

# Extern kwaliteitsbewakings- programma voor thiopurines

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# ISO 15189

- \* ISO 15189:2012 Medische laboratoria – Bijzondere eisen voor kwaliteit en competentie

*“Het laboratorium moet deelnemen aan een interlaboratoriumvergelijkingprogramma dat geschikt is voor het onderzoeken en interpreteren van onderzoeksresultaten.”*

# ISO 17043

## Conformity assessment – General requirement for proficiency testing

### 4.4.2 Preparation of proficiency test items

**4.4.2.1** The proficiency testing provider shall establish and implement procedures to ensure that proficiency test items are prepared in accordance with the plan described in 4.4.1.

**NOTE** It is advisable that the proficiency testing provider give due consideration to the preparation of sufficient numbers of proficiency test items, in order to allow for the need to replace any such proficiency test items lost or damaged during distribution, or intended to be provided for use after the results of the proficiency testing scheme have been evaluated. Such uses can include training aids for participants or use as a reference material.

**4.4.2.2** The proficiency testing provider shall establish and implement procedures to ensure appropriate acquisition, collection, preparation, handling, storage and, where required, disposal of all proficiency test items. The procedures shall ensure that materials used to manufacture proficiency test items are obtained in accordance with relevant regulatory and ethical requirements.

**4.4.2.3** Proficiency test items should match in terms of matrix, measurands and concentrations, as closely as practicable, the type of items or materials encountered in routine testing or calibration.

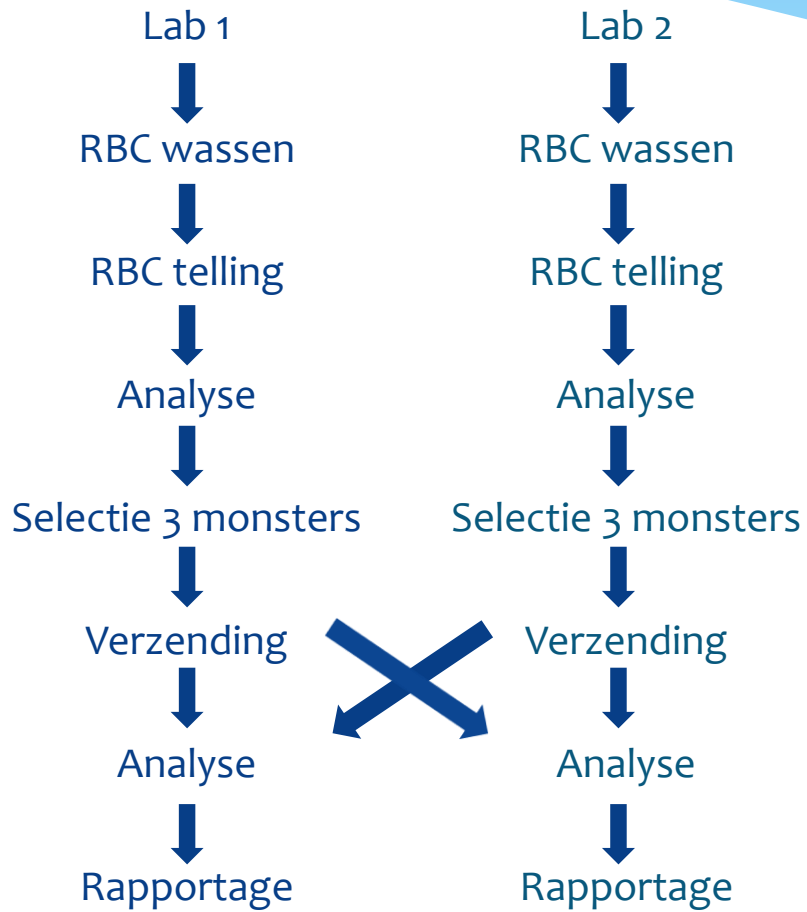
**4.4.2.4** In proficiency testing schemes that require participants to prepare or manipulate, or both prepare and manipulate, the proficiency test item and submit it to the proficiency testing provider, the proficiency testing provider shall issue instructions for preparation, packaging and transport of the proficiency test item.

# Opzet

- \* Geen 'regulier' monster te maken
- \* Commuteerbaarheid
  - \* The equivalence of the mathematical relationships among the results of different measurement procedures for a (reference) material and for representative samples of the type intended to be measured<sup>1</sup>
- \* Stabiliteit



# Opzet

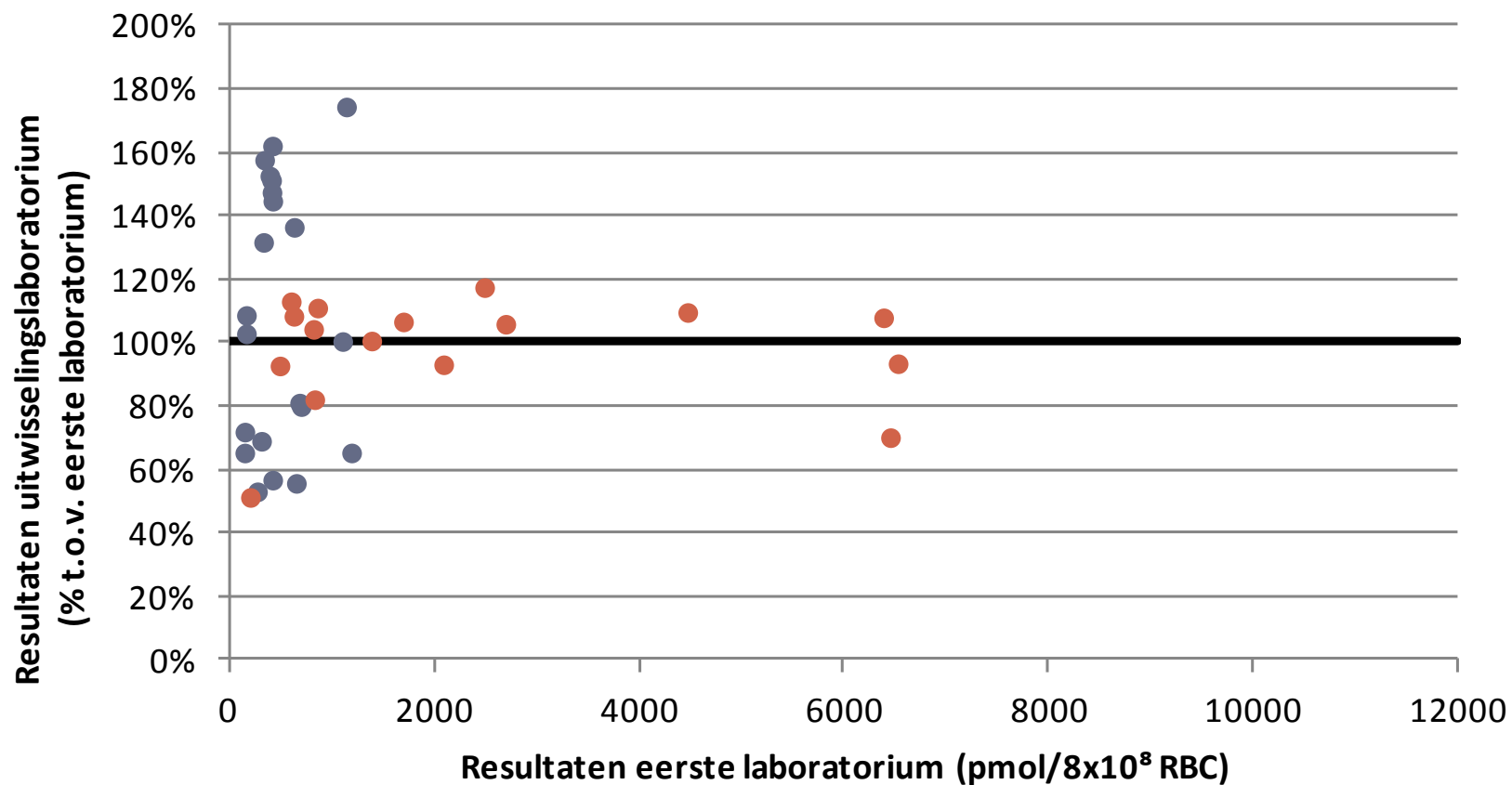


# Resultaten

- \* 2014 → 8 laboratoria (pilot)
- \* 2015 → 10 laboratoria
- \* 2016 → 12 laboratoria
  
- \* Acceptabel resultaat 80-120%

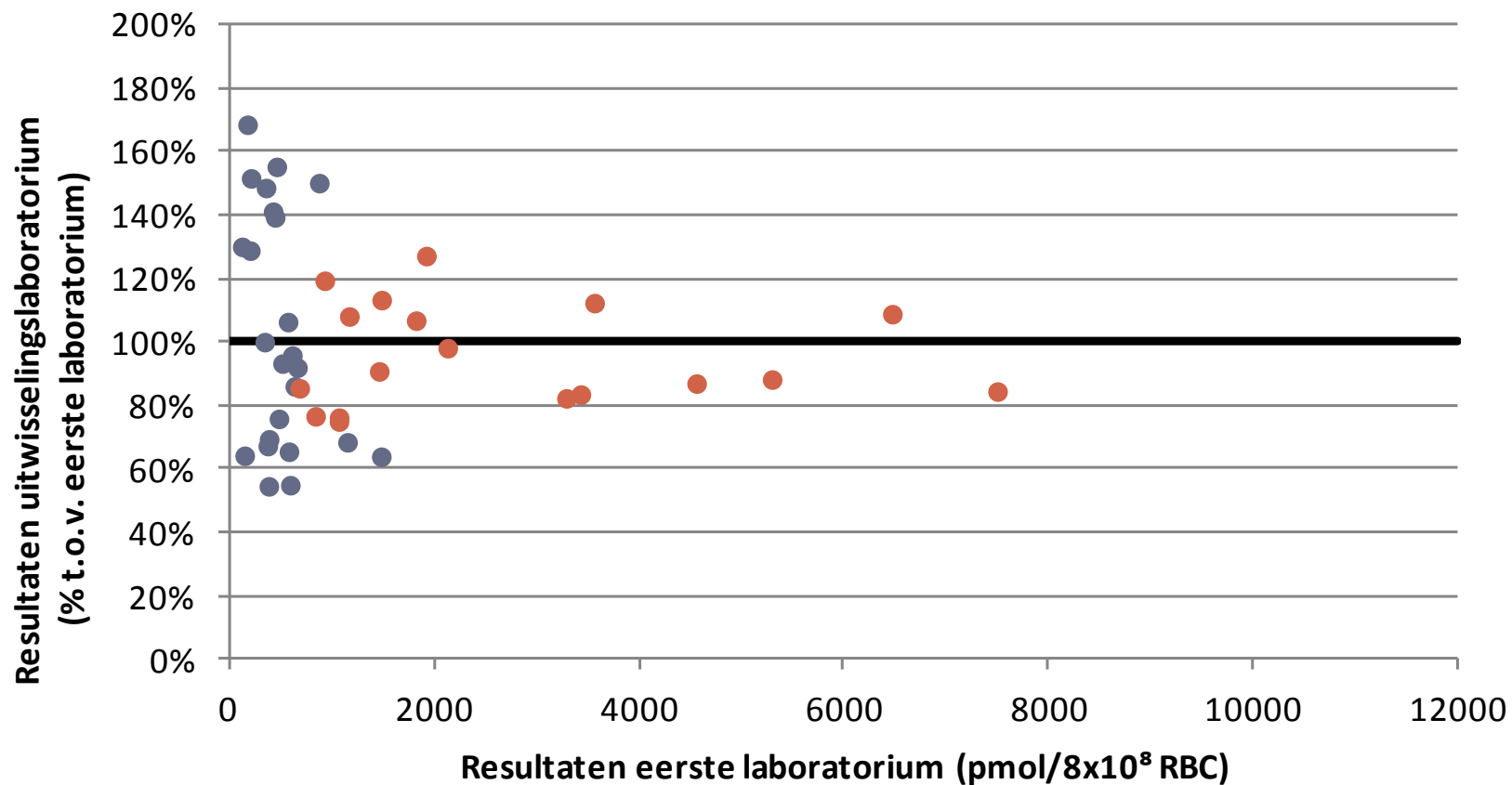
# 6-TGN 6-MMP

## Ronde 2014.1



# 6-TGN 6-MMP

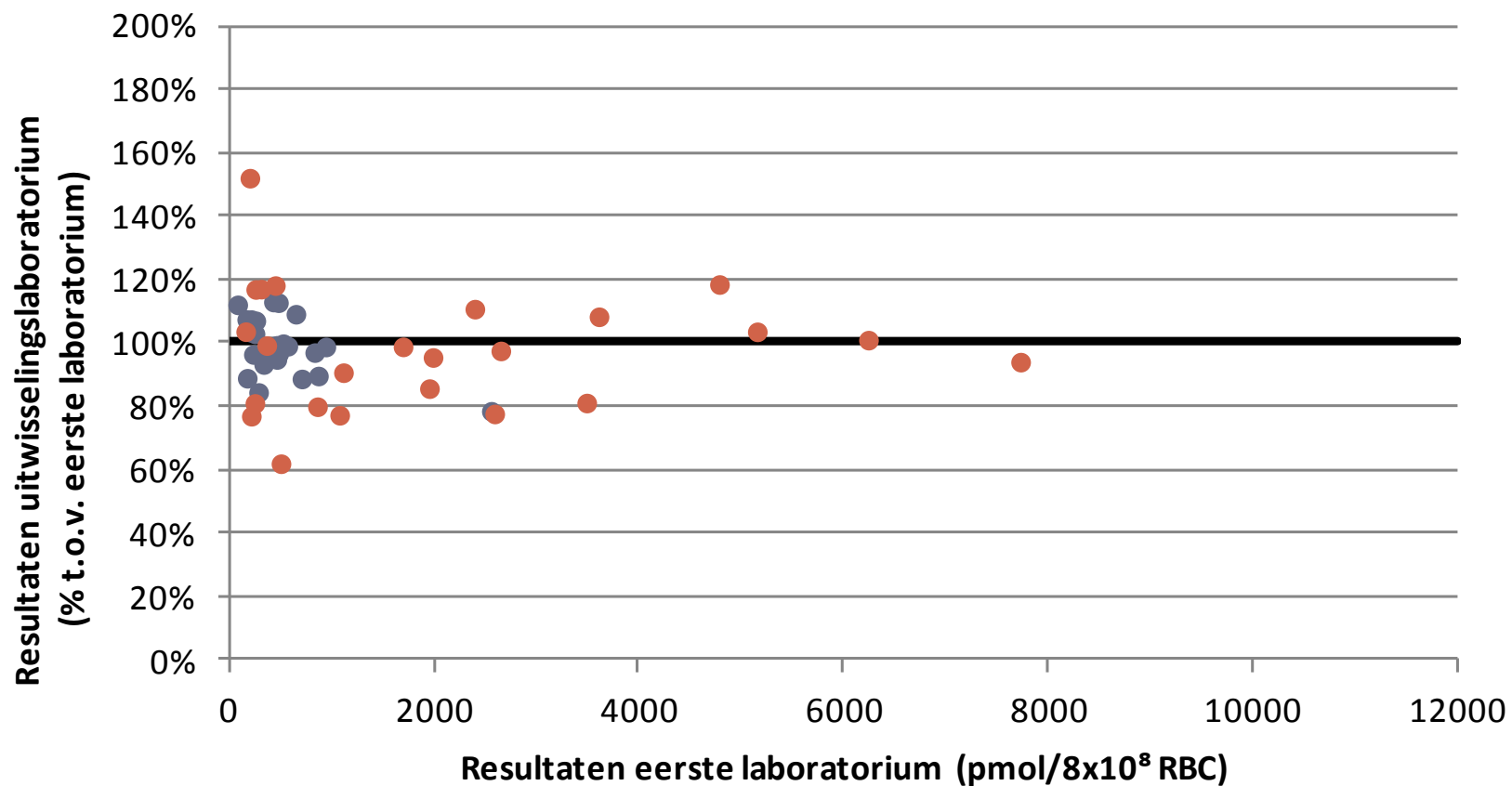
## Ronde 2014.2





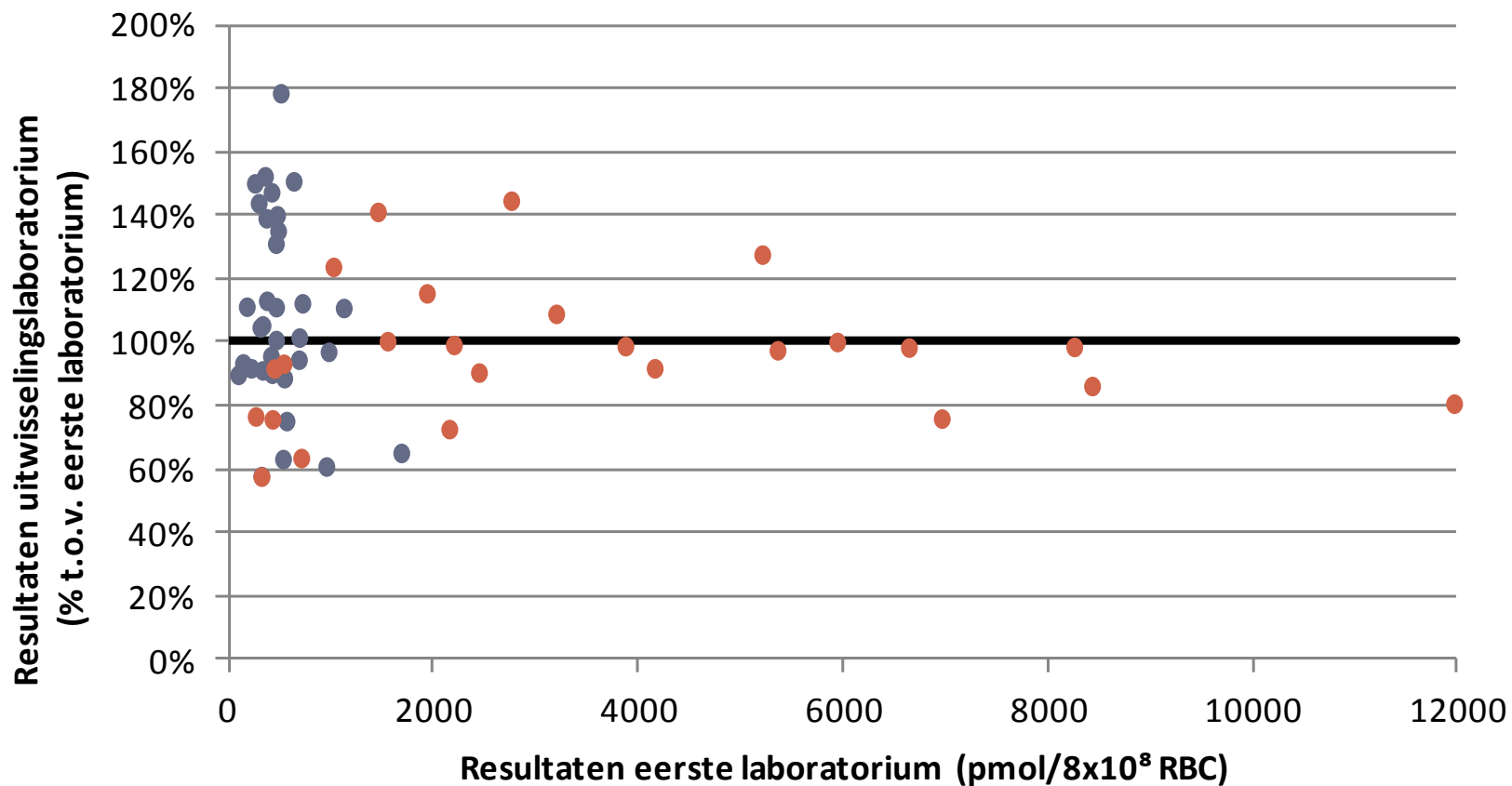
# 6-TGN 6-MMP

## Ronde 2015.3



# 6-TGN 6-MMP

## Ronde 2015.4

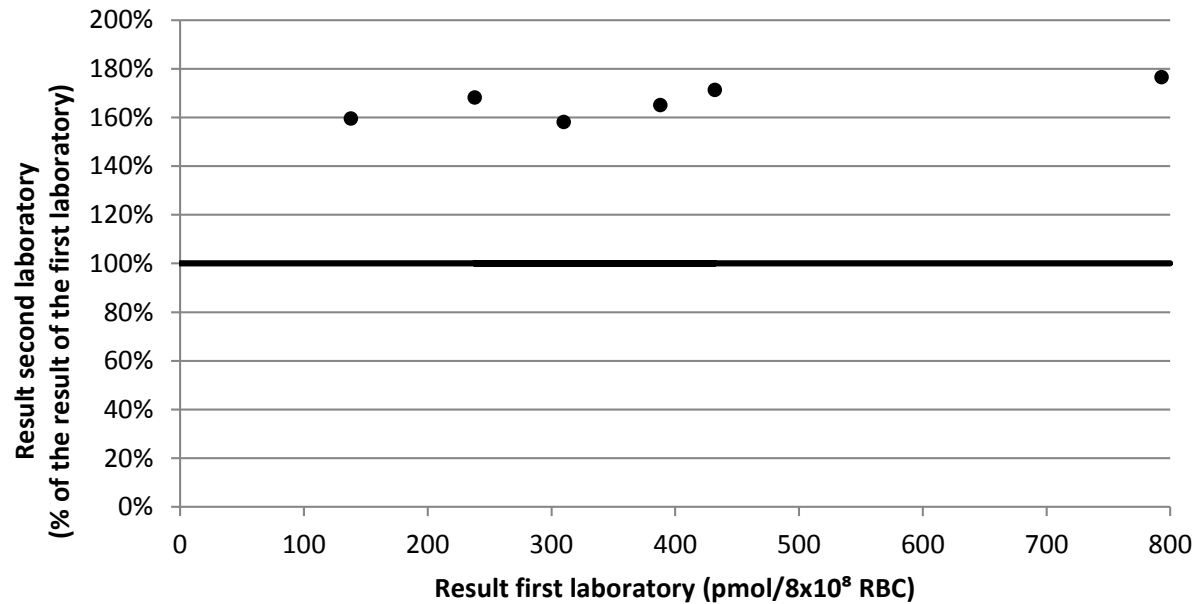


# Resultaten

Ronde	6-TGN			6-MMP		
	n	< ... or > ...	OK	n	< ... or > ...	OK
2014.1	21		19%	19	2	79%
2014.2	24		25%	20	4	80%
2014.3	23	1	52%	21	3	76%
2015.1	29	1	52%	30		67%
2015.2	30		43%	26	4	85%
2015.3	27	3	85%	26	4	65%
2015.4	33		55%	26	7	62%

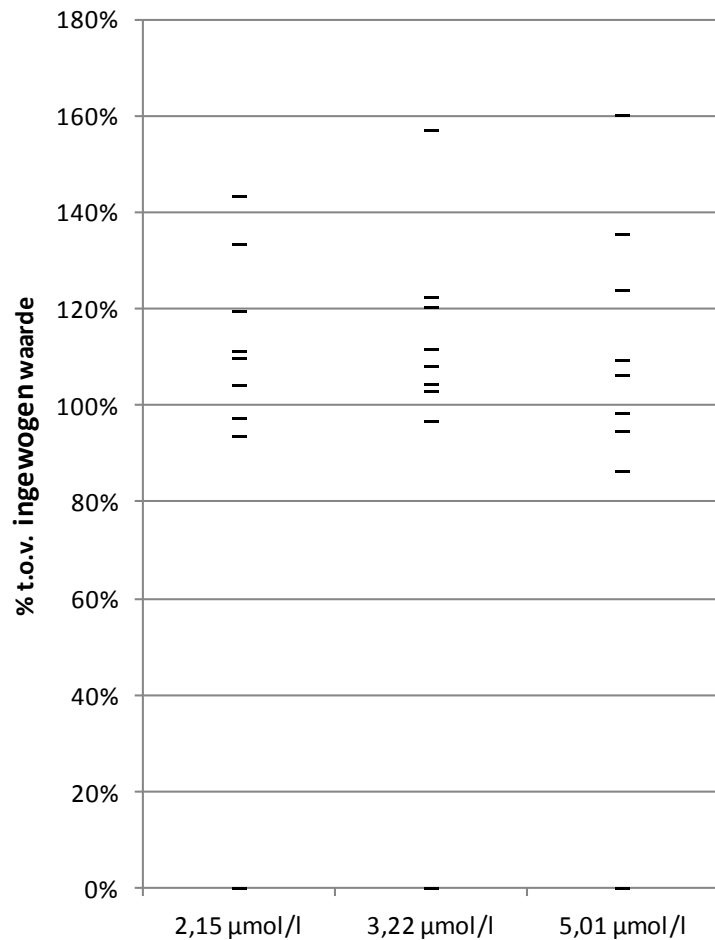
# Analysemethoden

- \* Hydrolyse
  - \* Exact 1 uur, 100 °C
- \* Kalibratoren
  - \* Matrix
  - \* Bereiding

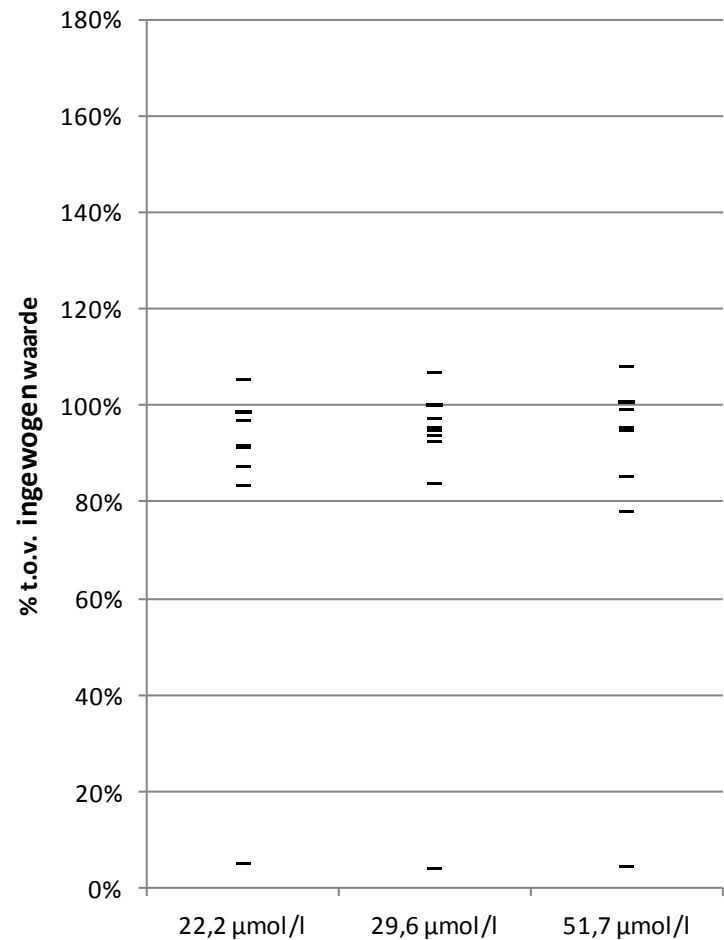


# Standaarden

## 6-TGN



## 6-MMP



# Standaarden

	4			6			2			7			8	
4				2015.3			2014.1							
				89%	78%		136%	131%	157%					
6	2015.3						2015.2						2014.3	
	96%	94%	96%				81%	85%	98%				68%	61%
2	2014.1			2015.2						2014.3			2015.1	
	144%	151%	174%	100%	89%	57%				100%	107%	96%	113%	26573%
7							2014.3						2014.2	
							107%	88%	99%				100%	106%
8				2014.3			2015.1			2014.2				
				46%	148%	116%	124%	107%	111%	92%	95%	86%		
9	2014.3			2014.2			2015.3			2015.2				
	140%	161%		129%	151%	139%	107%	112%	112%	145%	160%	149%		
1	2014.2			2015.1						2015.3			2014.1	
	141%	130%	148%	144%	139%					98%	84%	88%	79%	56%
5	2015.2			2014.1			2014.2			2015.1				
	159%	165%	158%	162%	152%	147%	150%	168%	155%	97%	149%	113%		
3	2015.1												2015.2	
	151%	136%	152%										94%	102%
10													2015.3	
													111%	96%



	4			6			2			7			8			9			1			5		
4				2015.3			2014.1									2014.3			2014.2			2015.2		
				89%	78%		136%	131%	157%							68%	70%	66%	64%	68%	76%	58%	60%	57%
6	2015.3						2015.2						2014.3			2014.2			2015.1			2014.1		
	96%	94%	96%				81%	85%	98%				68%	61%	65%	67%	69%	65%	78%	62%	72%	65%	55%	53%
2	2014.1			2015.2						2014.3			2015.1			2015.3						2014.2		
	144%	151%	174%	100%	89%	57%				100%	107%	96%	113%	26573%	111%	96%	102%	97%				54%	64%	55%
7							2014.3						2014.2			2015.2			2015.3			2015.1		
							107%	88%	99%				100%	106%	93%	68%	70%	52%	98%	84%	88%	86%	91%	99%
8				2014.3			2015.1			2014.2						2014.1								
				46%	148%	116%	124%	107%	111%	92%	95%	86%				68%	65%	80%						
9	2014.3			2014.2			2015.3			2015.2									2014.1					
	140%		161%	129%	151%	139%	107%	112%	112%	145%	160%	149%							102%	100%	108%			
1	2014.2			2015.1						2015.3			2014.1									2014.3		
	141%	130%	148%	144%	139%					98%	84%	88%	79%	56%	71%							108%	114%	98%
5	2015.2			2014.1			2014.2			2015.1									2014.3					
	159%	165%	158%	162%	152%	147%	150%	168%	155%	97%	149%	113%							136%	93%	87%			

# Opmerkingen

- \* Kies monsters met relevante (meetbare) waarden
- \* Gebruik van de verzendbox
- \* Patiëntgegevens op formulier
- \* Resultaat 8433,1 pmol/ $8 \times 10^8$  RBC



# Toekomst

