

HbA1c

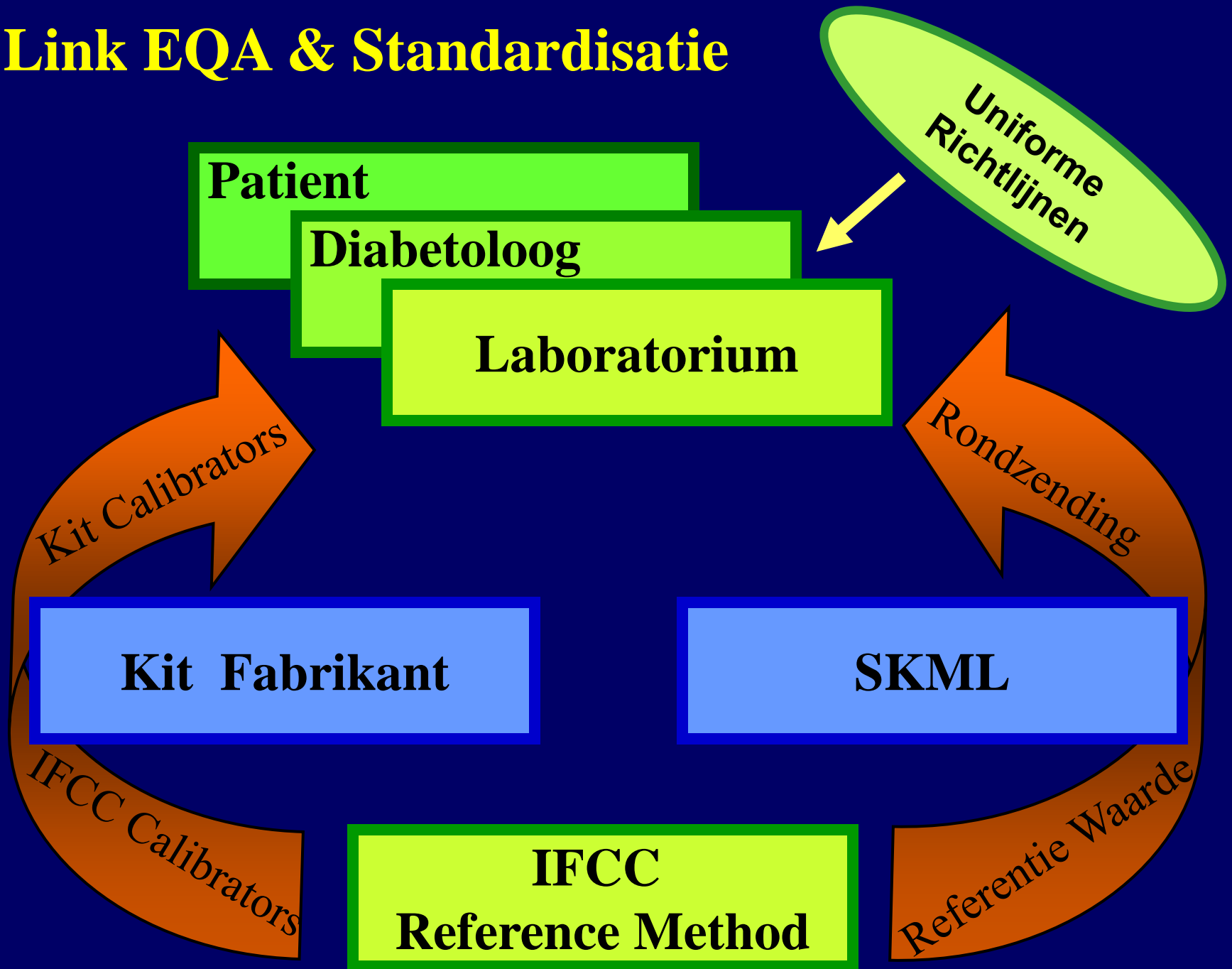
Komt het werk ooit klaar?

Cas Weykamp

SKML Sectie Algemene Chemie

Congres "De Waarde van de Expert" 9 juni 2015

Link EQA & Standardisatie



Effect Rondzending

**Rondzending stimuleert
Fabrikanten en Labs
Om goed te presteren.....**

**.....en draagt zo bij aan
Kwaliteits Verbetering HbA1c**

Effect Rondzending

Rondzending stimuleert

Fabrikanten en Laboratoria

Om goed te presteren ...

.....en dreven zij aan

Kwaliteitsverbetering HbA1c

Zou het echt?

HbA1c: Trend Kwaliteit 20 jaar

<i>Jaar</i>	<i>Bias Target*</i>	<i>Intralab CV</i>	<i>Interlab CV</i>
1993	----	6%	33%
1999	+3	5 %	16%
2002	-1	4%	12%
2007	-2	3%	5%
2014	0	2%	3%

Interlab CV 3%; Intralab CV 2%



Tijd om achterover te leunen?

Kwaliteit HbA1c Verbeterd



Paradigma Verandering



**HbA1c niet alleen Monitoring.....
.... Maar ook Diagnose Diabetes**

Normen Diagnose Diabetes

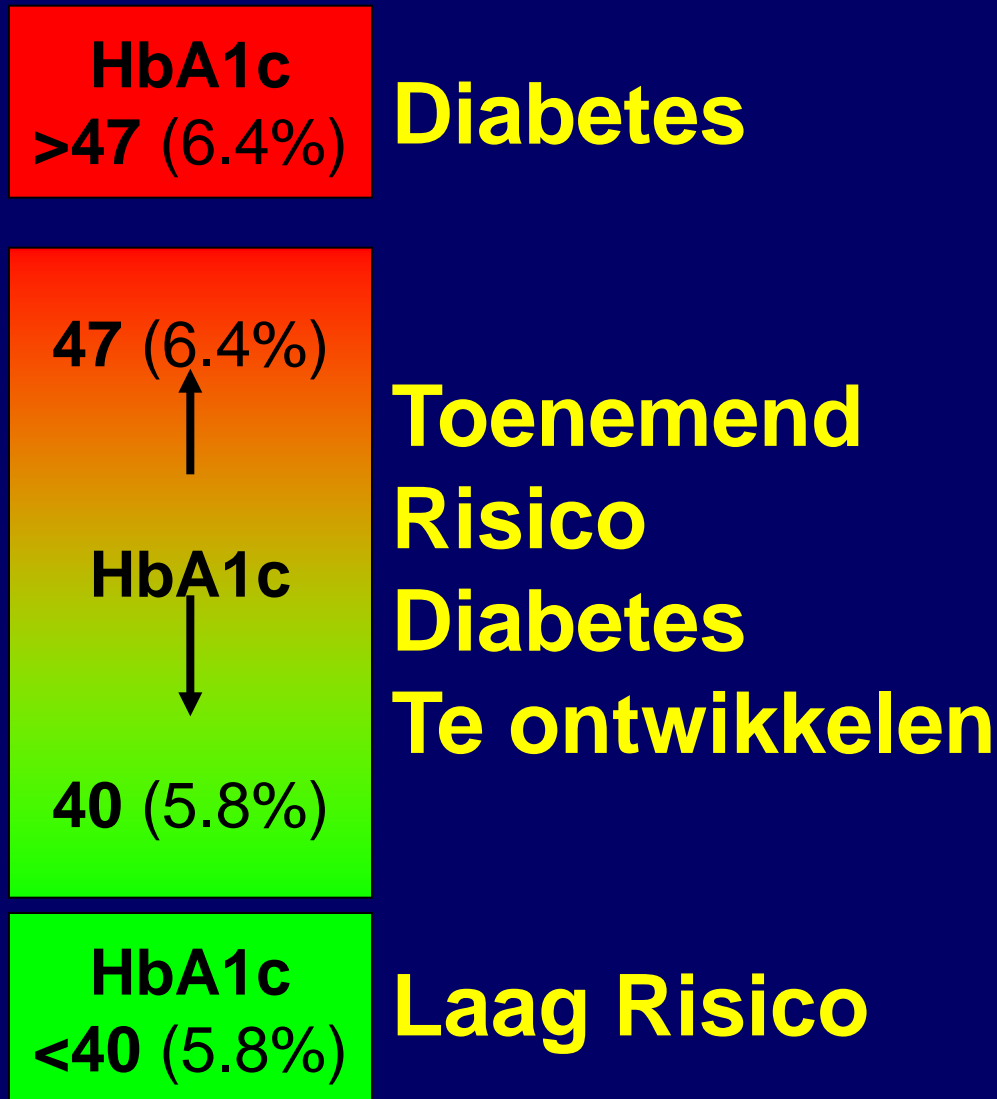
Jaar	Autoriteit
1979	NDDG (USA) and WHO
1997	ECDC (USA) and WHO
2009	IEC (ADA – EASD – IDF)

	1979 WHO	1997 WHO	2009 IEC
Gold Standard	Glucose Tolerance Test	Fasting Plasma Glucose	HbA1c
Concept	Glucose Concentration	Long Term Complications	Long Term Complications
Norms	FPG >140 2HPG >200	FPG >125 2HPG >200	HbA1c >47 (6.4%)
	FPG <140 2HPG 140-200	FPG 110-125	HbA1c 40 – 47 (5.8 – 6.4%)
Terminology “Doubt”	Impaired Glucose Tolerance	Impaired Fasting Glucose	Increasing Risk

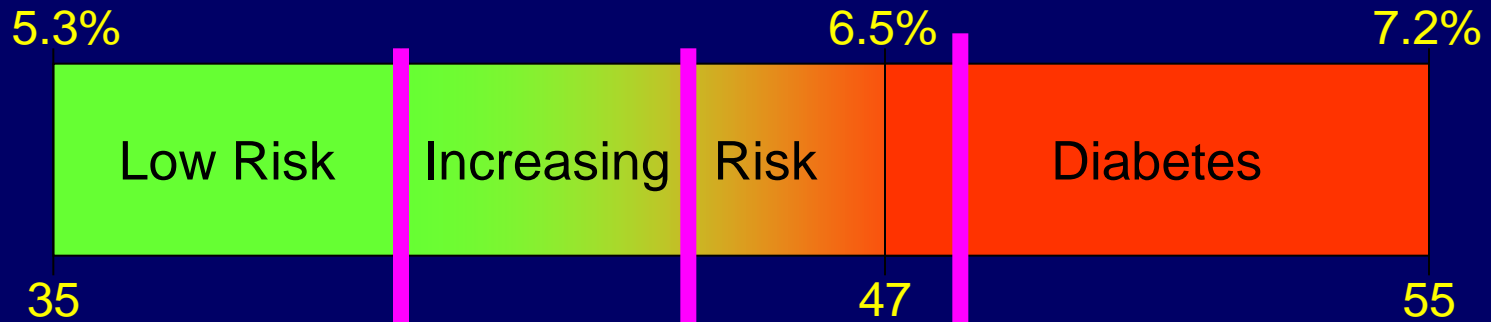
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Gold Standard	Glucose Tolerance Test	Fasting Plasma Glucose	HbA1c
Concept	Glucose Concentration	Glucose from Applications	Long Term Complications
Norms	FPG >200	FPG >125 2HPG >200	HbA1c >47 (6.4%)
	FPG <140 2HPG 140-200	FPG 110-125	HbA1c 40 – 47 (5.8 – 6.4%)
Terminology “Doubt”	Impaired Glucose Tolerance	Impaired Fasting Glucose	Increasing Risk

Dat schept Verantwoording!

Bottle-neck: Kleine Verschillen



Impact Bias



Bias + 4 mmol/mol

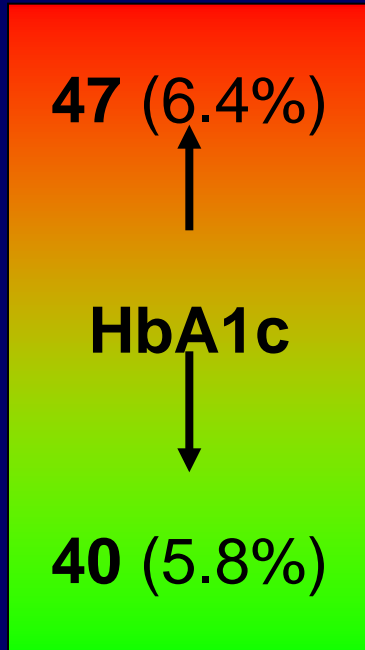
Green Bias

Bias - 4mmol/mol false low

Bottle-neck: Kleine Verschillen

HbA1c
>47 (6.4%)

Diabetes



**Toenemend
Risico**

Diabetes

Te ontwikkelen

HbA1c
<40 (5.8%)

Laag Risico

**SKML,
wat doe je
daarmee?**

SKML, wat doe je ermee?

Kijk naar jezelf:

Exit Gevriesdroogde Monsters

- Rondzendmonsters: volbloed
- Trueness Verifier: ingevroren volbloed

Scherp de Criteria aan in QBase

Bias Referentiewaarde	Score	% Labs
<0.6	2	20%
0.6 – 1.5	1	60%
>1.5	0	20%

SKML, wat doe je ermee?

Kijk naar jezelf:

Exit Gevriesdroogde Monsters

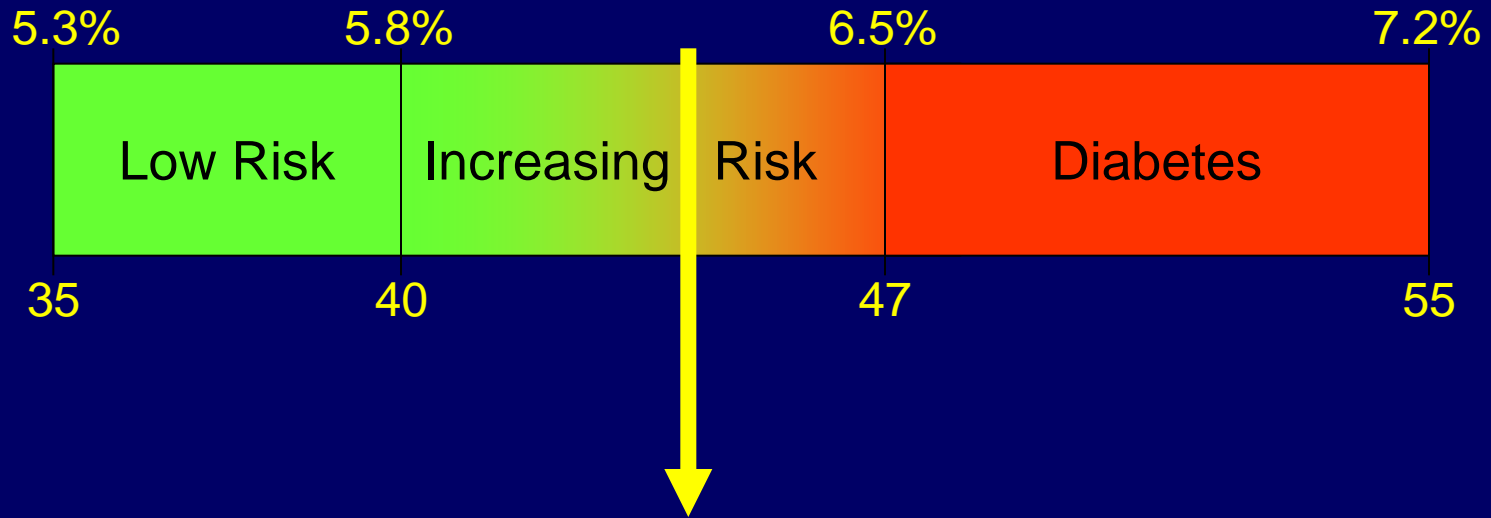
- Rondzendmonsters: volbloed
- Trueness Verifier: ingevroren volbloed

Te Streng?

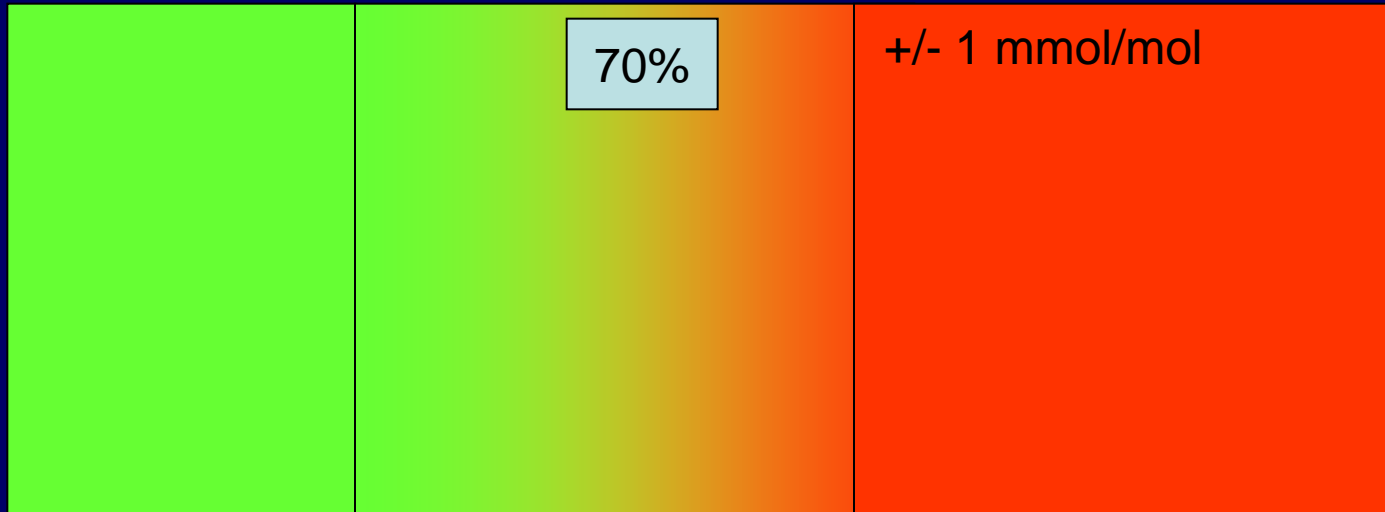
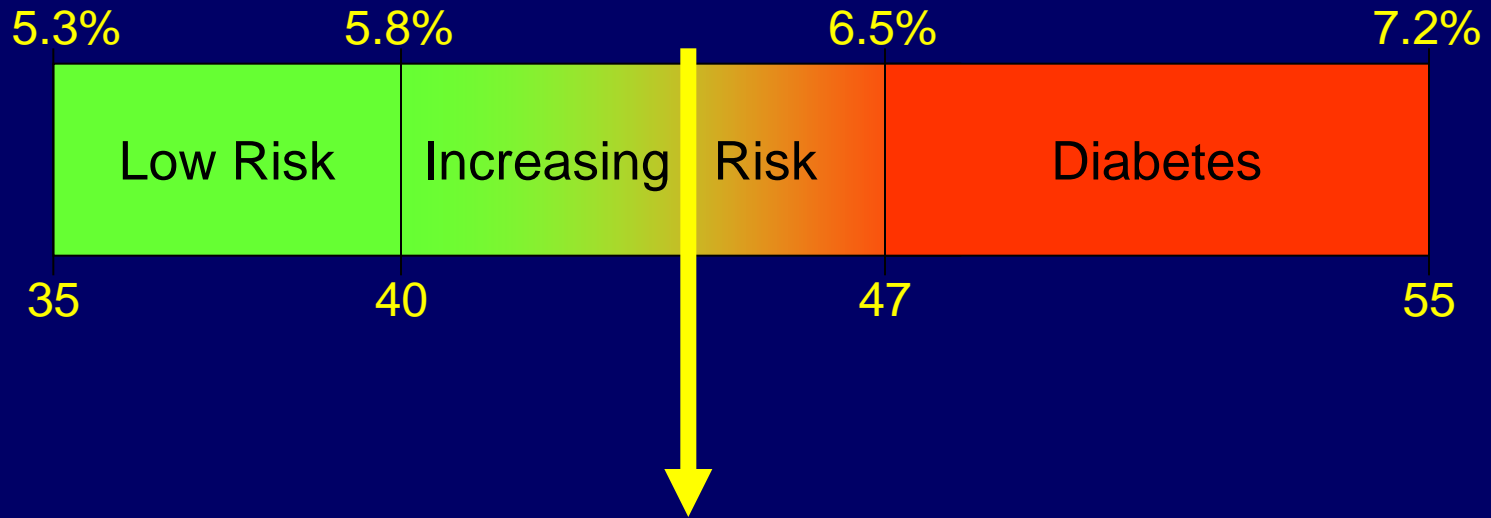
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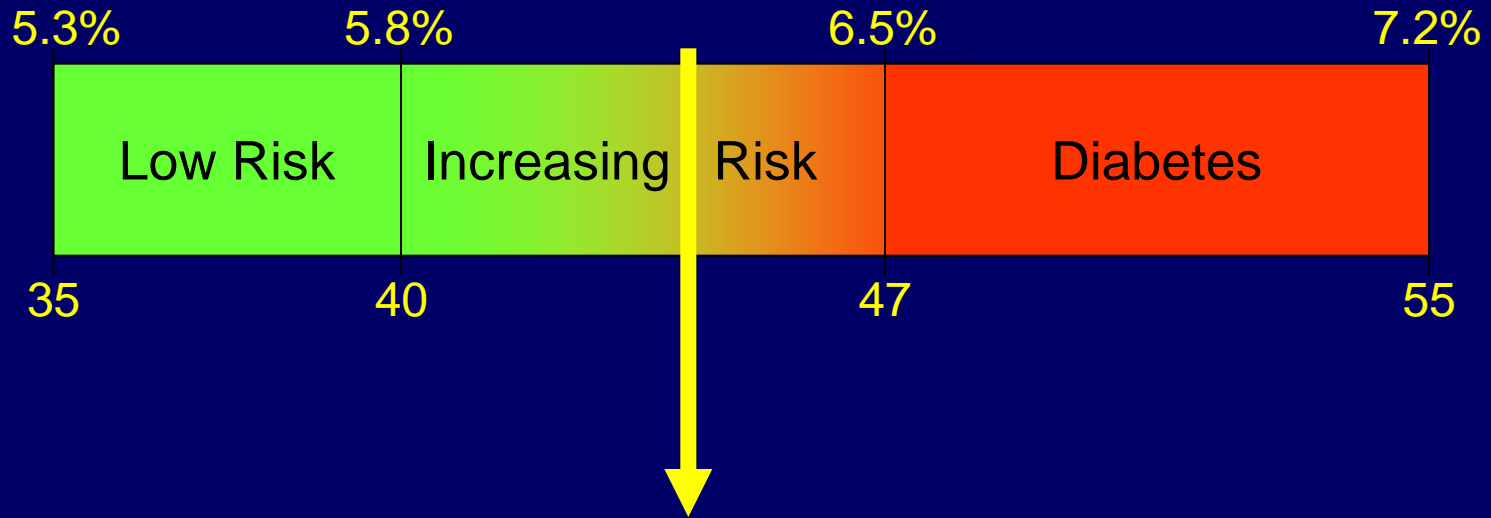
Te Streng? Impact praktijk



Prestatie Labs Mei 2015

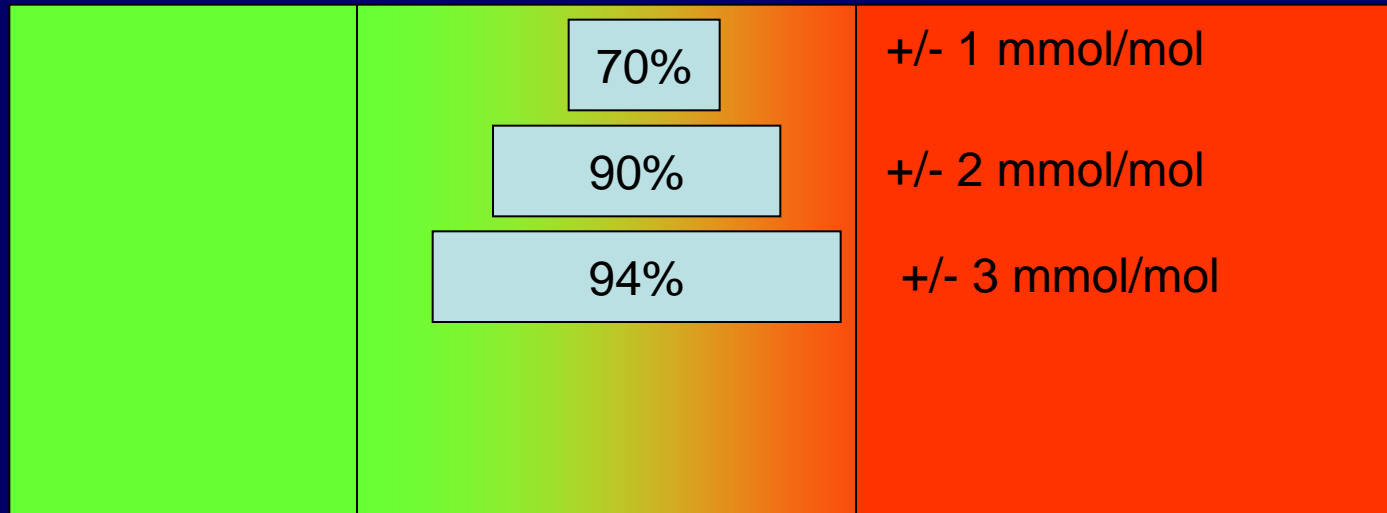
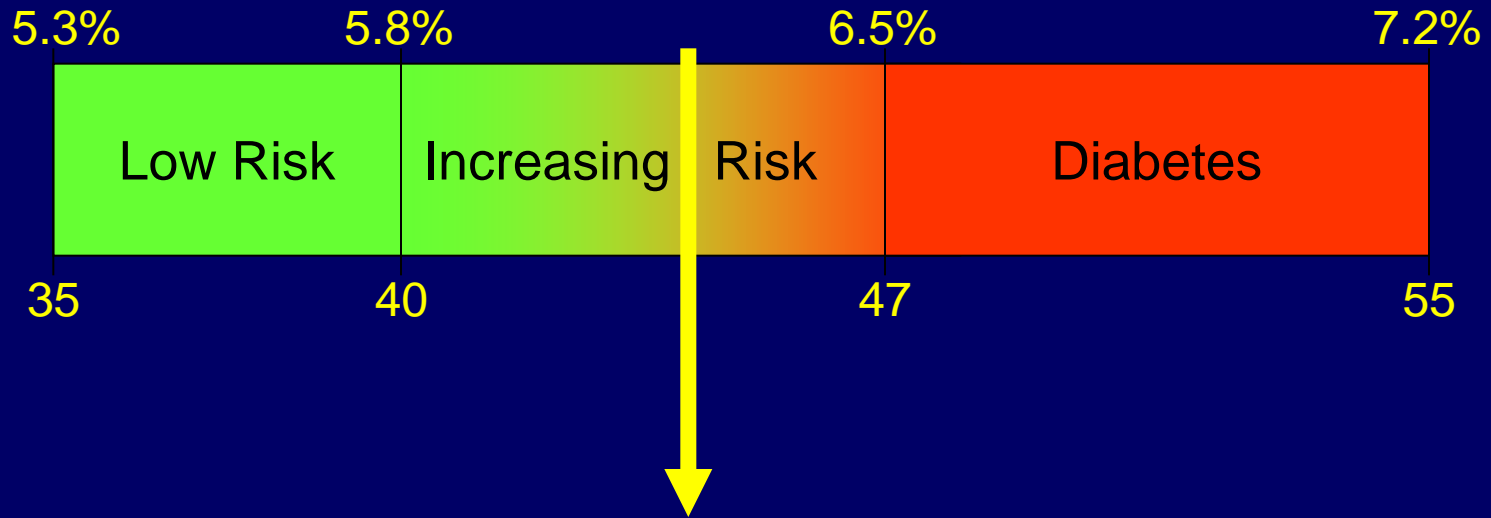


Prestatie Labs Mei 2015

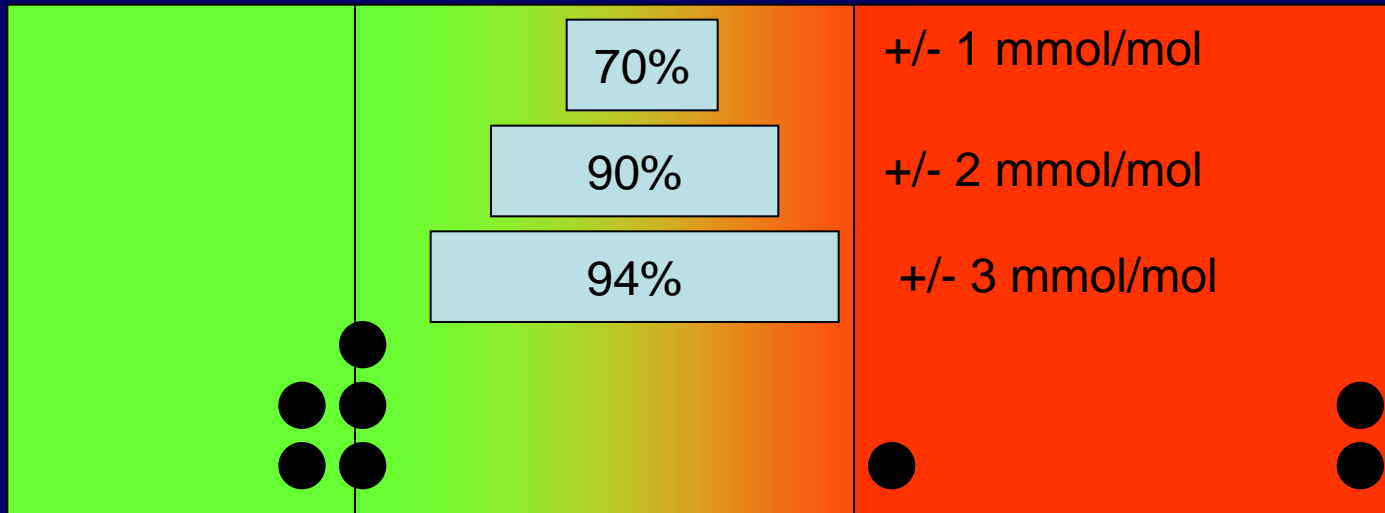
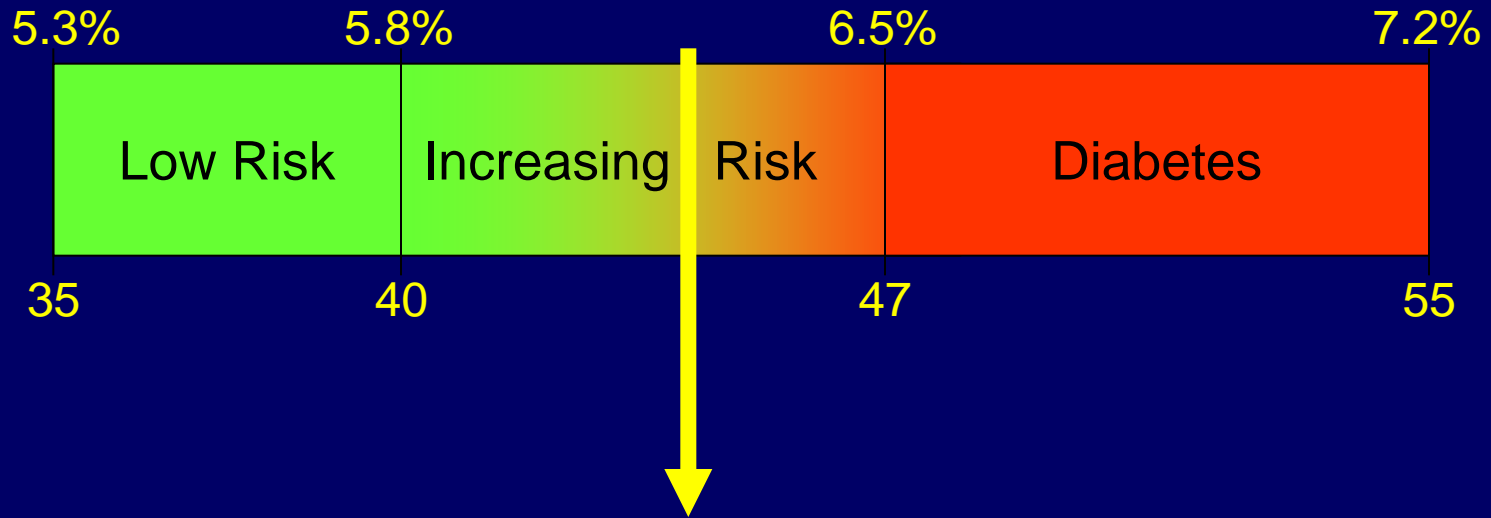


	70%	+/- 1 mmol/mol
	90%	+/- 2 mmol/mol

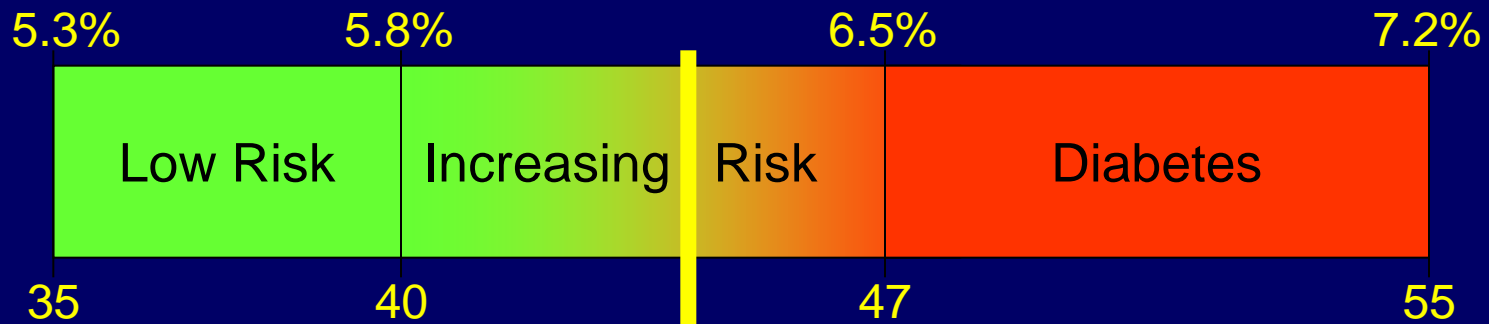
Prestatie Labs Mei 2015



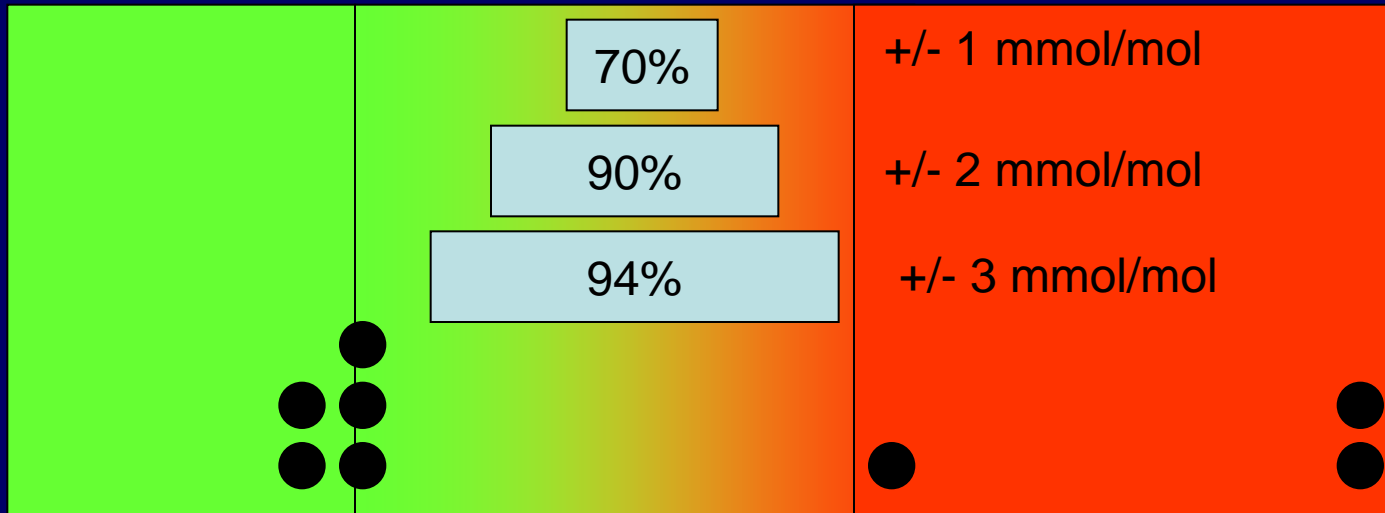
Prestatie Labs Mei 2015



Prestatie Labs Mei 2015



Goed Genoeg?



Internationaal Perspectief

IFCC

US

NL

Investigation of 2 Models to Set and Evaluate Quality Targets for Glycated Hemoglobin: Biological Variation and Sigma-Metrics

Cas Weykamp,^{1,2*} Garry John,³ Philippe Gillery,⁴ Emma English,⁵ Linong Ji,⁶ Erna Lenters-Westra,^{7,8} Randie R. Little,⁹ Gojka Roglic,¹⁰ David B. Sacks,¹¹ Izumi Takei¹² on behalf of the IFCC Task Force on Implementation of HbA_{1c} Standardization

BACKGROUND: A major objective of the IFCC Task Force on Implementation of HbA_{1c} Standardization is to develop a model to define quality targets for glycated hemoglobin (Hb A_{1c}).

METHODS: Two generic models, biological variation and sigma-metrics, are investigated. We selected variables in the models for Hb A_{1c} and used data of external quality assurance/performance testing programs to evaluate the suitability of the models to set and evaluate quality targets within and between laboratories.

RESULTS: In the biological variation model, 48% of individual laboratories and none of the 26 instrument groups met the minimum performance criterion. In the sigma-metrics model, with a total allowable error (TAE) set at 5 mmol/mol (0.46% NGSP), 77% of the individual laboratories and 12 of 26 instrument groups met the 2 σ criterion.

TAE and risk levels of 2 σ and 4 σ for routine laboratories and laboratories performing clinical trials, respectively. These goals should serve as a starting point for discussion with international stakeholders in the field of diabetes.

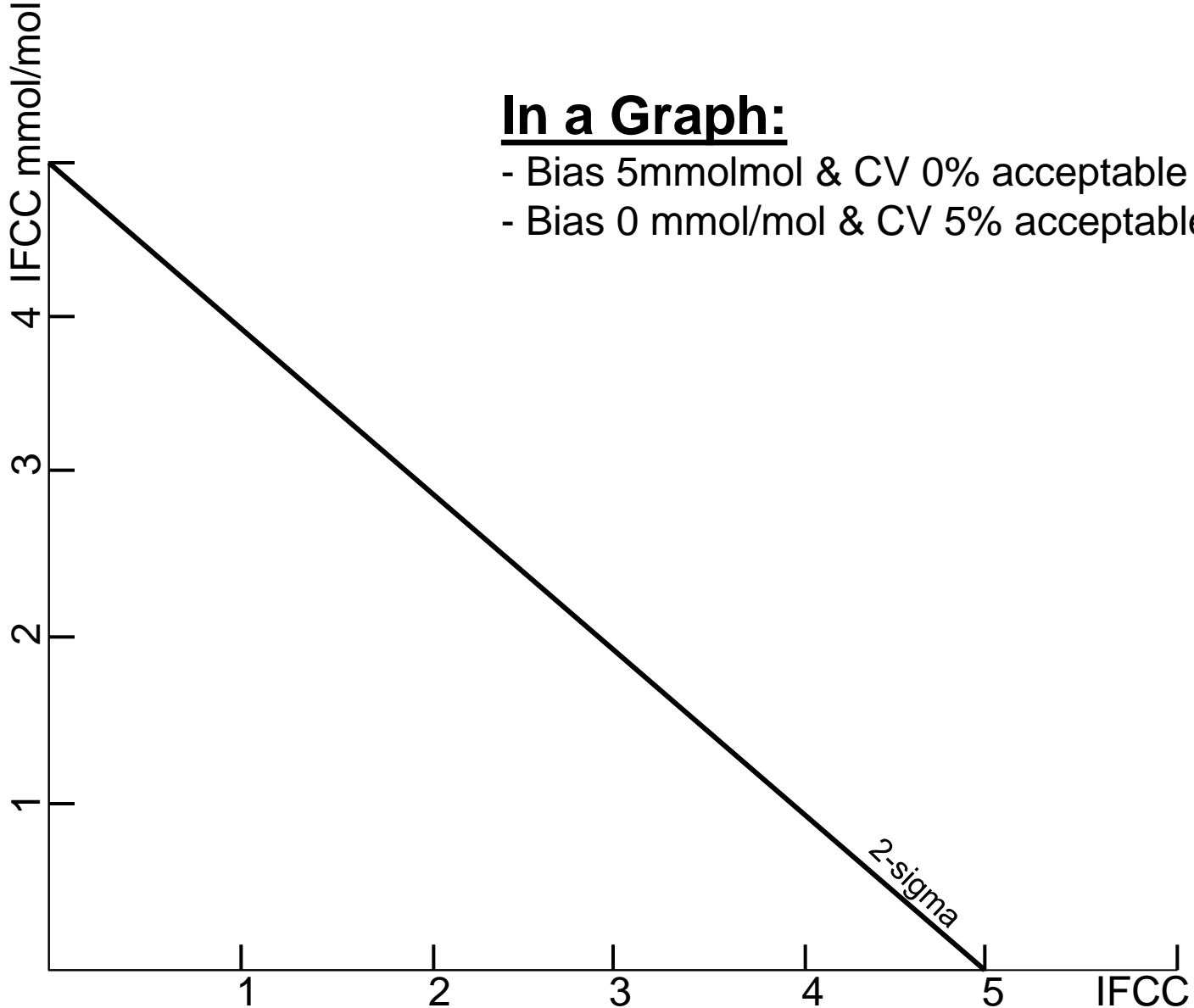
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A major objective of the IFCC Task Force on Implementation of HbA_{1c} Standardization (TF-HbA_{1c})¹³ is to "[d]evelop quality targets for the measurement" of glycated hemoglobin (Hb A_{1c}) and, "on the basis of these targets, and in conjunction with professional bodies, advise on the use of Hb A_{1c} for monitoring, diagnosis, and screening of diabetes and glucose intolerance" (1). This article addresses the development of a model to set and evaluate quality targets. A suitable model should be applicable both within and between laboratories. The IFCC is an international organization that advises on

Concept:

Total Error en Sigmamatrix

Bias in Concentration units

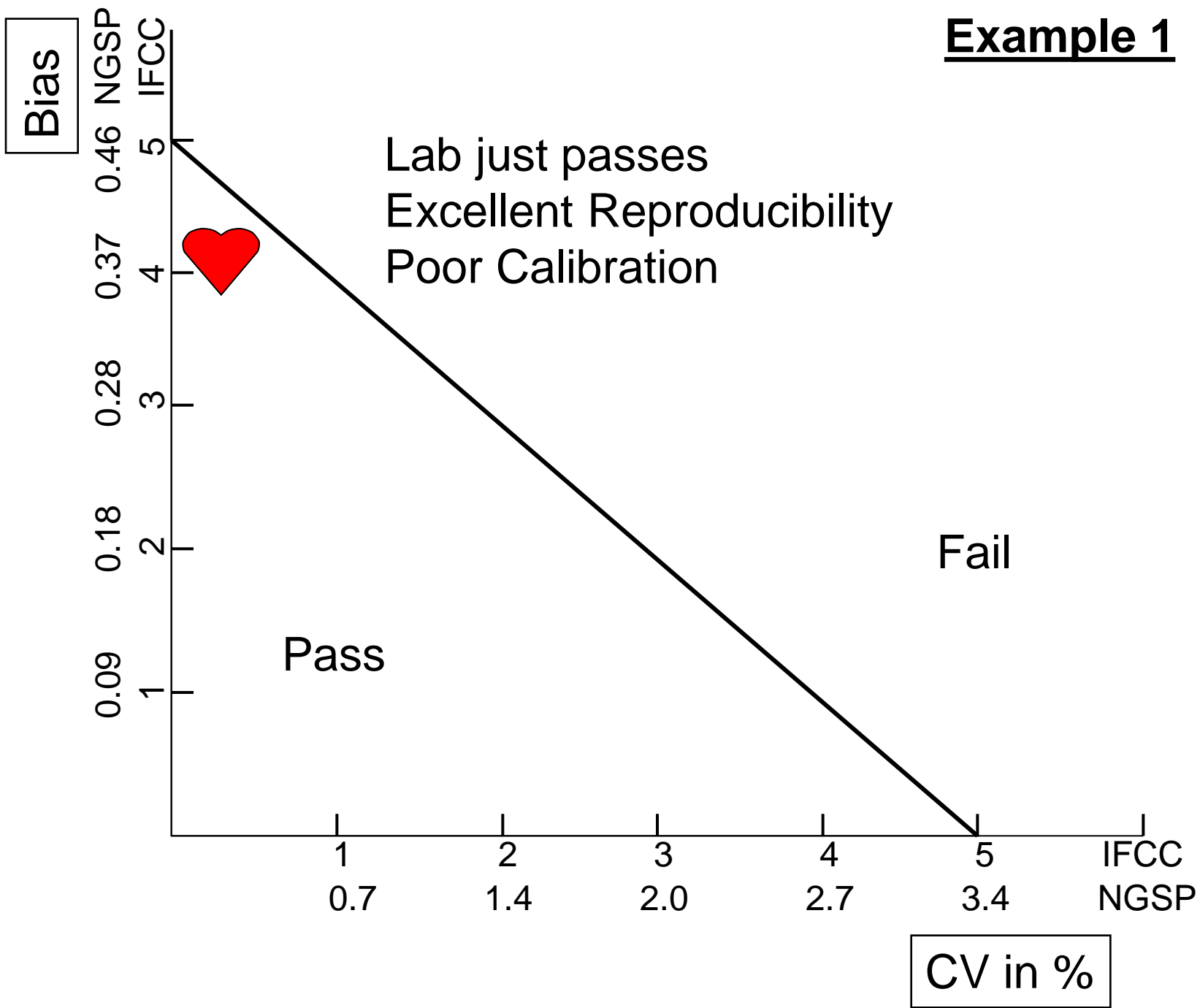


In a Graph:

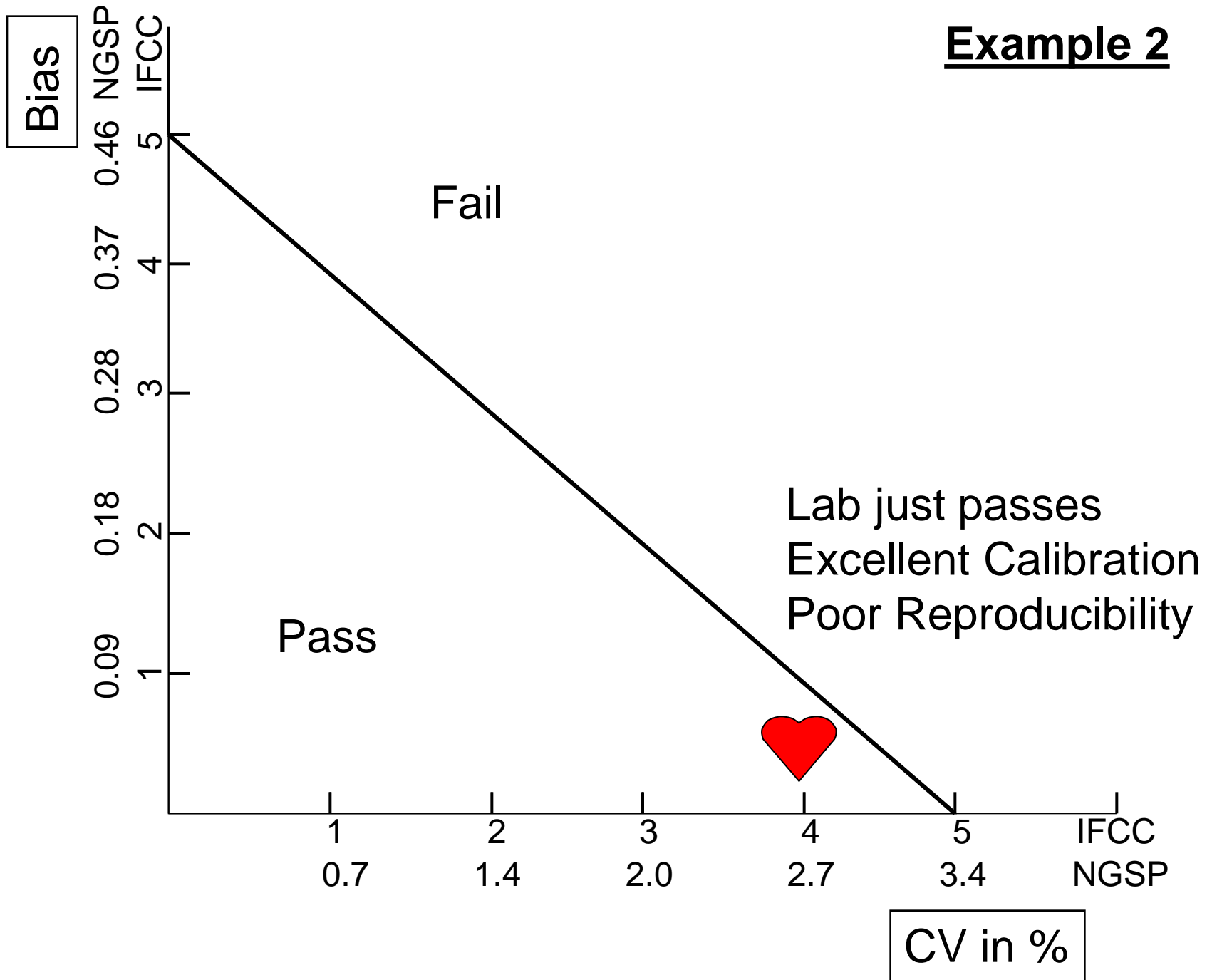
- Bias 5mmol/mol & CV 0% acceptable
- Bias 0 mmol/mol & CV 5% acceptable

Imprecision in % CV units

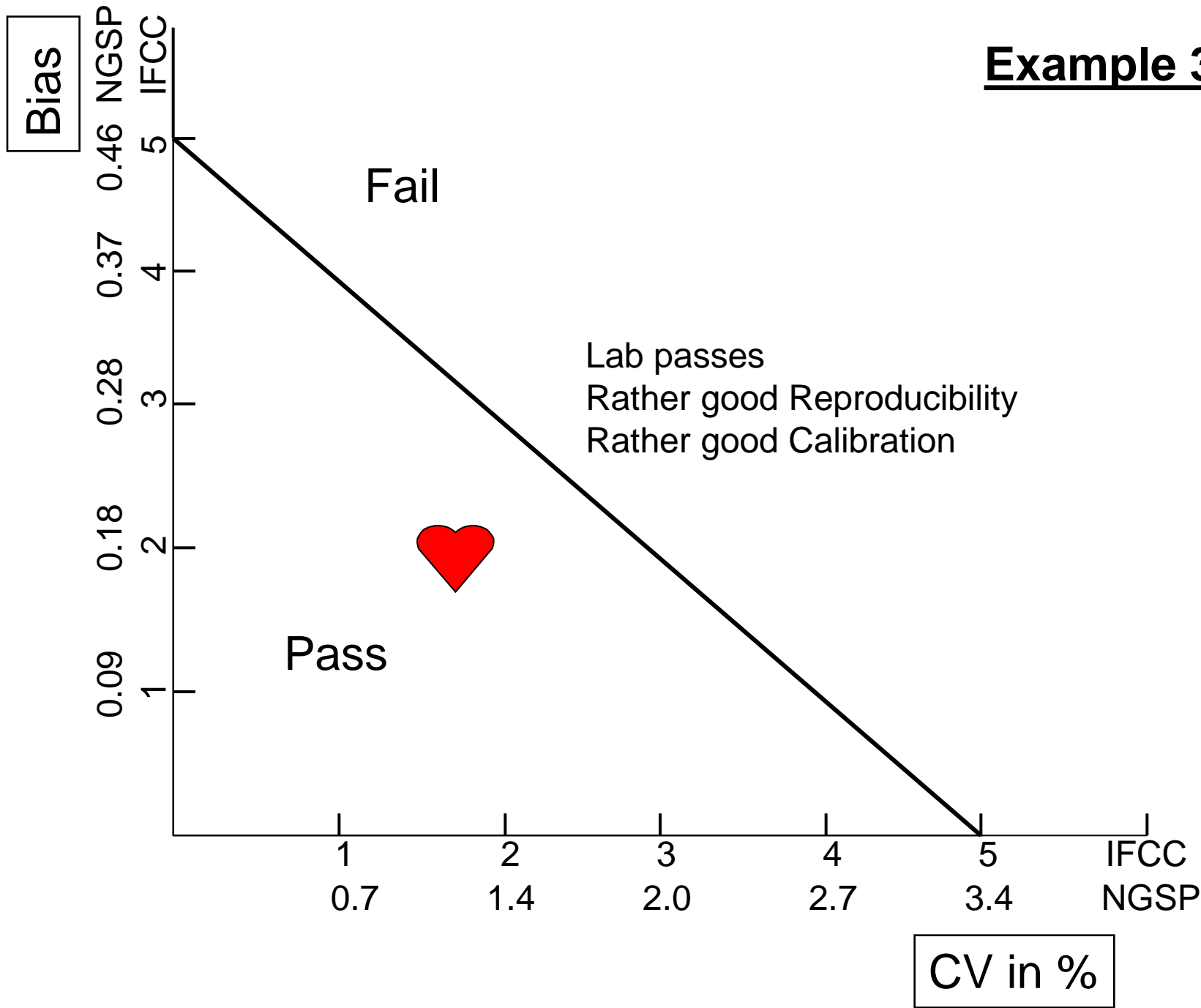
Example 1



Example 2



Example 3



Toepassing Model

- **Individueel Laboratorium**
- **Groep Laboratoria (alle Menarini Users)**
- **Nationaal Niveau (alle labs)**

Toepassing Model

- **Individueel Laboratorium**
- **Groep Laboratoria (alle Menarini Users)**
- **Nationaal Niveau (alle labs)**

Toepassing Nationaal Niveau

Obama

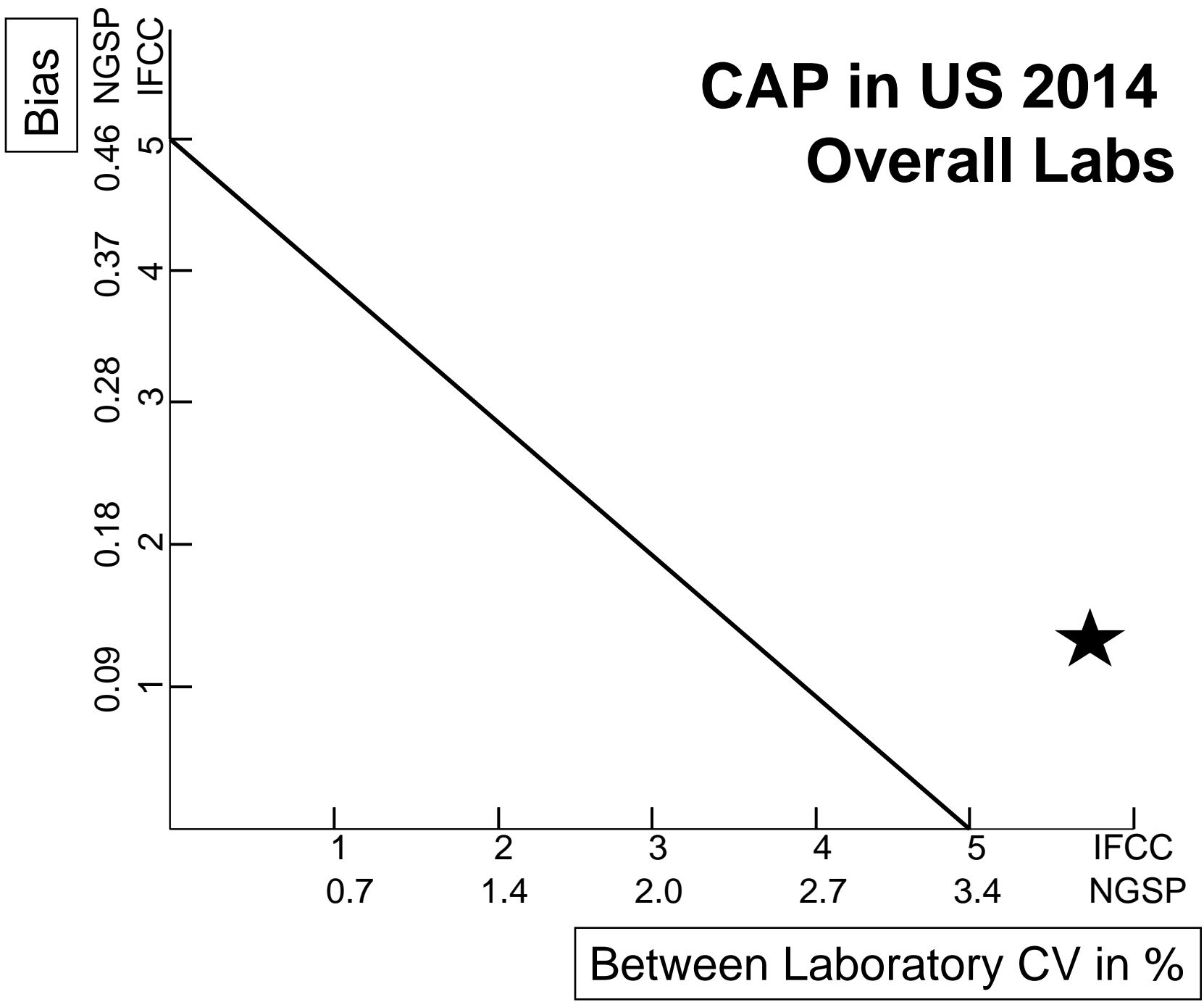
“Als ik ergens in één van de duizenden laboratoria in de VS een HbA1c laat meten.....

..... Mag ik dan verwachten dat aan de criteria van de IFCC voldaan wordt?

(95% labs meet juiste waarde +/- 5 mmol/mol)

CAP in US 2014

Overall Labs



Toepassing Nationaal Niveau

Obama

Niet dus.

Hoe komt dat dan?

Toepassing Nationaal Niveau

Obama

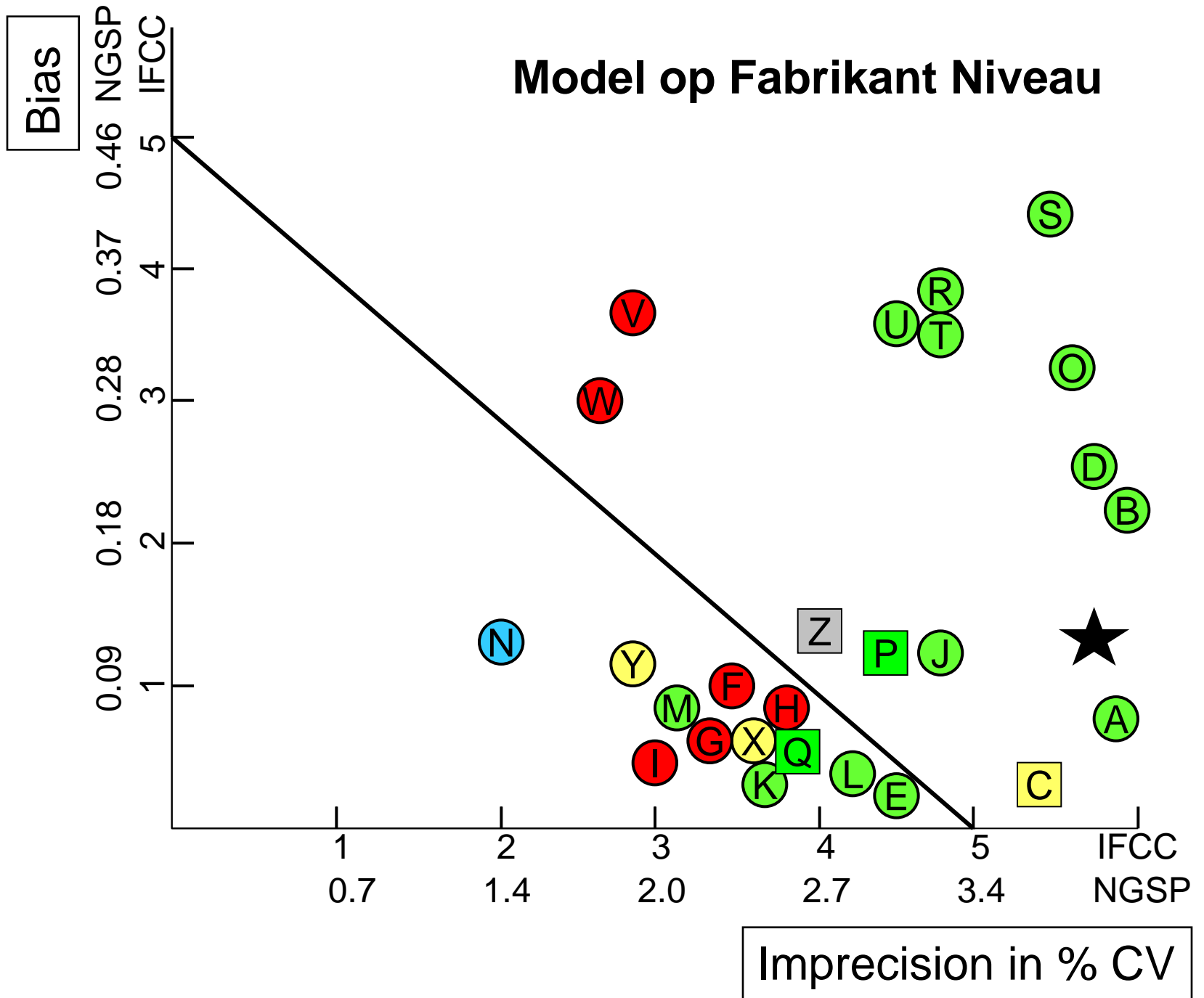
Niet dus.

Hoe komt dat dan?



Toepassing Fabrikant niveau

Model op Fabrikant Niveau



Toepassing Nationaal Niveau

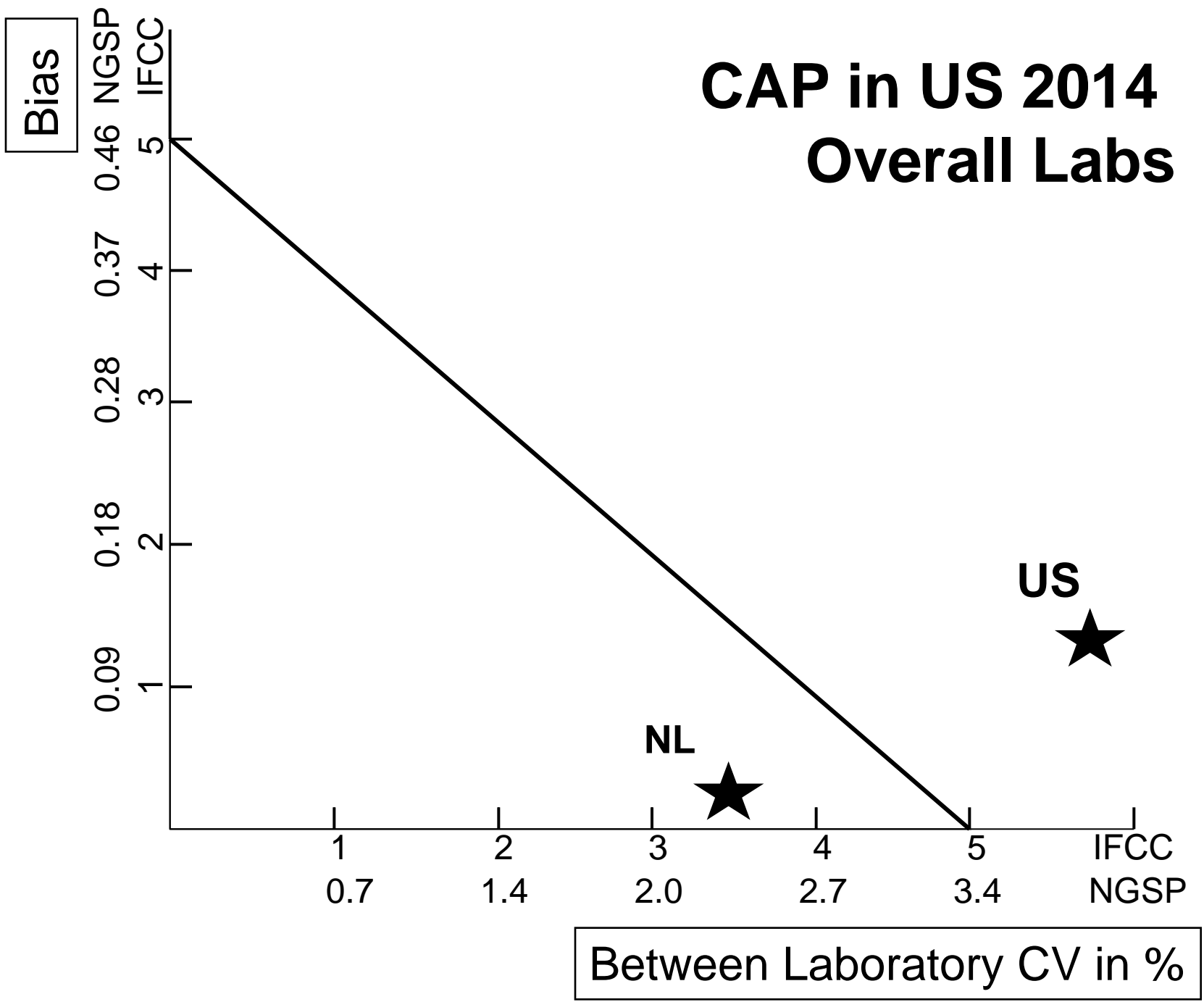
Mark Rutte

“Als ik ergens in één van de honderd laboratoria in Nederland een HbA1c laat meten.....

..... mag ik dan verwachten dat aan de criteria van de IFCC voldaan wordt?

(95% labs meet juiste waarde +/- 5 mmol/mol)

CAP in US 2014 Overall Labs



Toepassing Nationaal Niveau

Mark Rutte

Mooi beter dan VS dus.

Per Fabrikant?



SKML Januari 2016

Toepassing Nationaal Niveau

Mark Rutte

Mooi beter dan VS dus.

Per Fabrikant?

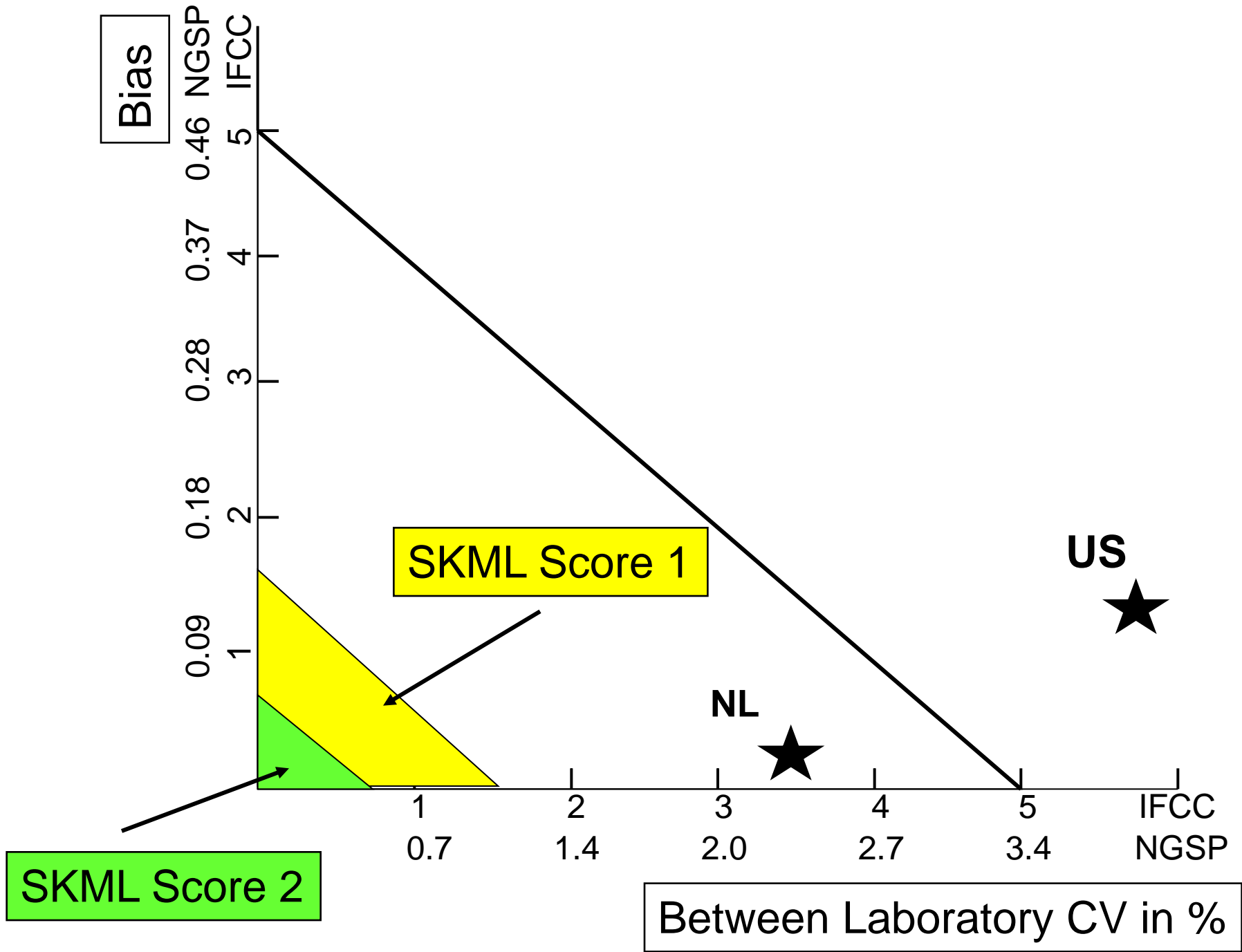


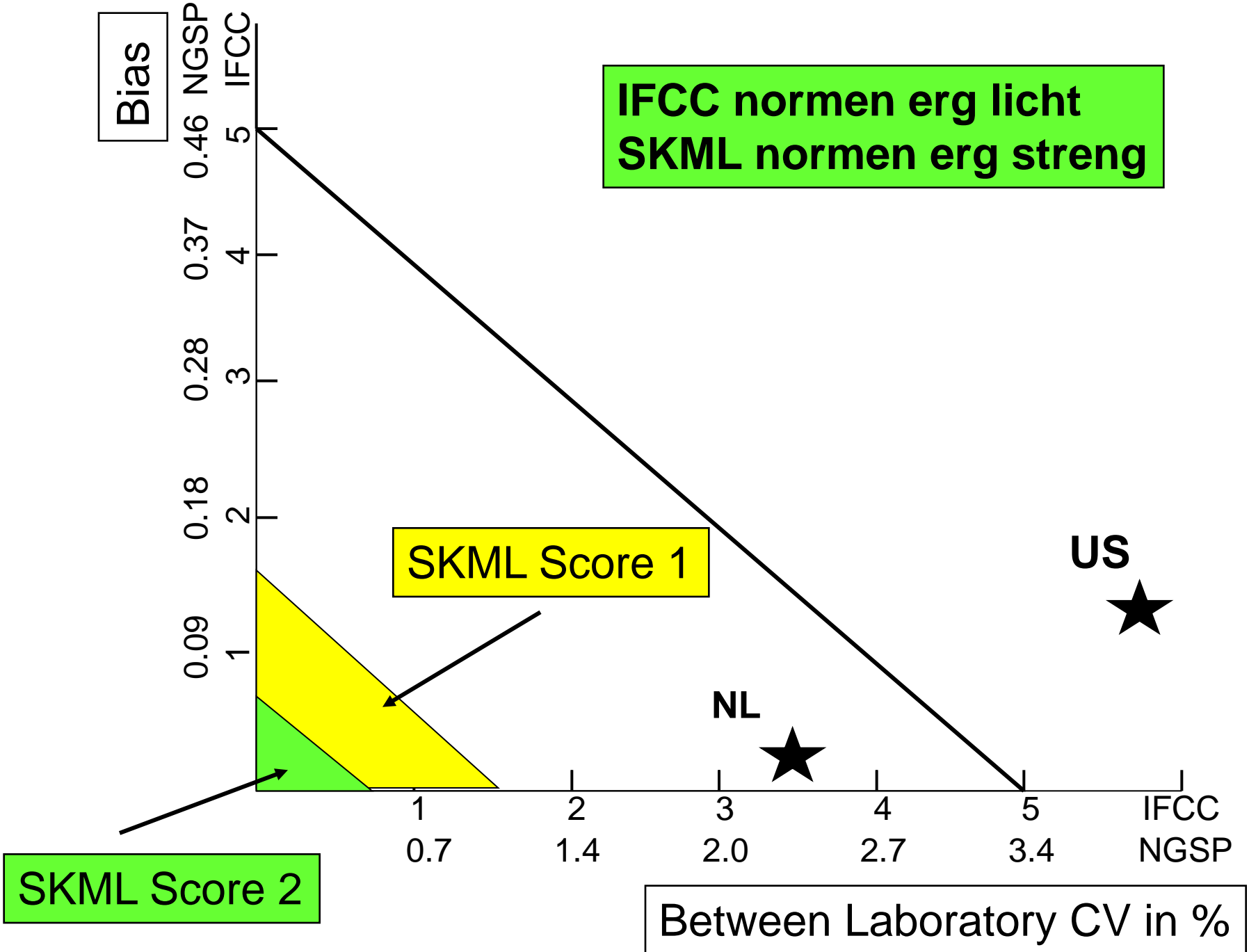
SKML Januari 2016

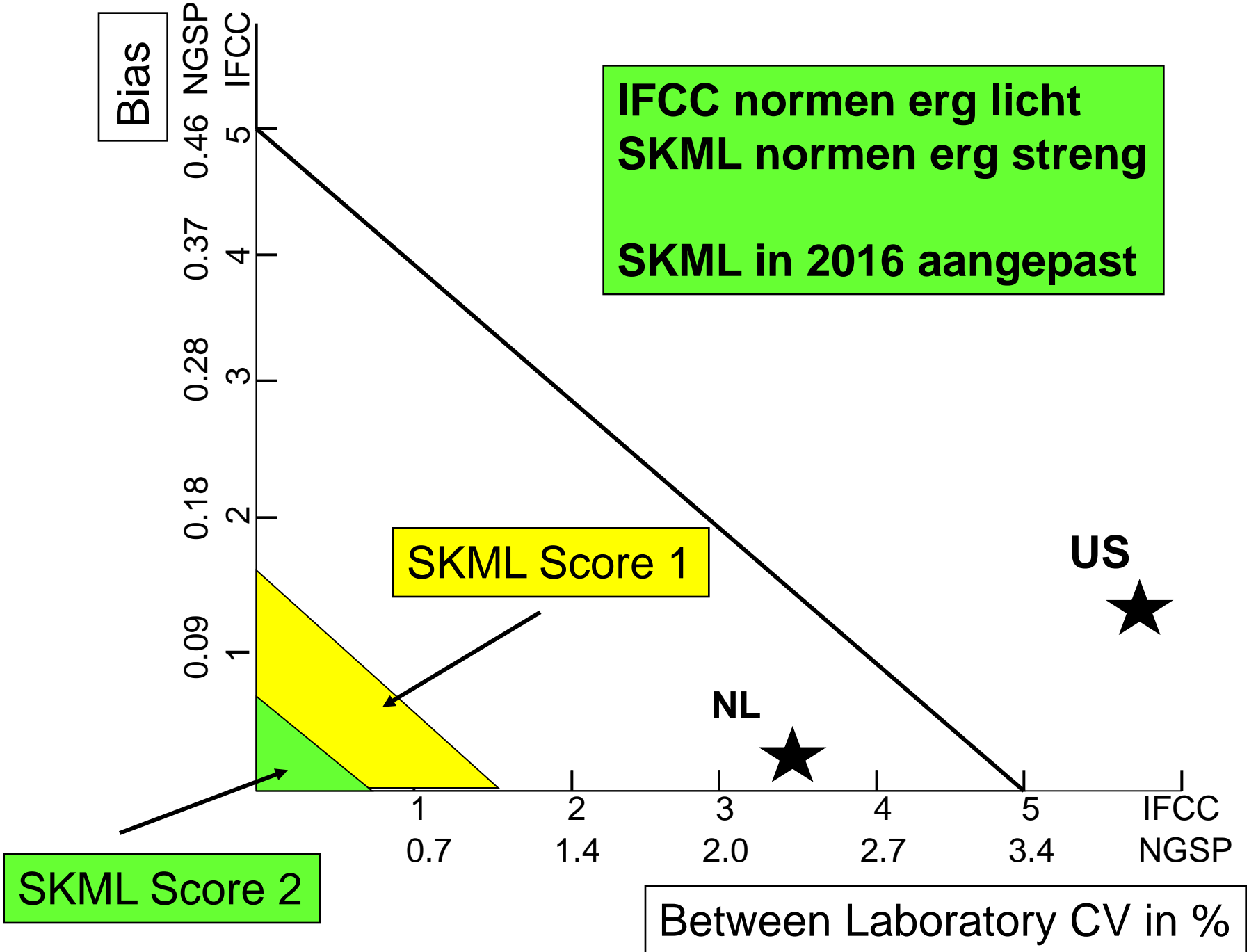
Terug naar

Criteria Scores 2, 1 en 0

SKML







Investigation of 2 Models to Set and Evaluate Quality Targets for Glycated Hemoglobin: Biological Variation and Sigma-Metrics

Cas Weykamp
Randie R. Litt

**IFCC Paper is gecompliceerder
Vandaag geen tijd om
Op in te gaan.....**

.....Lees Zelf.....

**.....of wacht op Jaarbrief 2015
Sectie Algemene Chemie**

BACKGROUND: A model for the implementation of quality targets for glycated hemoglobin (Hb A_{1c})

METHODS: Two general sigma-metrics, are used in the models for Hb A_{1c} assurance/performance suitability of the model within and between

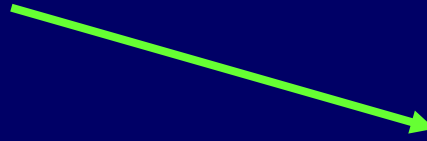
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Samenvatting

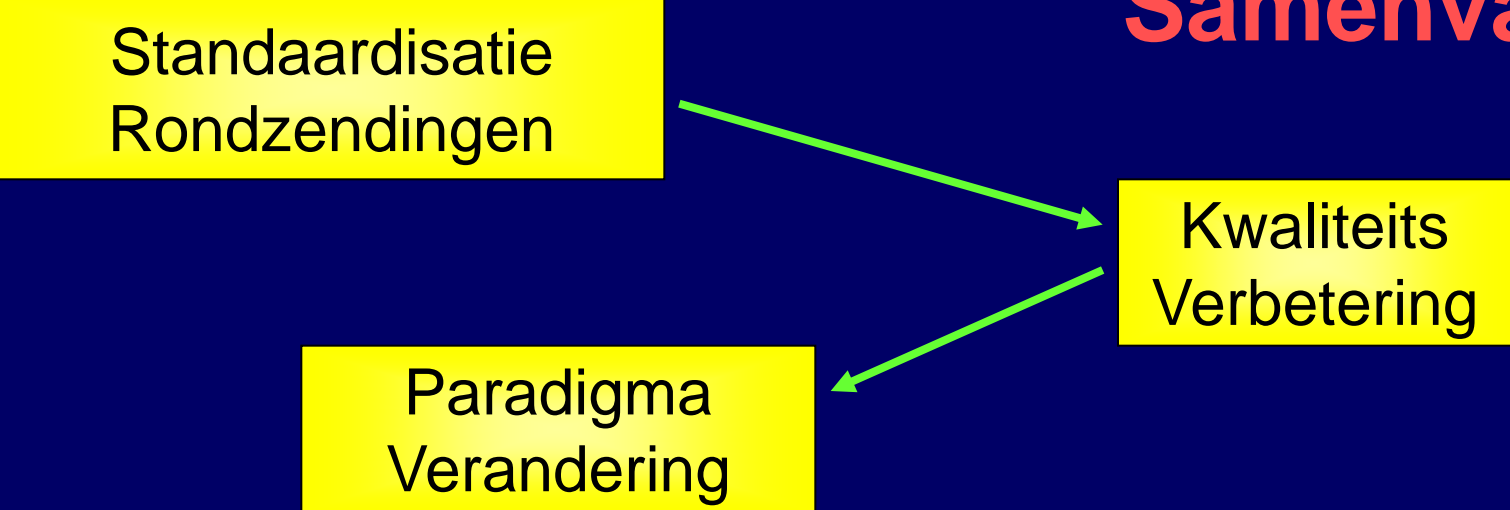
Samenvatting

Standaardisatie
Rondzendingen

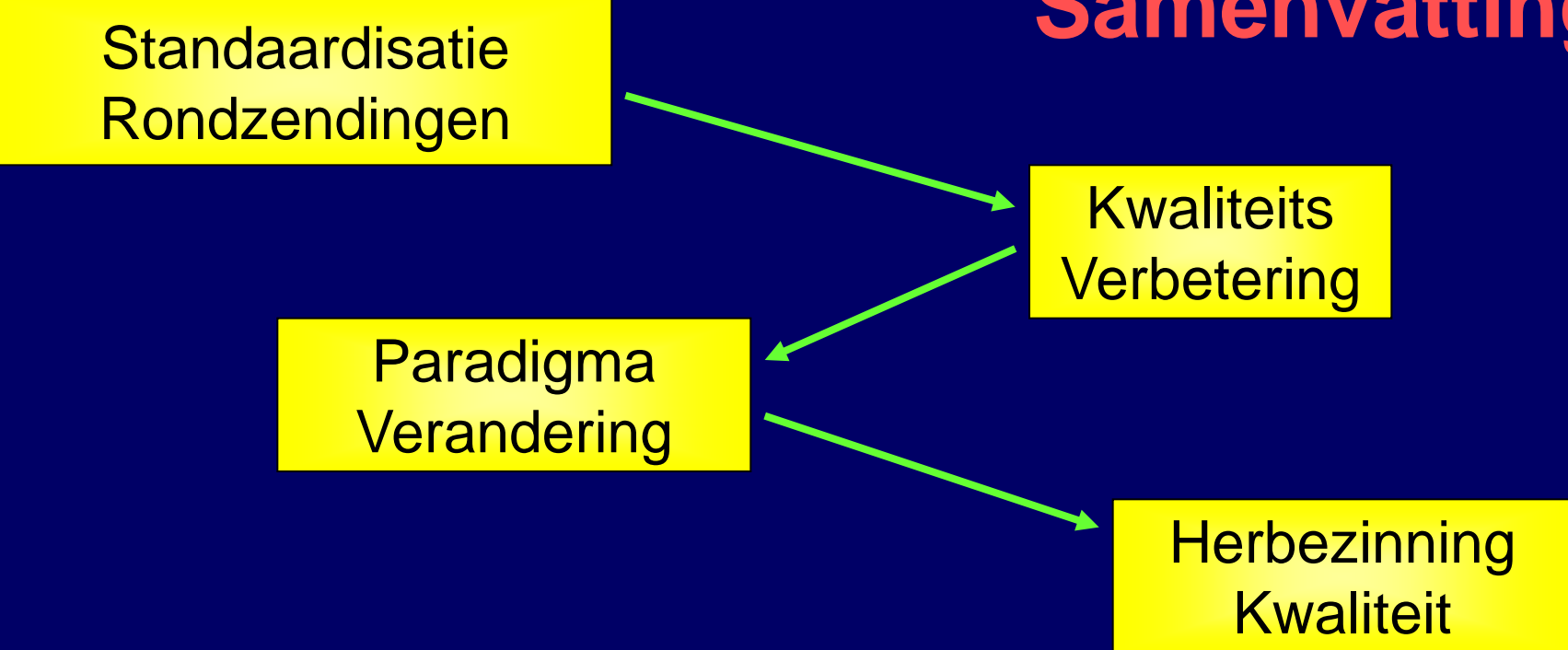


Kwaliteits
Verbetering

Samenvatting



Samenvatting



Samenvatting

Standaardisatie
Rondzendingen

Kwaliteits
Verbetering

Paradigma
Verandering

Herbezinning
Kwaliteit

Volbloed Monsters:	Januari 2015
Ingevroren Calibratoren:	Juli 2015
Definitieve Normen:	Januari 2016

Samenvatting

Standaardisatie
Rondzendingen

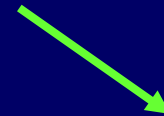
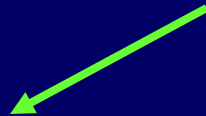
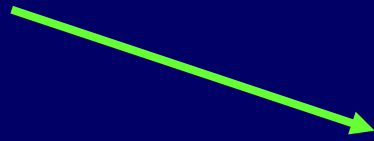
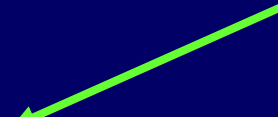
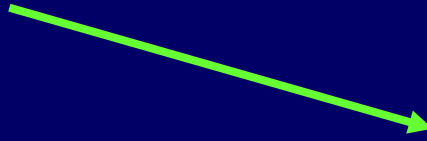
Kwaliteits
Verbetering

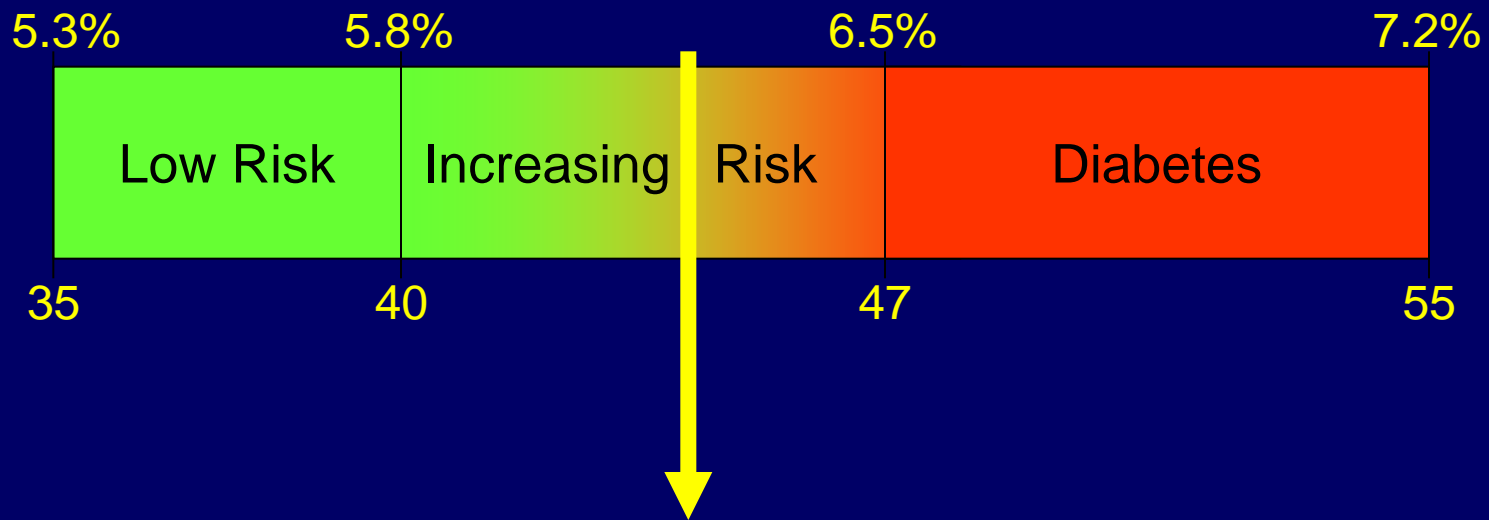
Paradigma
Verandering

Herbezinning
Kwaliteit

Volbloed Monsters:	Januari 2015
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Werk Klaar?





Bedankt voor uw Aandacht