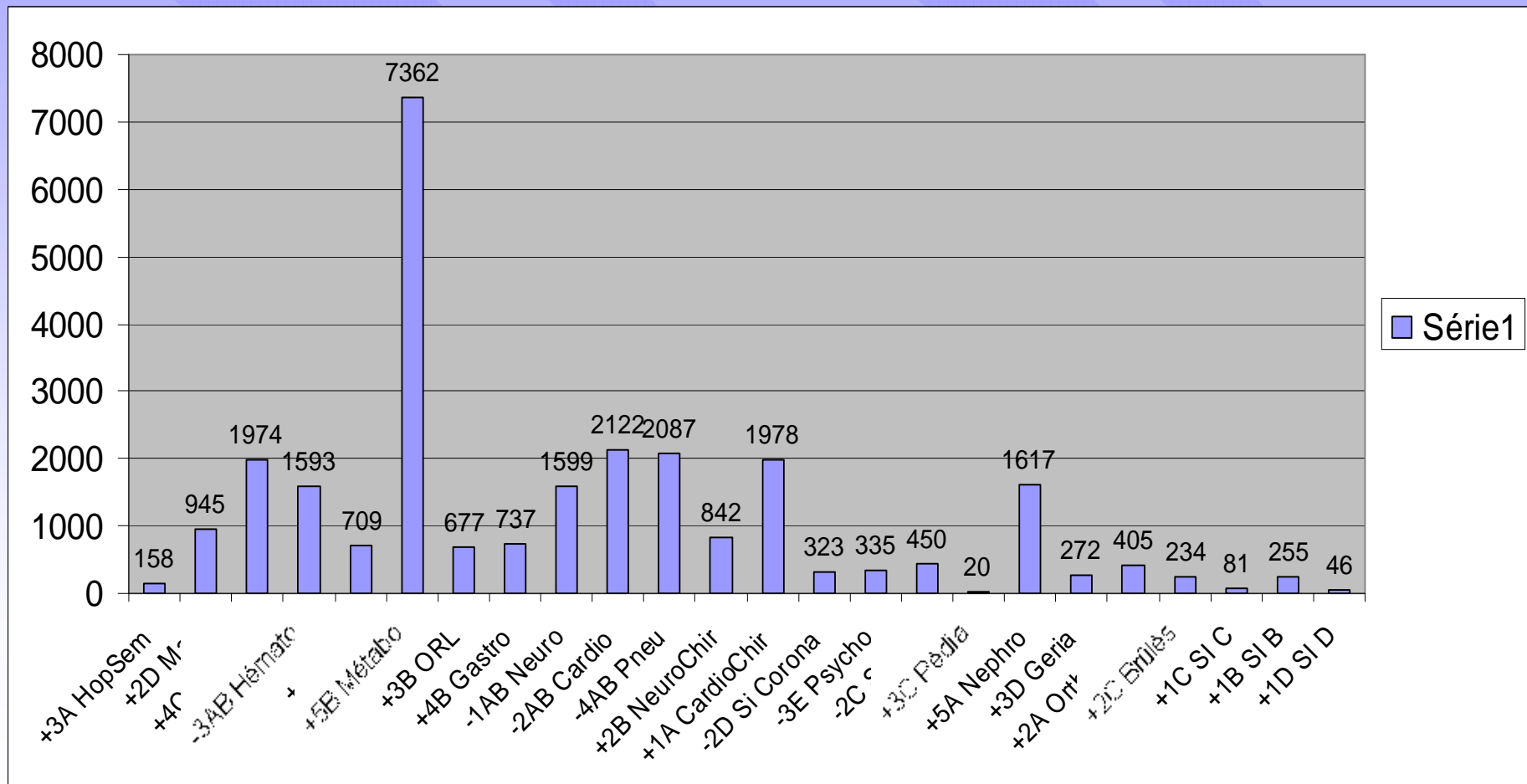
27000 glycaemias realized from March 05 to this day.

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.
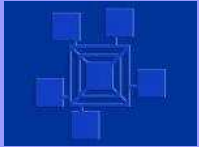
Repeatability

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

	Level 1	Level 2
Labo mean	54,4	327
Standard deviation	1,65	10,52
CV	3,03	3,22
	55	329
	56	342
	55	329
	54	330
	54	312
	57	321
	54	331
	51	317
	53	316
	55	343
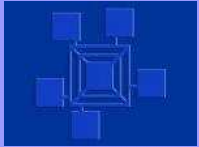
Reproducibility

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

	Level 1	Level 2
Labo mean	55,5	319,2
Standard deviation	2,92	9,55
CV	5,26	2,99
	55	316
	58	330
	57	333
	59	329
	57	316
	57	325
	49	305
	54	308
	53	314
	56	316
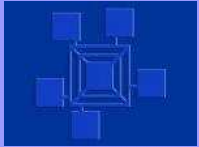
Linearity

Linearity test kit (Roche)
mg/dl

Level	Reference	Labo
1	39	30
2	62	60
3	131	148
4	315	319
5	472	537
6	510	HA

Linear regression:

Y= -12,4095 + 1.1345 X
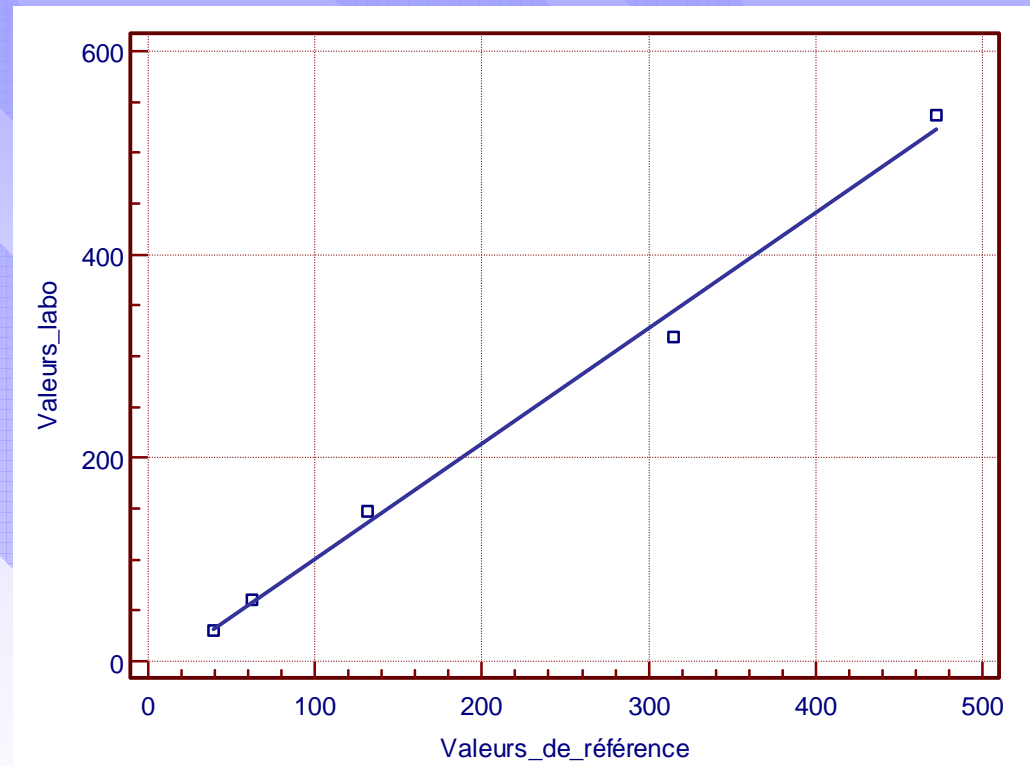
Level 6 not considered because out of the range accepted by the Accu-Chek Inform.

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).

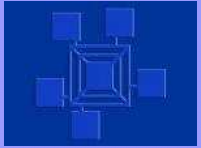# Plasma strips VS WB strips

Method

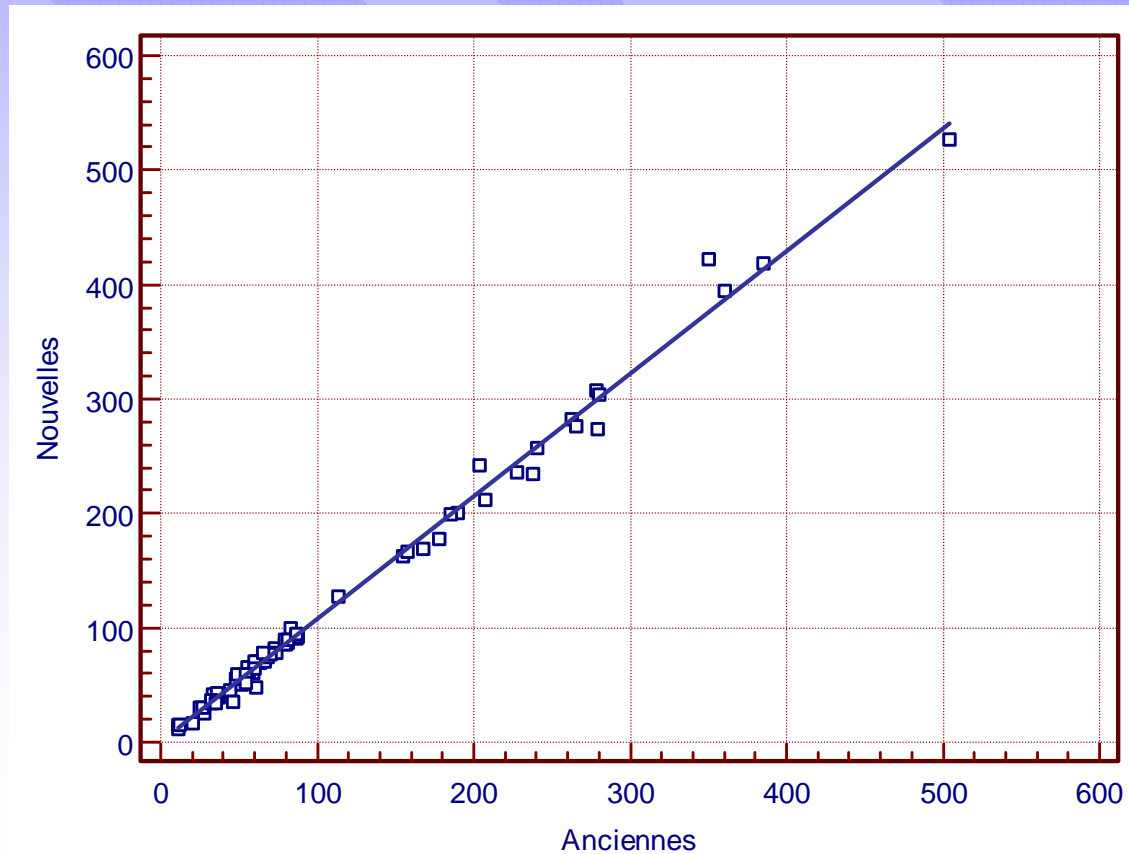Measure of the glycaemia of each of the samples with the plasma and then the WB test strips.
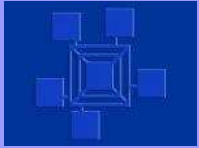
Results

Considering the 70 samples together:

- Correlation: r = 0,9965

- Regression: New strips = 0,2090 + 1,0726 × Former strips
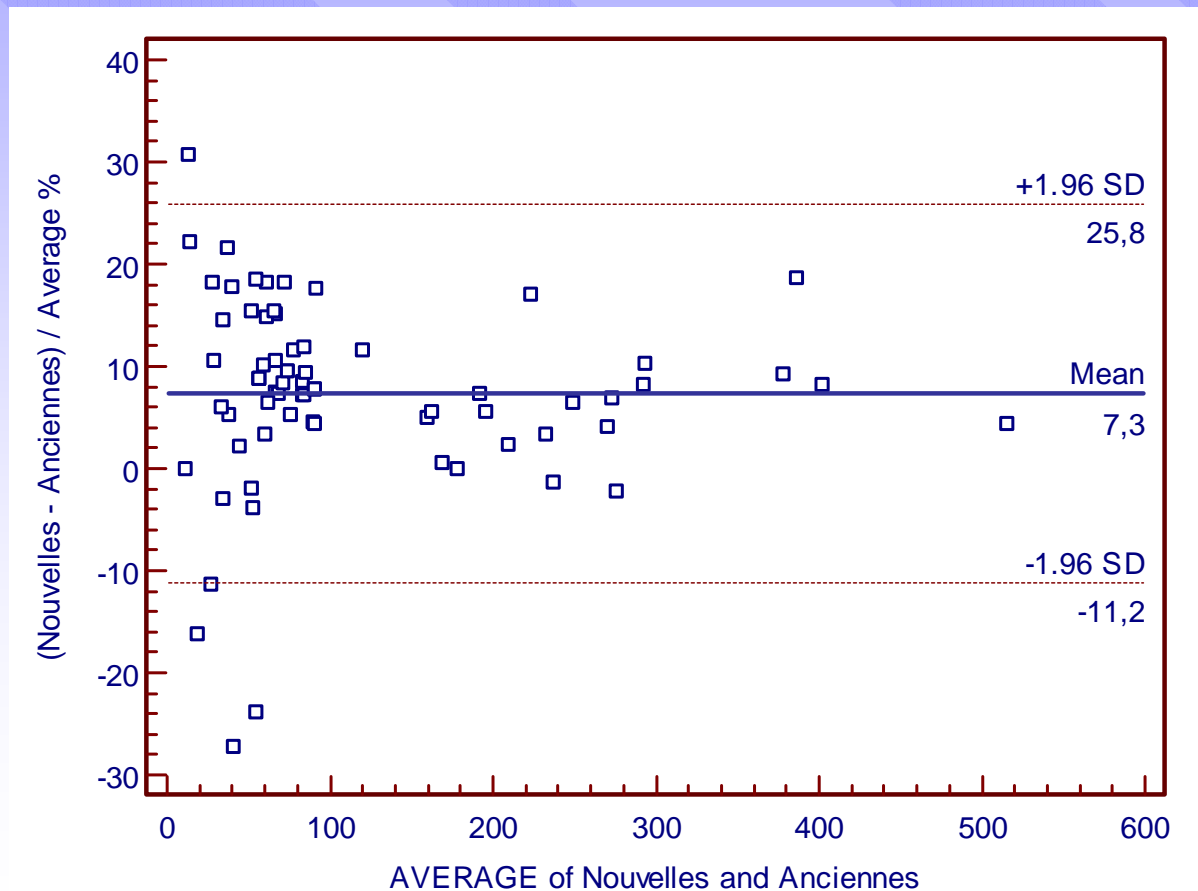
- Wilcoxon test: $p < 0.0001$

Plasma strips VS WB strips
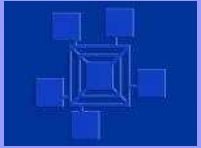
- Linear regression

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.

Plasma strips VS Analyzer

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.

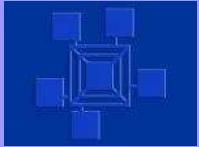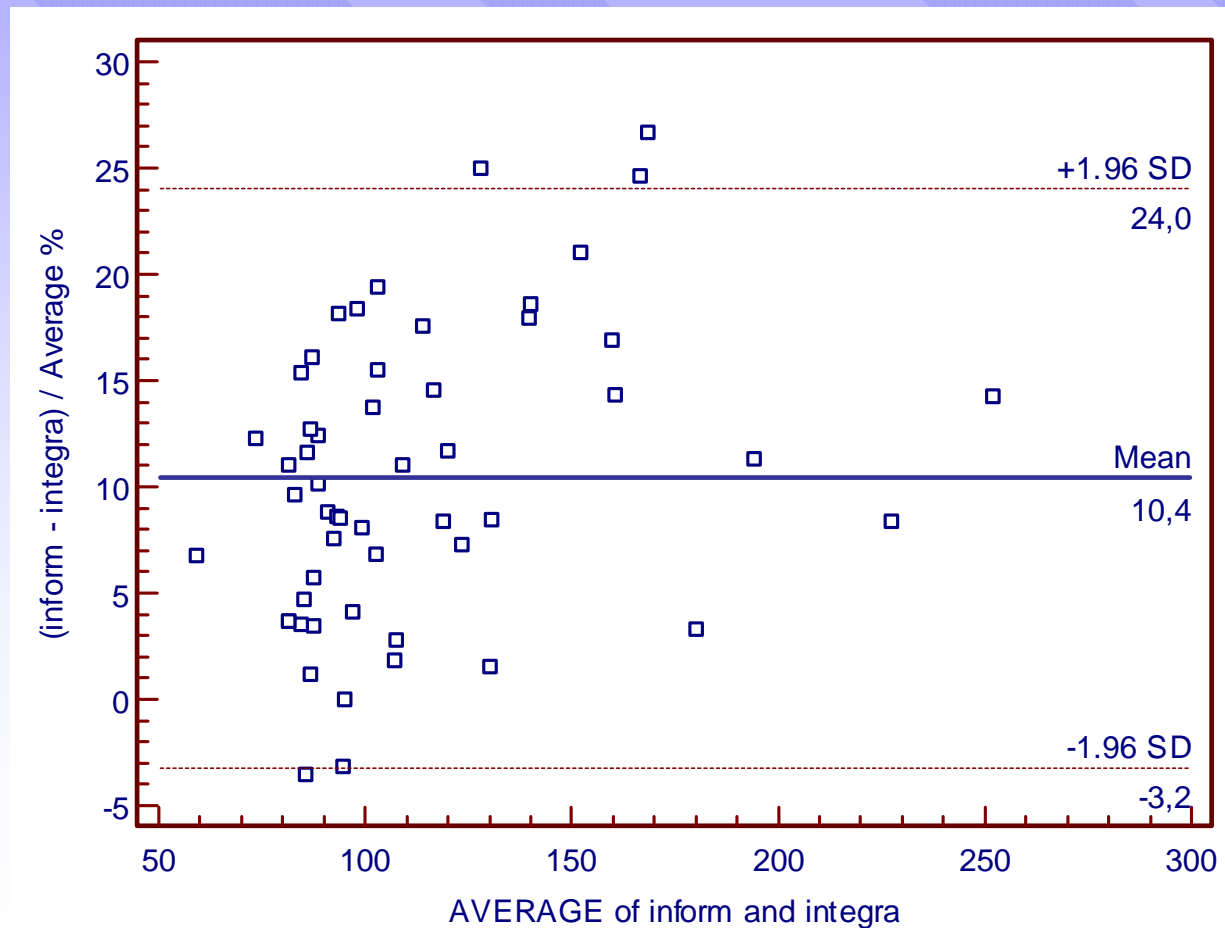Analyzer: Integra 700 (Roche).
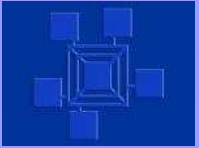
Plasma strips VS Analyzer

Results

Plasma strips VS Integra

- Correlation: r = 0,9780

- Regression: New test strips = -6.1860 + 1,1766 × Integra

- Mann-Whitney test: p = 0.0351
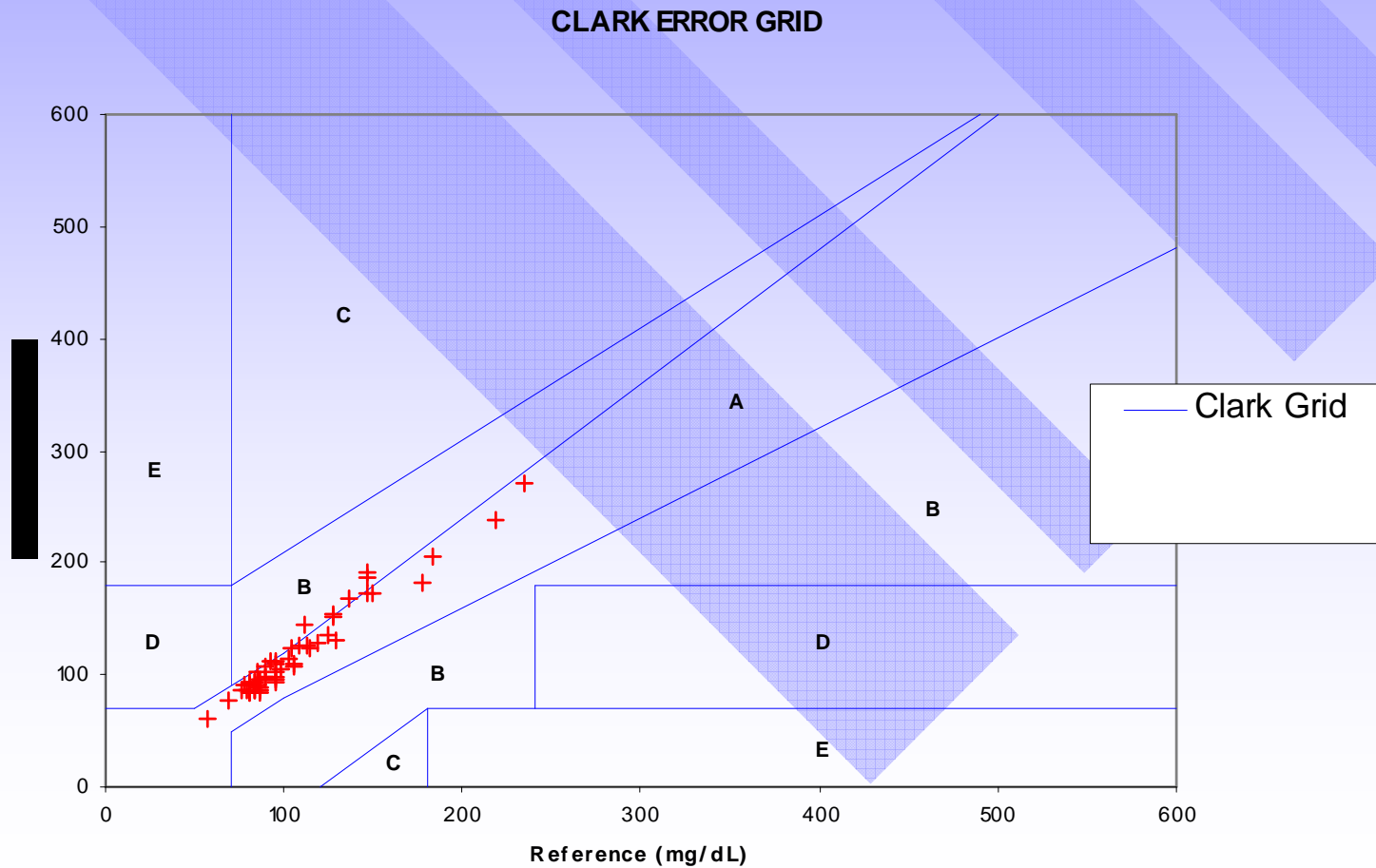
Plasma strips VS Analyzer

- 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.**

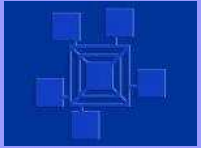Good correlation.

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.
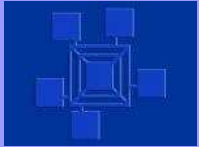
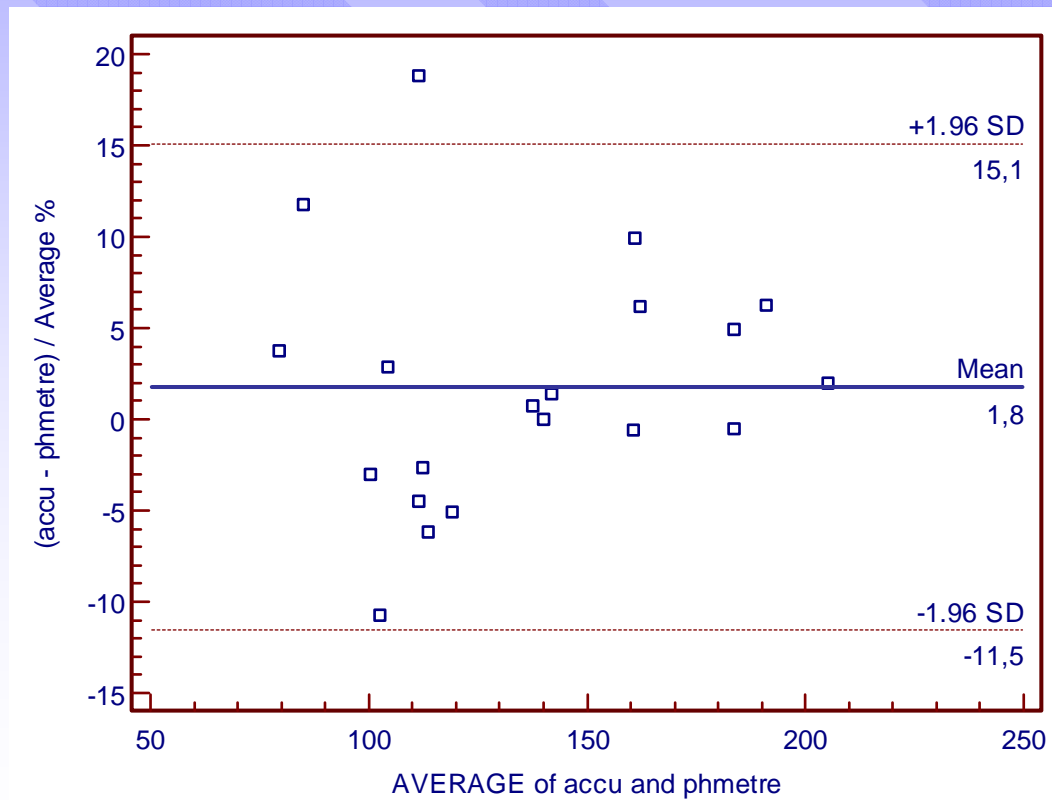# Plasma strips VS Blood gas analyzer
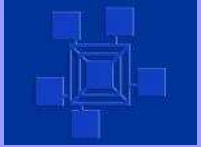
Results

For all the 20 samples:

- Correlation: p = 0,9778

- Regression: New strips = -2,7847 + 1,0409 × Bayer 865

- Wilcoxon test: p = 0,2579

Plasma strips VS Blood gas analyzer
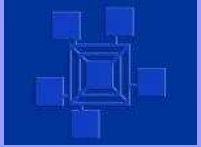
- Bland-Altman plot

Plasma strips VS Blood gas analyzer

<u>Conclusions</u>

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.
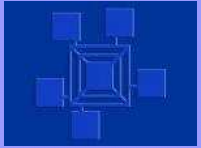
Capillary VS Venous

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.
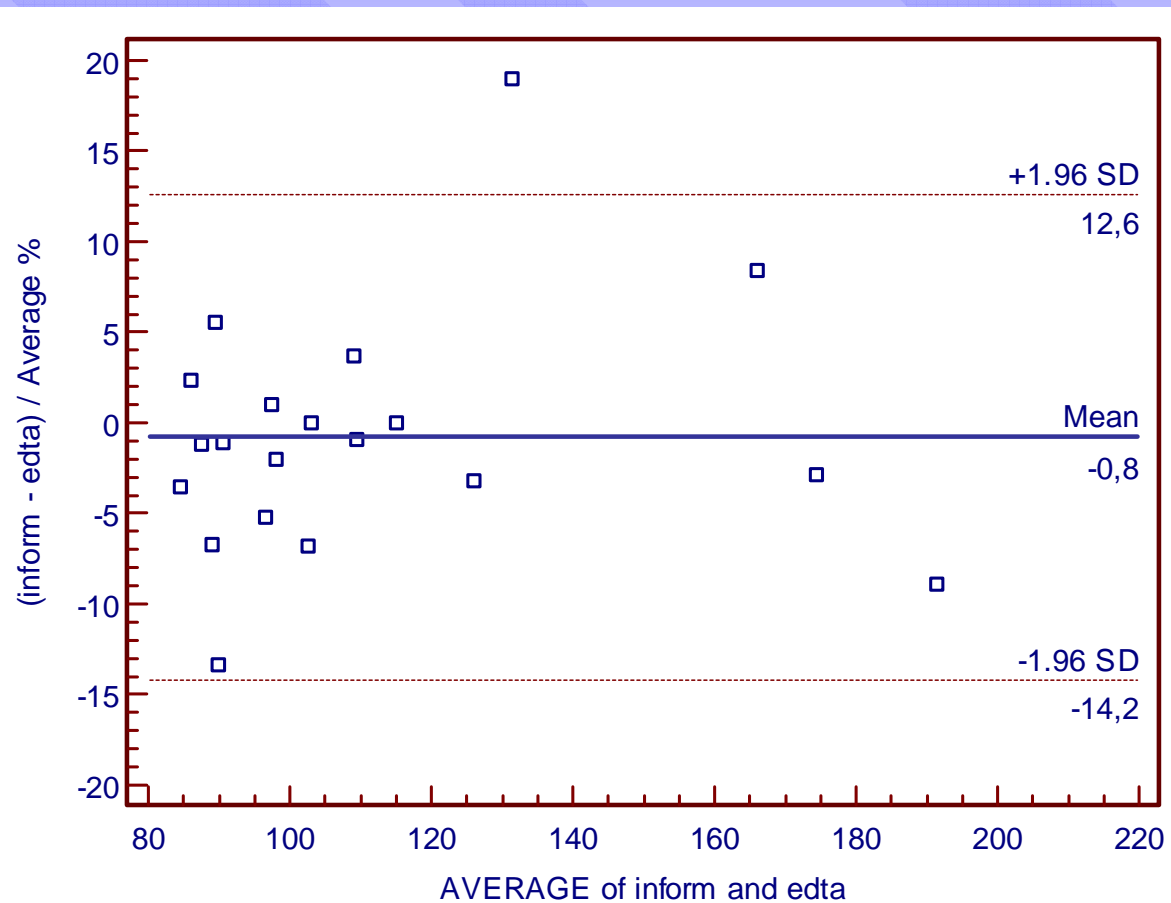
Capillary VS Venous

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

<u>Conclusions</u>

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.