

# Ervaringen Sectie Stolling met Kwaliteitscontrole POCT

Symposium: De rol van Laboratoria in de moderne Trombosezorg

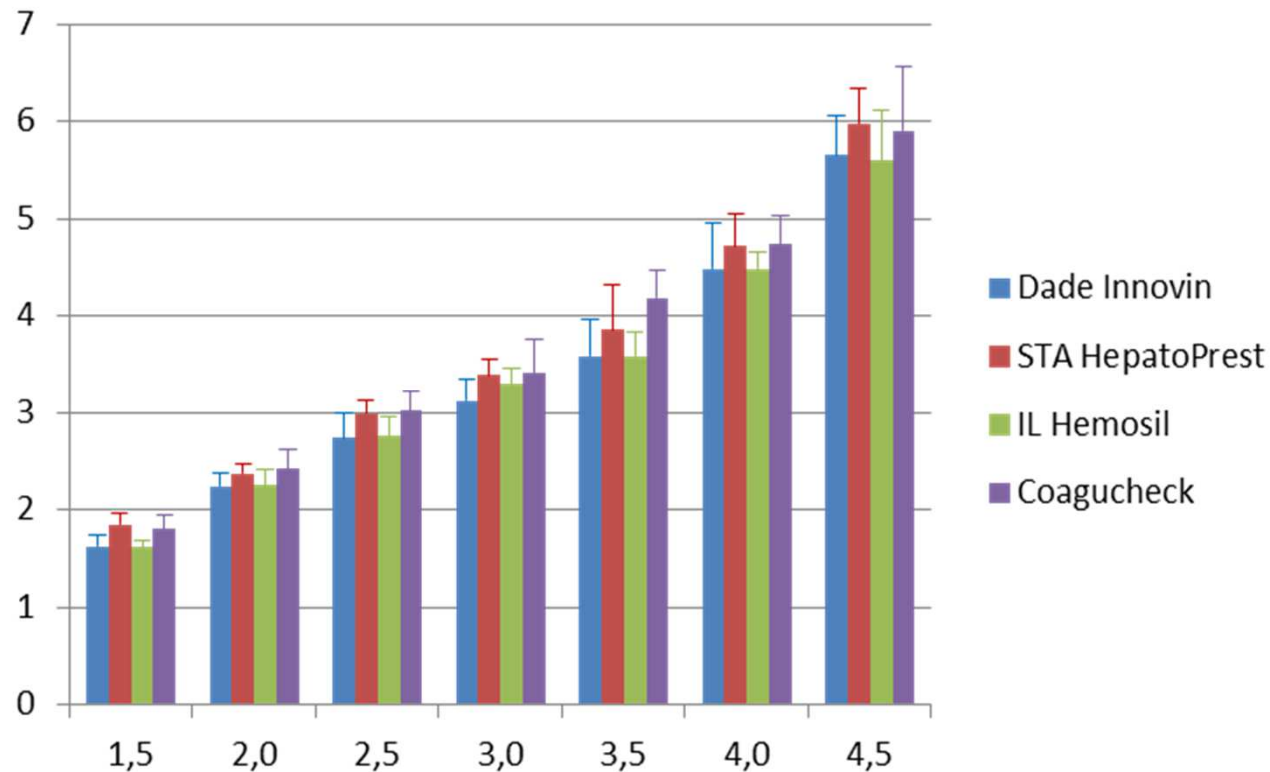
ECAT / SKS

Chris Hackeng | 9 november 2016 |

# Rondzending INR (POCT)

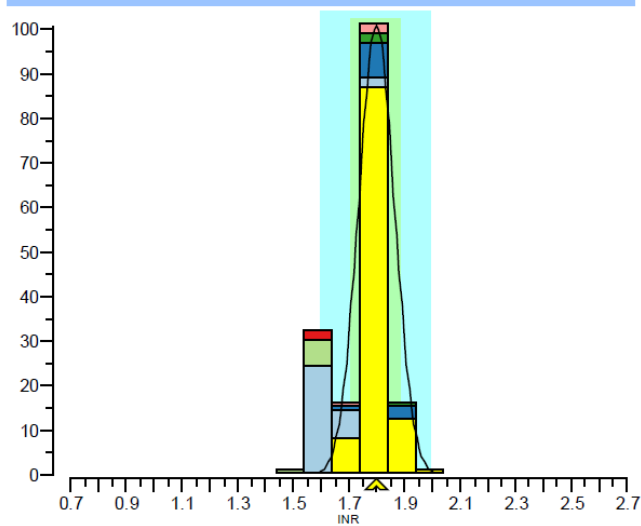
- **Staken werkzaamheden RELAC laboratorium eind 2014**
- **Start rondzending INR SKML én ECAT per 1-1-2015**
- **Ca 165 deelnemers (105 POCT “coagucheck”), 60 analysers**
- **Naast de reguliere SKML stolling**
  - **PT**
  - **aPTT**
  - **fibrinogeen**
  - **antitrombine**
  - **factor VIII**
  - **PT-INR**
- **Monsters met “streefwaarden” INR 1.5 - 4.5 , met intervalstappen van INR 0.5**

# Resultaten 2016

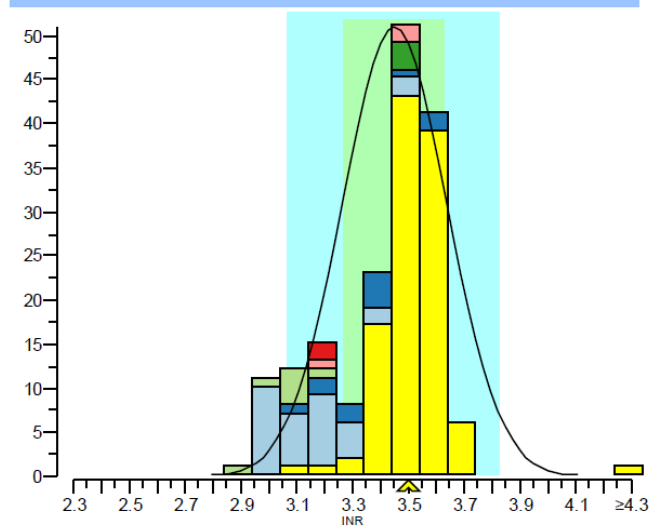


Per waarde 1<sup>e</sup> monster van 2016, de 4 grootste groepen

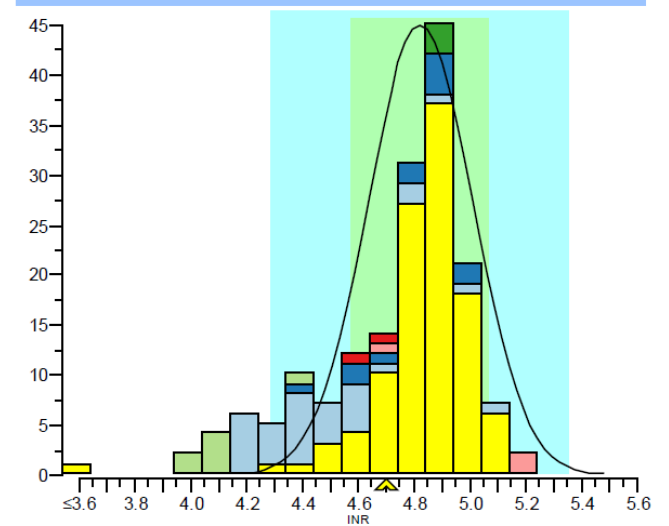
# Rondzendingsresultaat 2016



	cons.	meth.	ALTM	lab
gem.	1.80	1.80	1.80	1.8
SD	0.06	0.06	0.06	
n	108	108	167	
nu	1	1	34	



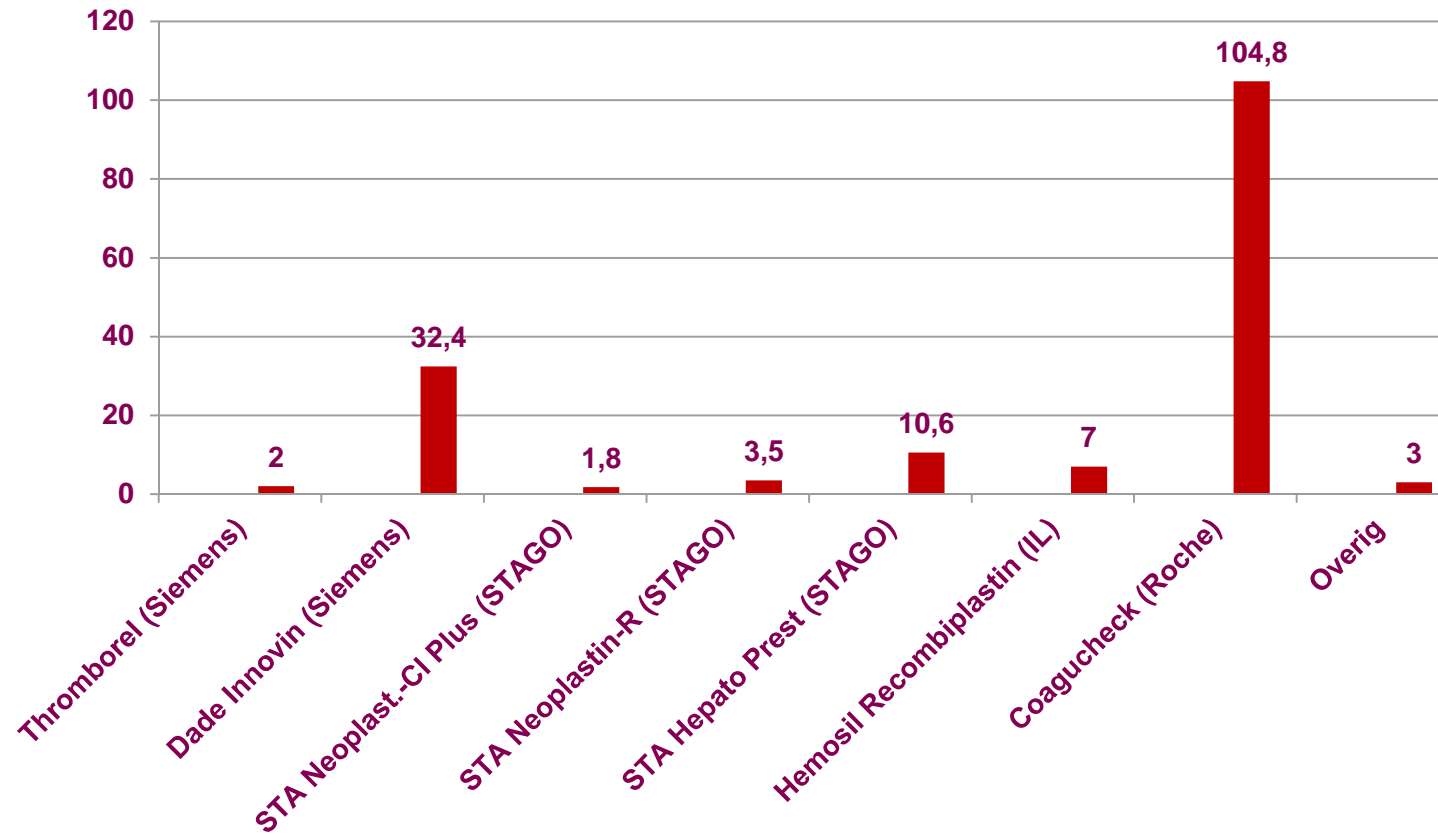
	cons.	meth.	ALTM	lab
gem.	3.53	3.53	3.45	3.5
SD	0.10	0.10	0.19	
n	110	110	169	
nu	3	3	1	



	cons.	meth.	ALTM	lab
gem.	4.87	4.87	4.82	4.7
SD	0.12	0.12	0.19	
n	108	108	167	
nu	6	6	13	

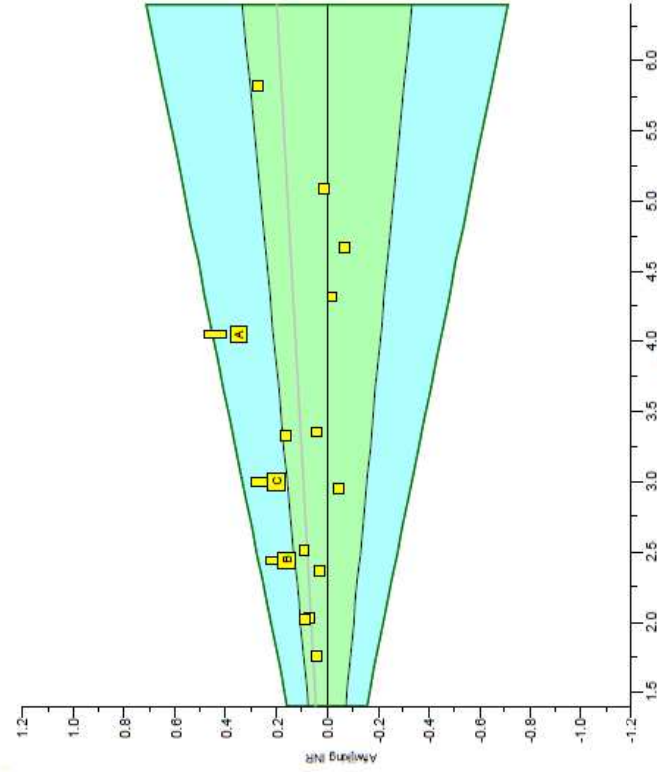


# Verdeling gebruikers 2016



# PT-INR

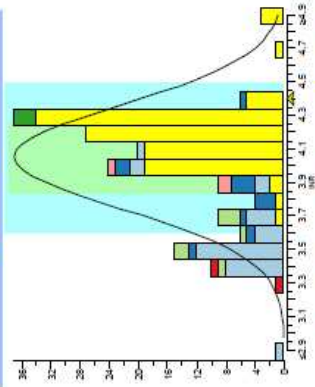
eenheid : INR



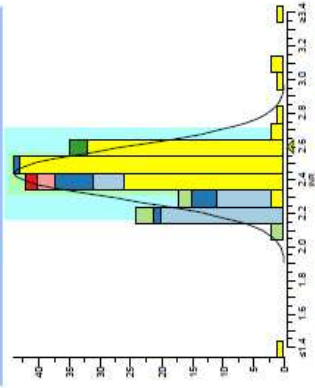
	2016.3	cumulatief
Juistheid	+7.4%	+3.2%
Precisie	0.55%	3.9%
Aantal	3	15
Uitbijters	0	0
Sigma-TE	-1.5	3.0
Sigma-SA	5.4	6.0
Score pictogram		
Regressielijn		

Consensusgroep	ALTM
Methode	CoaguChek XS
Analyser	CoaguCheck XS
Uw factor	0.0 + 1.000.x
Methode factor	0.0 + 1.000.x

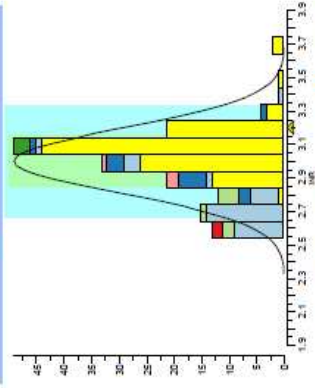
2016.3 A



2016.3 B



2016.3 C

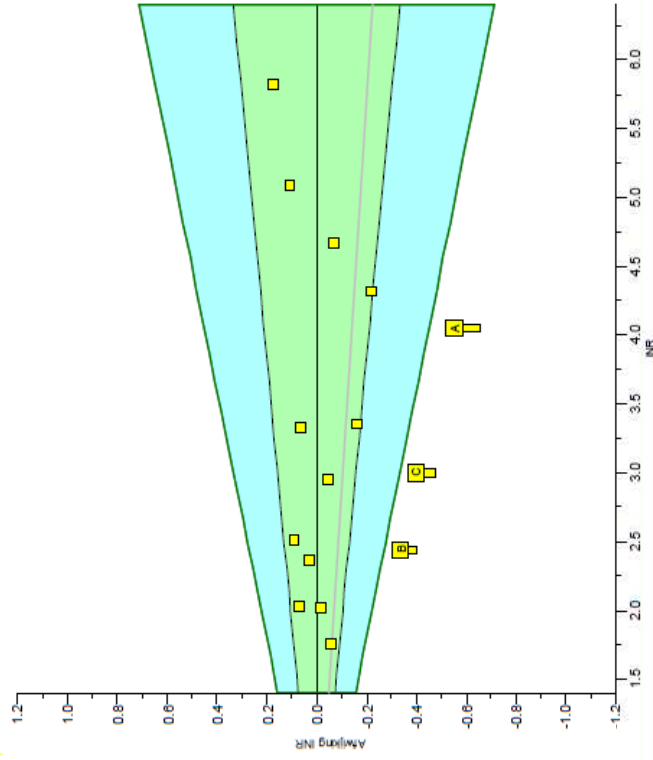


Legenda

- CoaguChek XS
- Dade Innovin (Siemens)
- STA Hepato Prest (STAGO)
- Thromborel-S (Siemens)
- Hemosil Recombiplastin 2G (LL)
- Andere preparaten

# PT-INR

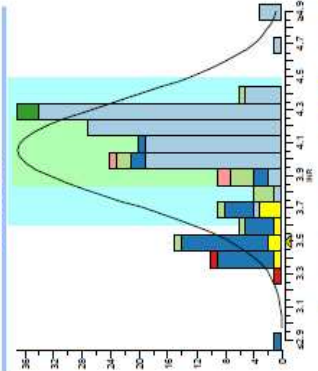
eenheid : INR



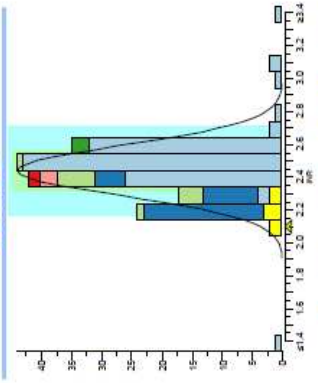
	2016.3	cumulatief
Juistheid	-14%	-4.1%
Precisie	0.24%	7.1%
Aantal	3	15
Uitbijfers	0	0
Sigma-TE	-3.0	2.5
Sigma-SA	-2.2	6.0
Score pictogram		
Regressielijn	$0.00 + 0.965.x$	$0.00 + 0.965.x$

Consensusgroep	ALTM
Methode	HemosIL Recombiplastin 2G (I.L.)
Analyser	ACL TOP (alle typen)
Uw factor	0.0 + 1.000.x
Methode factor	0.0 + 1.000.x

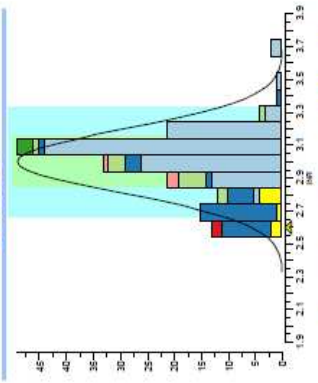
2016.3 A



2016.3 B



2016.3 C



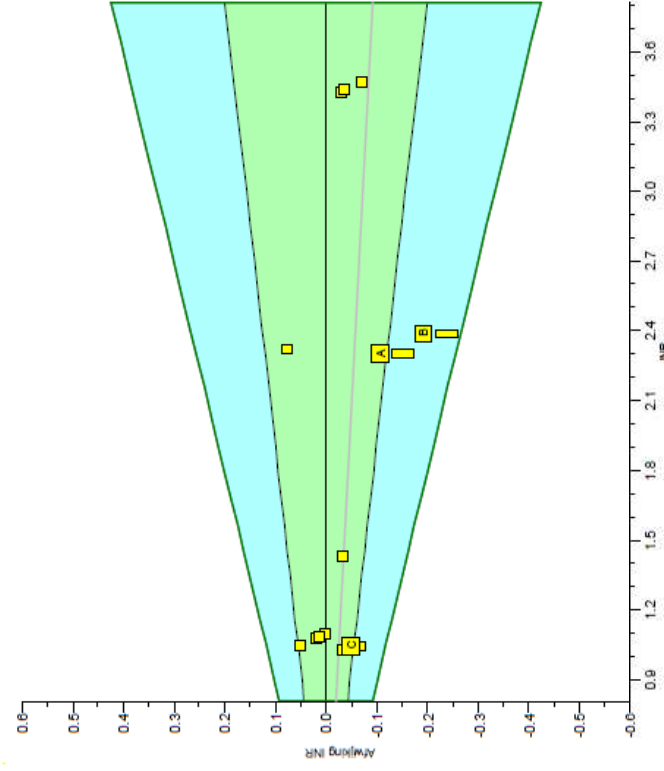
Legenda

- HemosIL Recombiplastin 2G (I.L.)
- CoaguChek XS
- STA Neoplastin-R (STAGO)
- STA Hepato Prest (STAGO)
- Andere preparaten
- Daede Innovin (Siemens)
- Thromborel-S (Siemens)



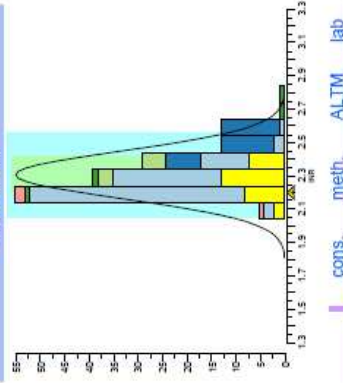
# PT-INR

eenheid : INR

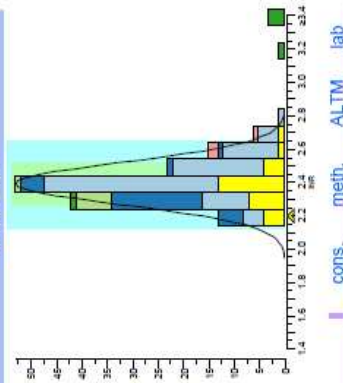


	2016.3	cumulatief
Juistheid	-6.1%	-2.4%
Precisie	2.2%	3.7%
Aantal	3	15
Uitbijters	0	0
Sigma-TE	0.1	3.2
Sigma-SA	6.0	6.0
Score pictogram		
Regressielijn	0.00 + 0.975.x	
Consensusgroep	ALTM	
Methode	HemosIL Recombiplastin 2G (I.L.)	
Analyser	ACL TOP (alle typen)	
Uw factor	0.0 + 1.000.x	
Methode factor	0.0 + 1.000.x	

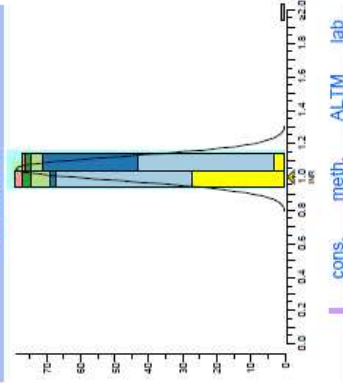
2016.3 A



2016.3 B



2016.3 C



## Legenda

HemosIL Recombiplastin 2G (I.L.)

Dade Innovin (Siemens)

STA Hepato Prest (STAGO)

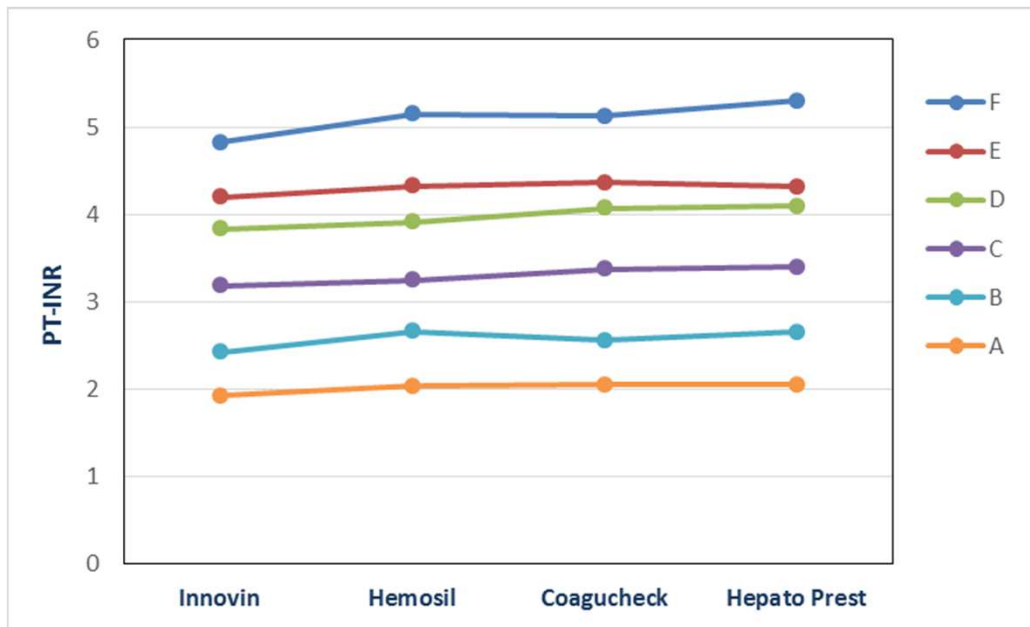
STA Neoplastin-R (STAGO)

STA Neoplastin-CI Plus (STAGO)



# Score methodiek

Op methodegroep, of ALTM?



Gemiddelde 6 monsters 2015  
Per methode

## Conclusies:

1. De verschillen tussen de verschillende preparaten waren in 2015 gering.
2. Derhalve is scoren op ALTM gerechtvaardigd (per 2016.3).

# Coagucheck



## Volbloed (capillair) analyser

- Opbrengen geresuspendeerd plasma





# Coagulation

## *Evaluation of the CoaguChek XS System*

- An AC voltage is applied and the admittance of the sample is determined. This value reflects the haematocrit of the blood sample, and is used to compensate the haematocrit influence on the PT measurement.

International Evaluation  
Workshop

25 November 2005  
Heidelberg, Germany

# Coagulation

## *Evaluation of the CoaguChek XS System*

*S. Kitchen:* Does the device give an alert when the haematocrit is too low or too high?

*V. Unkrig:* No, the device does not give an alert. The specified haematocrit range is 25% to 55%.

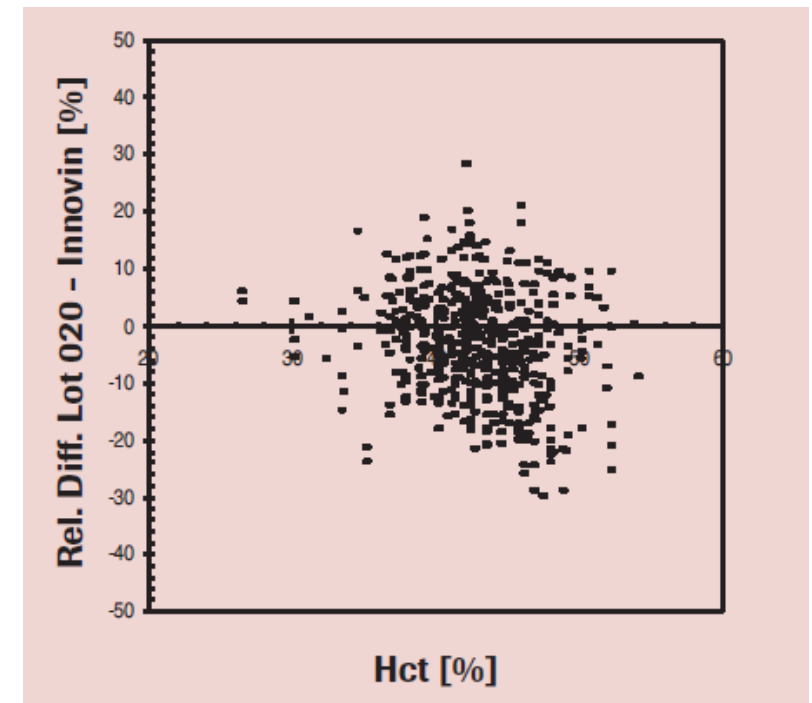
If the haematocrit of the sample is out of this range the meter gives a reliable INR value or an error message.

*A. van den Besselaar:* The INR values of the CoaguChek XS system are corrected by the haematocrit. This correction is not performed in the PT determinations with the thromboplastins in the laboratory. Thus, the good agreement between the laboratory reagents seen in our own studies, which I will report on later, and the CoaguChek XS system is remarkable.

# Coagulation

## *Evaluation of the CoaguChek XS System*

The INR results of the CoaguChek XS system were not biased by haematocrit in a haematocrit range from 25% to 55% (Figure 6.7), and by fibrinogen between 167 mg/dl and 600 mg/dl (Figure 6.8).



**Indien uitslaggegeven wordt, dan maximaal 10 % afwijking  
(mondelinge communicatie Roche)**

# Vergelijkbaarheid (SKML)

- **Coagucheck**
  - 100  $\mu$ L geresuspendeerd plasma (AD)
  - 100  $\mu$ L 16 mM  $\text{CaCl}_2$
  - Eind: Plasma 1:2,  $\text{CaCl}_2$  8 mM
  - Hematocriet 0.0 L/L
  
- **Analyser (STA-Evo)**
  - 50  $\mu$ L geresuspendeerd plasma (AD) (1:10)
  - 100  $\mu$ L Hepatoprest reagens
  - 50  $\mu$ L 10 mM  $\text{CaCl}_2$
  - Eind: Plasma 1:40,  $\text{CaCl}_2$  2.5 mM



# Lastige keuzes.....

- **Scoren op methodegroep**
  - Statistisch niet haalbaar
- **Splitsing rapportage**  
**Coagucheck en analysers**
  - Lijkt reële keuze
  - Overleg SKML
- **Invoeren referentielab**
  - Enkele, meerdere methoden?
  - Referentiemethode: Manual Tilt Tube Method, referentie preparaten

