

HbA1c

*Performance by your country, manufacturer, lab
in European perspective
Discussion some other issues*

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Workshop Discussion Points

1. EurA1c results Ireland

2. IFCC Model Quality Targets: your lab/IEQAS

3. Variants

4. HbA1c for diagnosis

5. HbA1c and POCT

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“EurA1c”

Concept

Once a year the respective European EQA/PT Organizers use the same 2 samples

Information

- Overall performance in Europe
- Performance per country
- Performance per manufacturer
- Performance per country per manufacturer

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Concept

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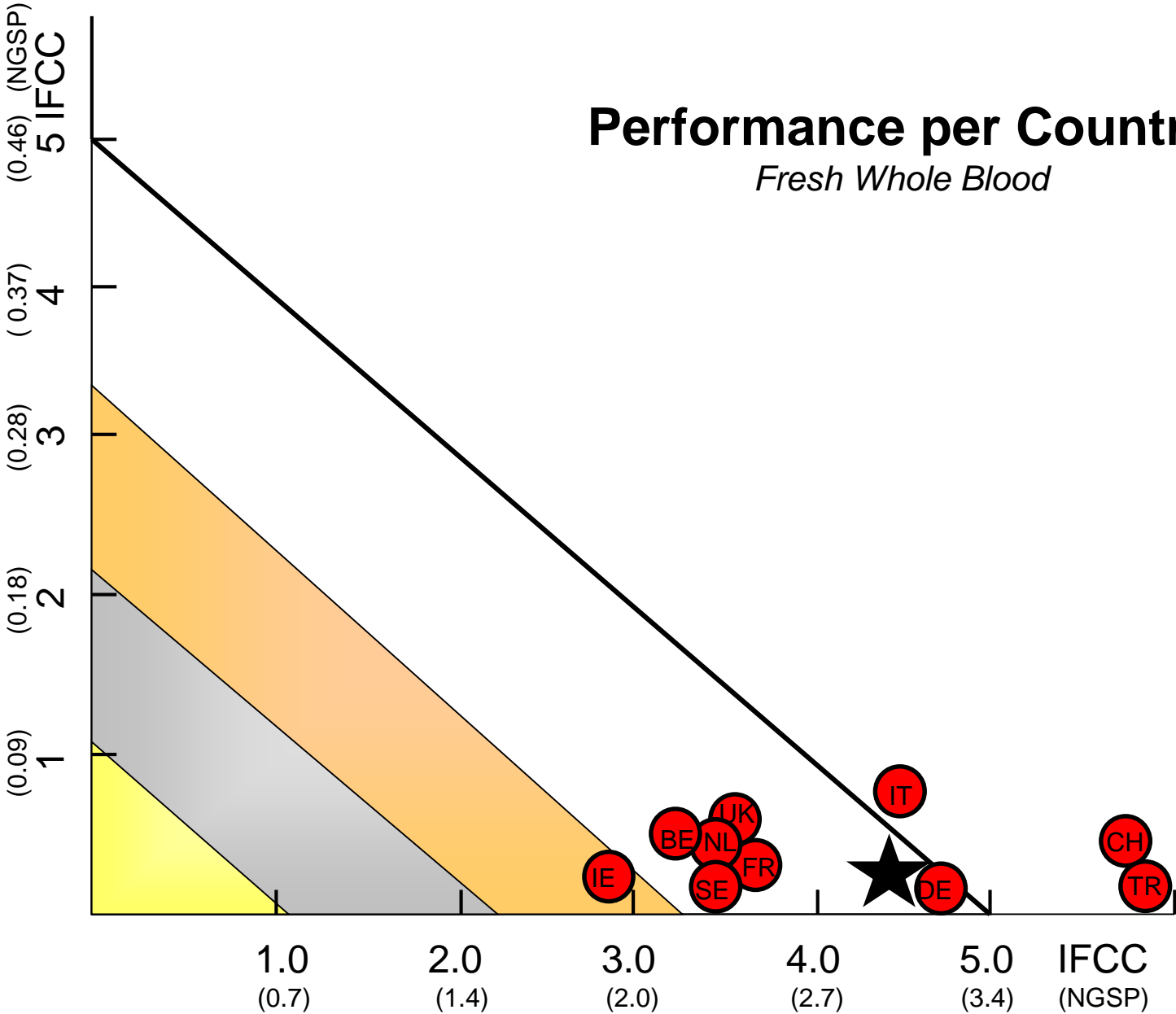
Information

- Overall performance in Europe
- **Performance per country**
- Performance per manufacturer
- Performance per country per manufacturer

Bias

Performance per Country

Fresh Whole Blood



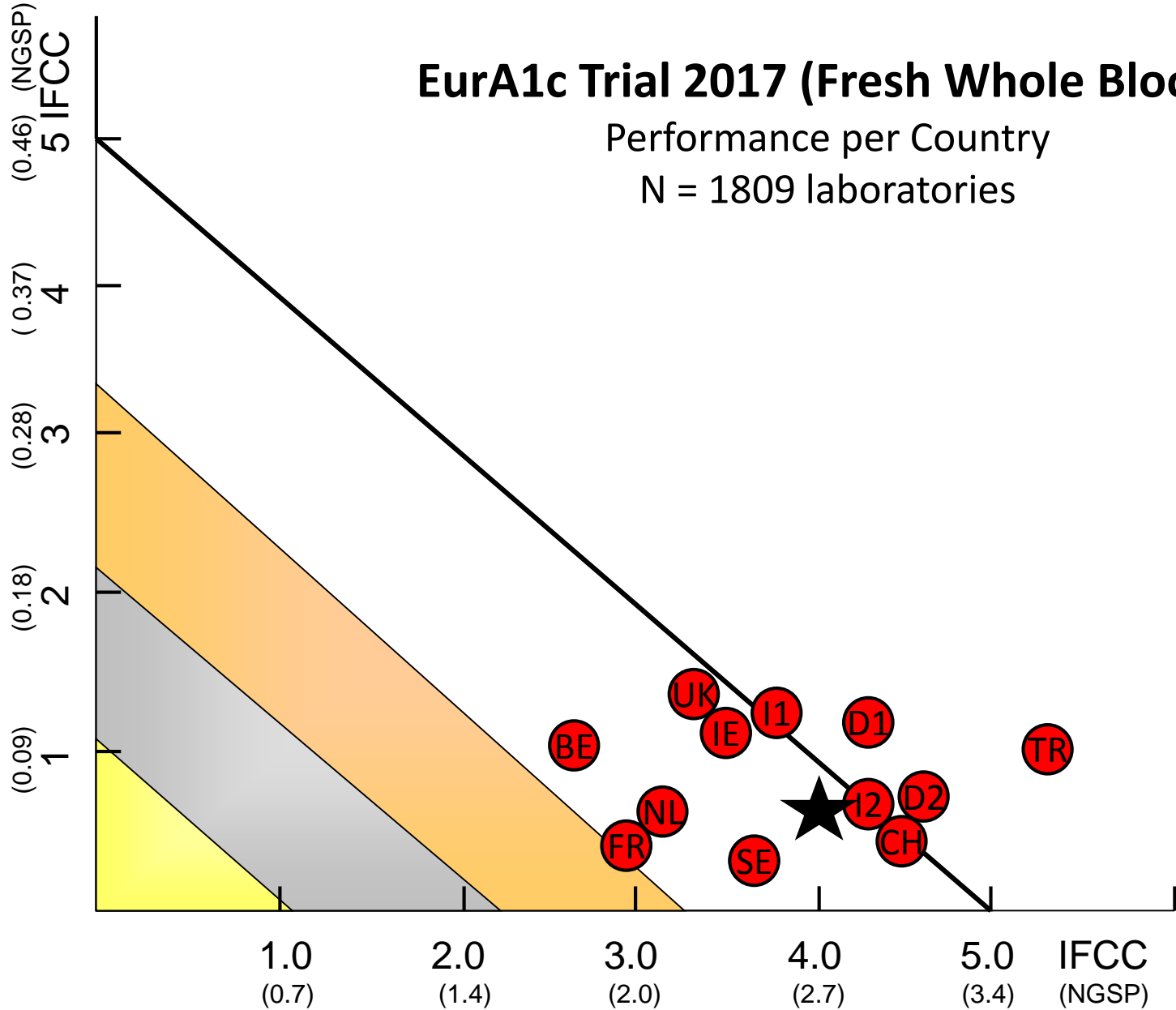
Imprecision in CV in %

Bias

EurA1c Trial 2017 (Fresh Whole Blood)

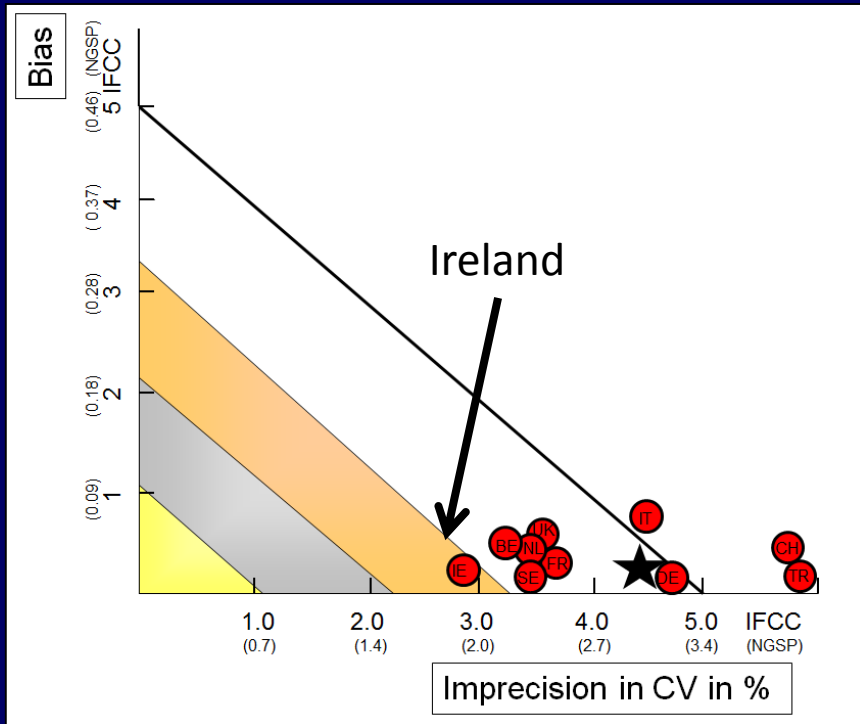
Performance per Country

N = 1809 laboratories

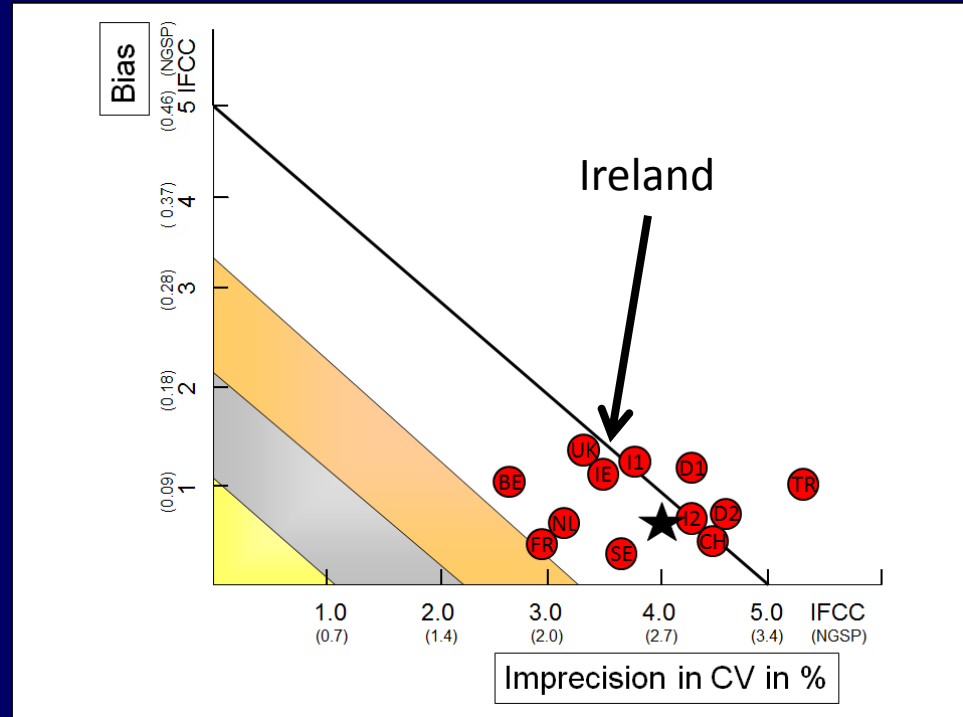


Imprecision in CV in %

Performance per Country



EurA1c 2016



EurA1c 2017

Excellent performance in one year.....

.....does not warrant excellent performance in the next year

“EurA1c”

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Once a year the respective European EQA/PT Organizers use the same 2 samples

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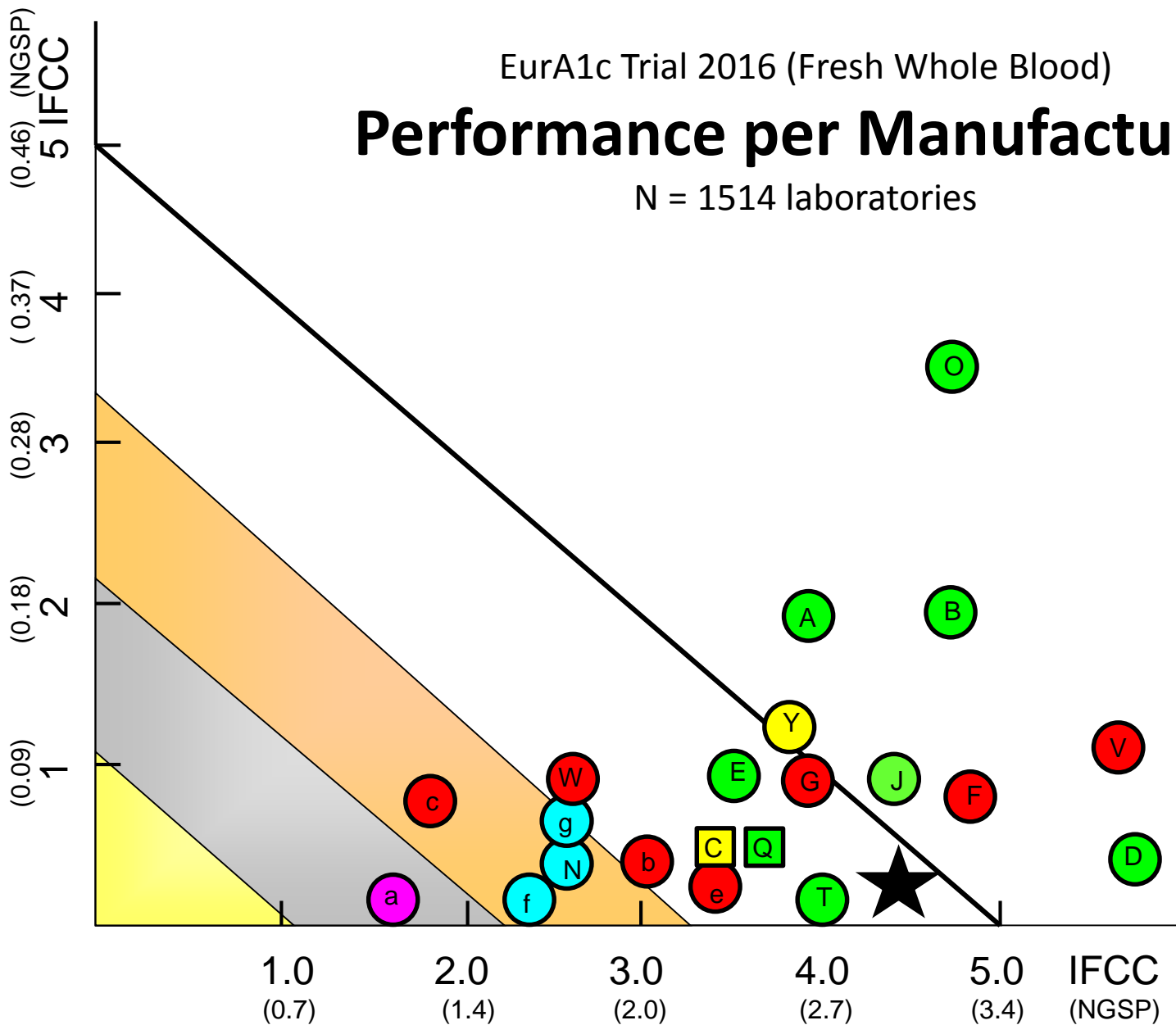
- Overall performance in Europe
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Bias

EurA1c Trial 2016 (Fresh Whole Blood)

Performance per Manufacturer

N = 1514 laboratories

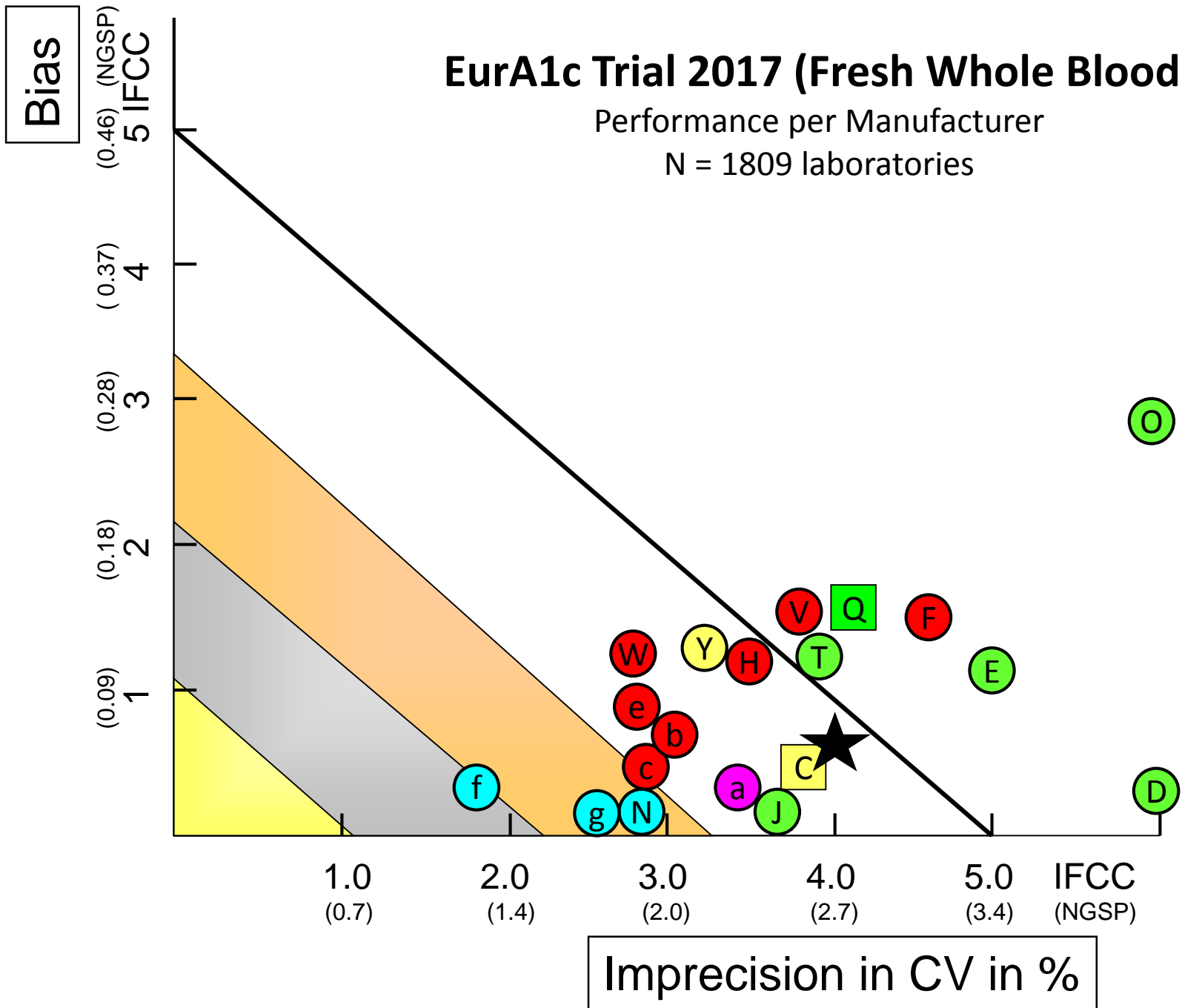


Imprecision in CV in %

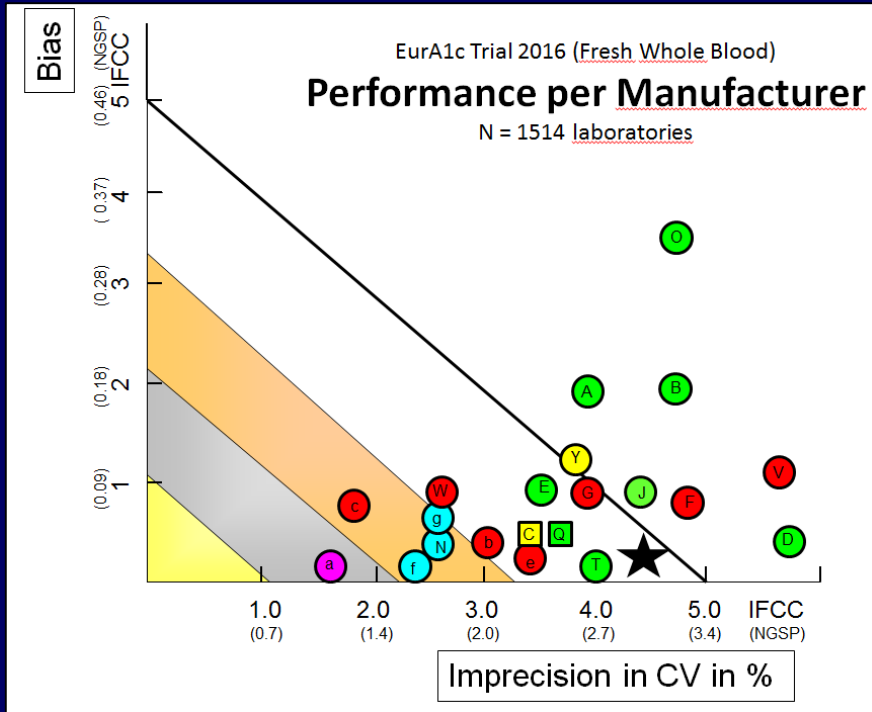
EurA1c Trial 2017 (Fresh Whole Blood)

Performance per Manufacturer

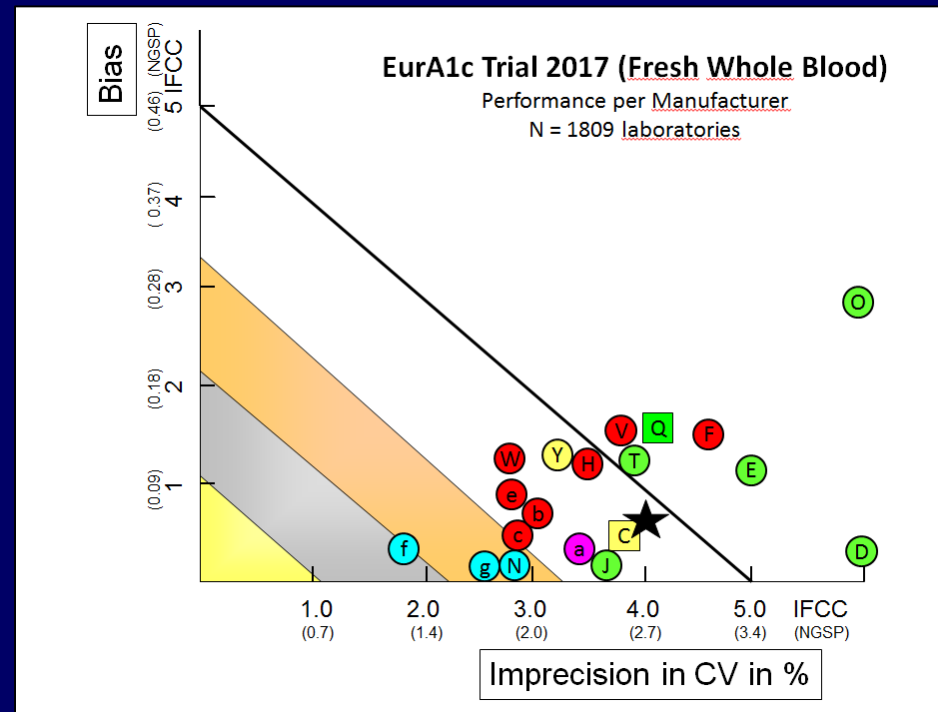
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Performance per Manufacturer



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“EurA1c”

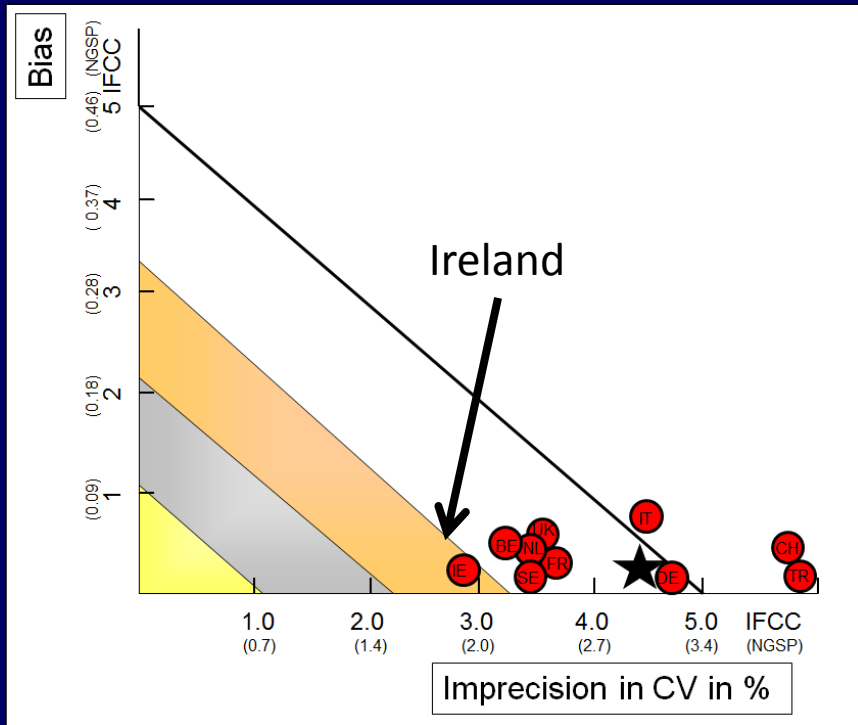
Concept

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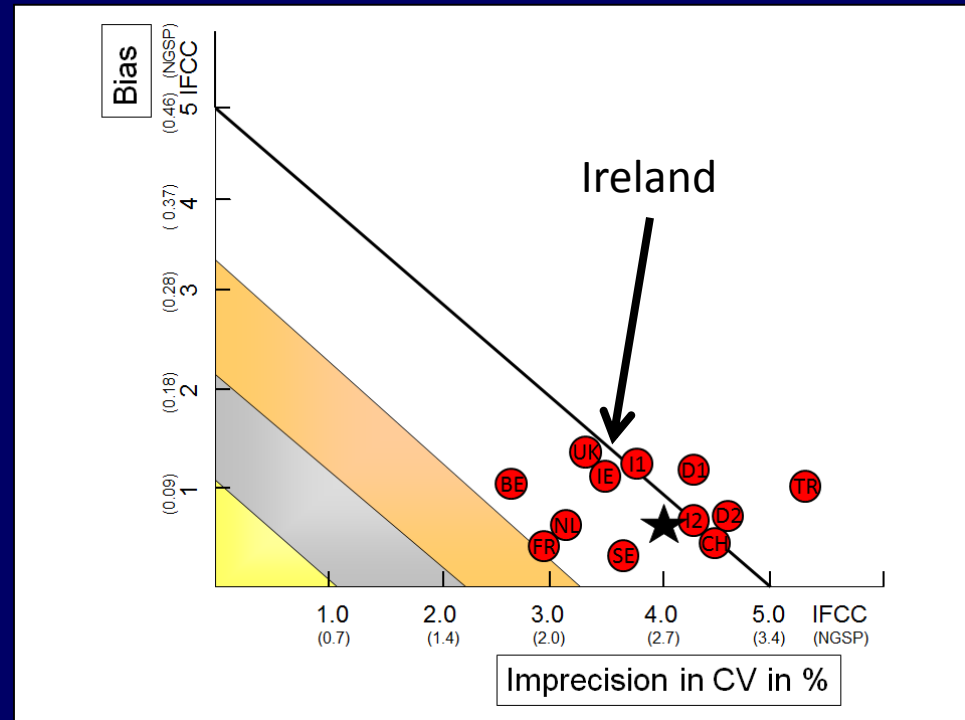
Information

- Overall performance in Europe
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- Performance per manufacturer
- **Performance per country per manufacturer**

Why Ireland not best country 2017?



EurA1c 2016



EurA1c 2017

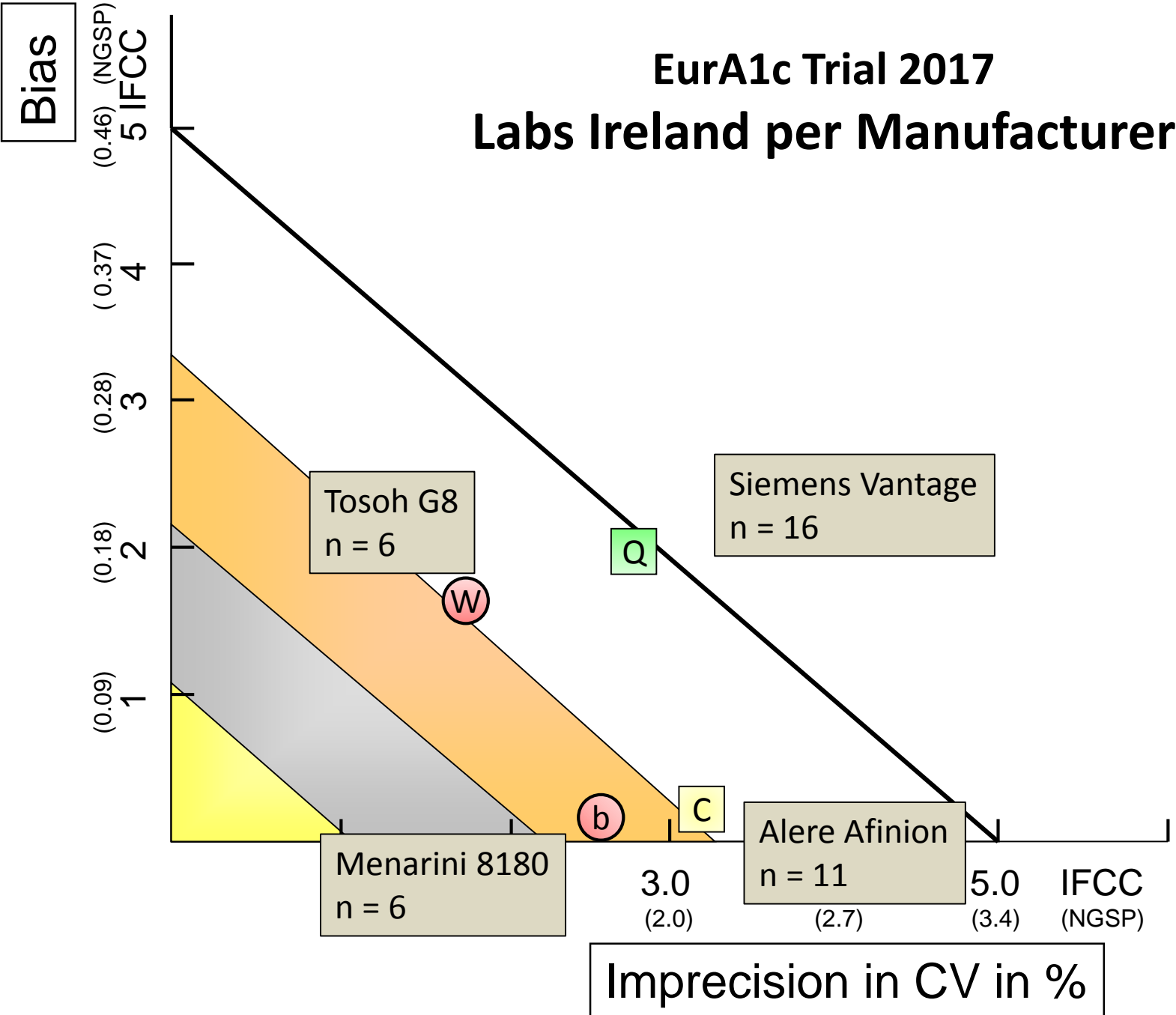
Why Ireland not best performing country 2017?

Are it the Labs?

Are it the Manufacturers?

Manufacturer specifically in Ireland?

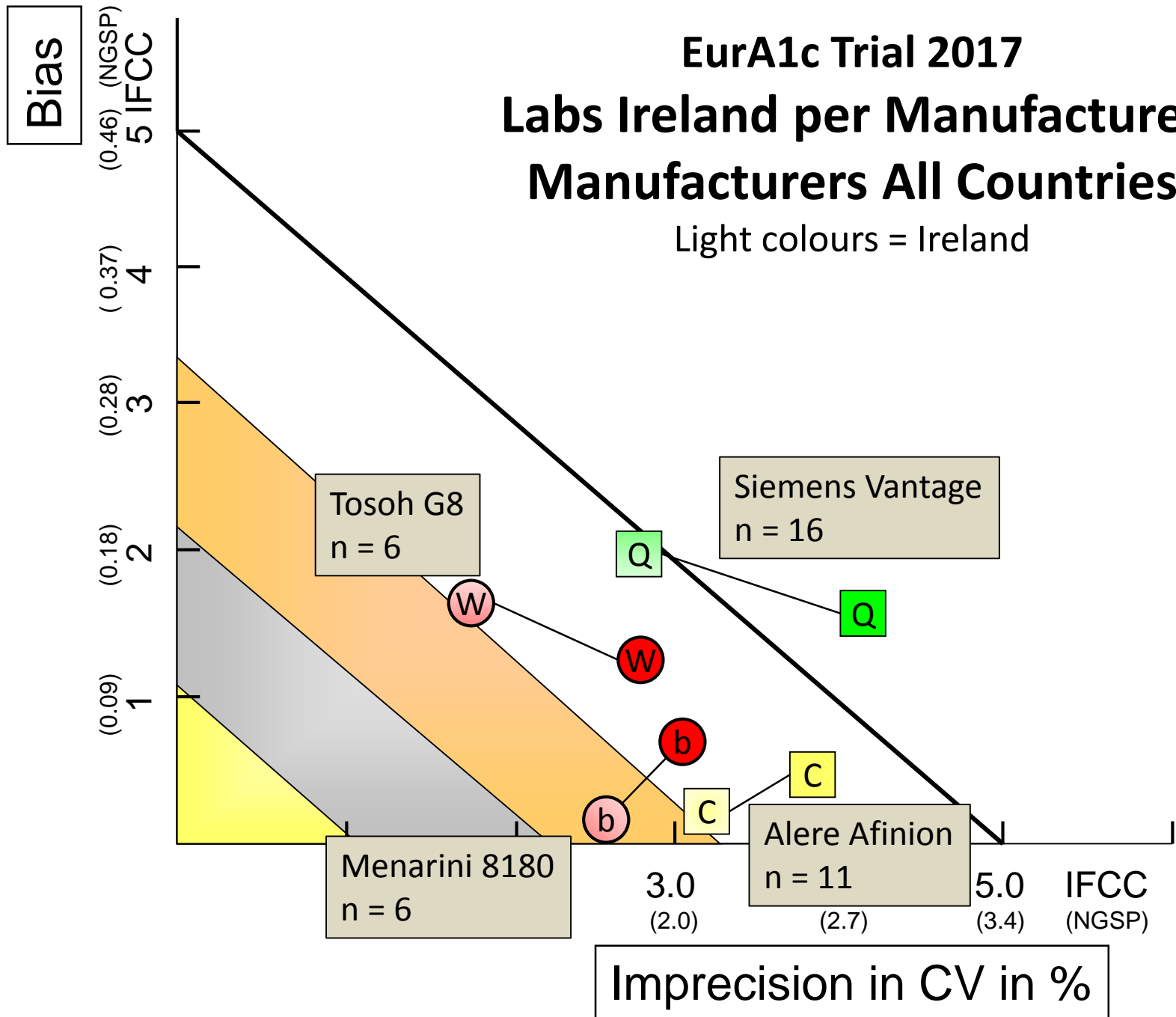
EurA1c Trial 2017 Labs Ireland per Manufacturer



EurA1c Trial 2017

Labs Ireland per Manufacturer Manufacturers All Countries

Light colours = Ireland



Why Ireland not best performing country 2017?

Are it the Labs?

Are it the Manufacturers?

Manufacturer specifically in Ireland?

Between Lab CV per manufacturer low
Bias Siemens Vantage and Tosoh G8 high
Therefore high overall CV for Ireland
Therefore not the 2017 champion

Why Ireland not best performing country 2017?

Are it the Labs?

Are it the Manufacturers?

Manufacturer specifically in Ireland?

Between Lab CV per manufacturer low
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Conclusion:

It are the manufacturers: SiemensVantage and Tosoh G8
have a substantial positive bias

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How can I know my performance: IFCC Model

Option 1

Fill Imprecision and Bias Internal QC

Option 2

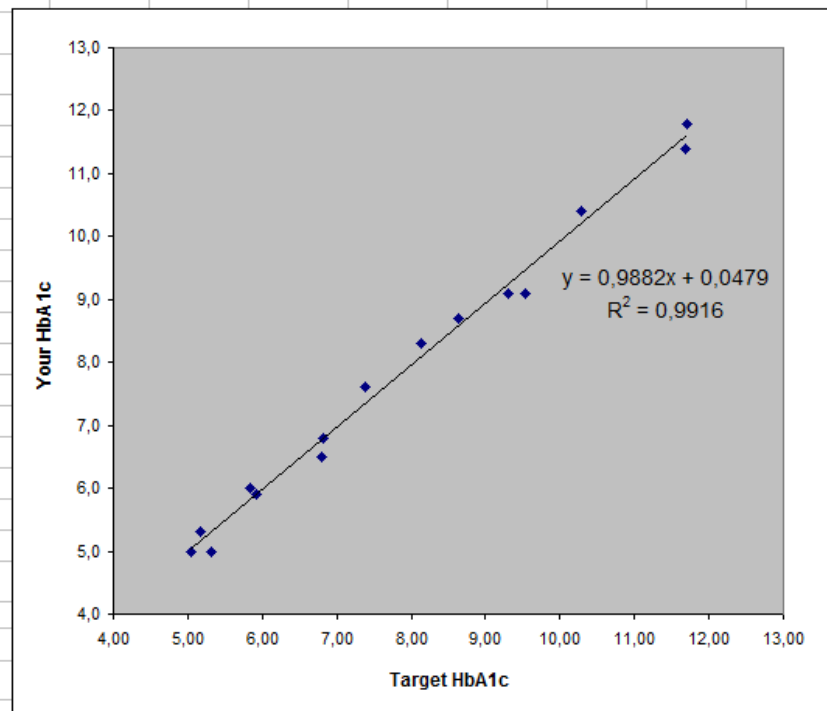
Fill: Imprecision Internal QC Bias IEQAS

Option 3

Fill Bias and Imprecision from IEQAS

Option 3: Fill data IEQAS

Calculation Imprecision							
x (target)	y (your)	x'	y'	(x') ²	(y') ²	(x'y')	
6,79	6,5	-1,05	-1,29	1,10	1,66	1,35	
10,28	10,4	2,44	2,61	5,95	6,81	6,37	
6,82	6,8	-1,02	-0,99	1,04	0,98	1,01	
8,63	8,7	0,79	0,91	0,62	0,83	0,72	
5,32	5,0	-2,52	-2,79	6,35	7,78	7,03	
5,84	6,0	-2,00	-1,79	4,00	3,20	3,58	
11,71	11,8	3,87	4,01	14,98	16,08	15,52	
9,53	9,1	1,69	1,31	2,86	1,72	2,21	
5,04	5,0	-2,80	-2,79	7,84	7,78	7,81	
7,38	7,6	-0,46	-0,19	0,21	0,04	0,09	
11,69	11,4	3,85	3,61	14,82	13,03	13,90	
5,93	5,9	-1,91	-1,89	3,65	3,57	3,61	
5,17	5,3	-2,67	-2,49	7,13	6,20	6,65	
8,14	8,3	0,30	0,51	0,09	0,26	0,15	
9,30	9,1	1,46	1,31	2,13	1,72	1,91	
Mean	7,84	7,79		Sum	72,77	71,66	71,91



Imprecision 2,8
Bias -0,05

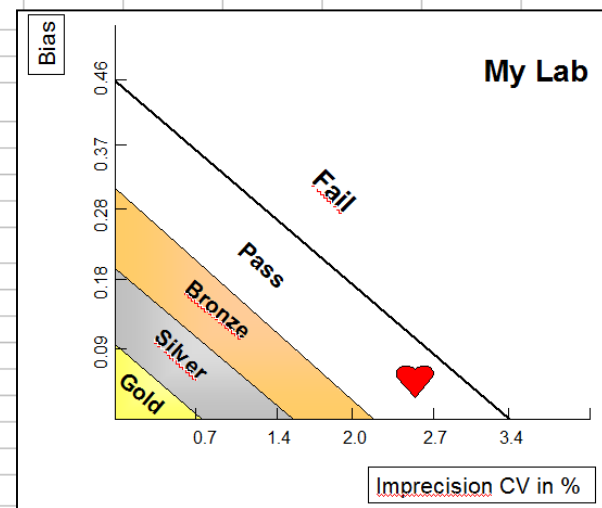
$$x' = (x_i - \bar{x})$$

$$y' = (y_i - \bar{y})$$

$$r = \sqrt{\frac{(\sum x' y')^2}{\sum (x')^2 \cdot \sum (y')^2}} \quad r^2 = \frac{(\sum x' y')^2}{\sum (x')^2 \cdot \sum (y')^2}$$

$$\text{Imprecision} = \sqrt{\frac{\sum (y')^2 \cdot (1 - r^2)}{(n - 2)}} \times 100\%$$

$$\text{Bias} = y - x$$



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Variant Controversy

“Do you want to see Variants in your HbA1c test?”

No!

HbA1c is meant to diagnose or monitor diabetes and therefore I do not want information on Variants

Yes!

Visibility of variants may indicate the presence of clinical conditions associated with altered erythrocyte lifespan and thus prevent wrong interpretation of the result. In addition, knowledge is of use for genetic counseling

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HbA1c for Diagnosis?

Many Reasons to say “Yes”

Biology

- Reflects chronic glycemia (2-3 months)
- Independent acute factors (e.g. stress; exercise)
- Very low intra-individual variability (CV ~1%)

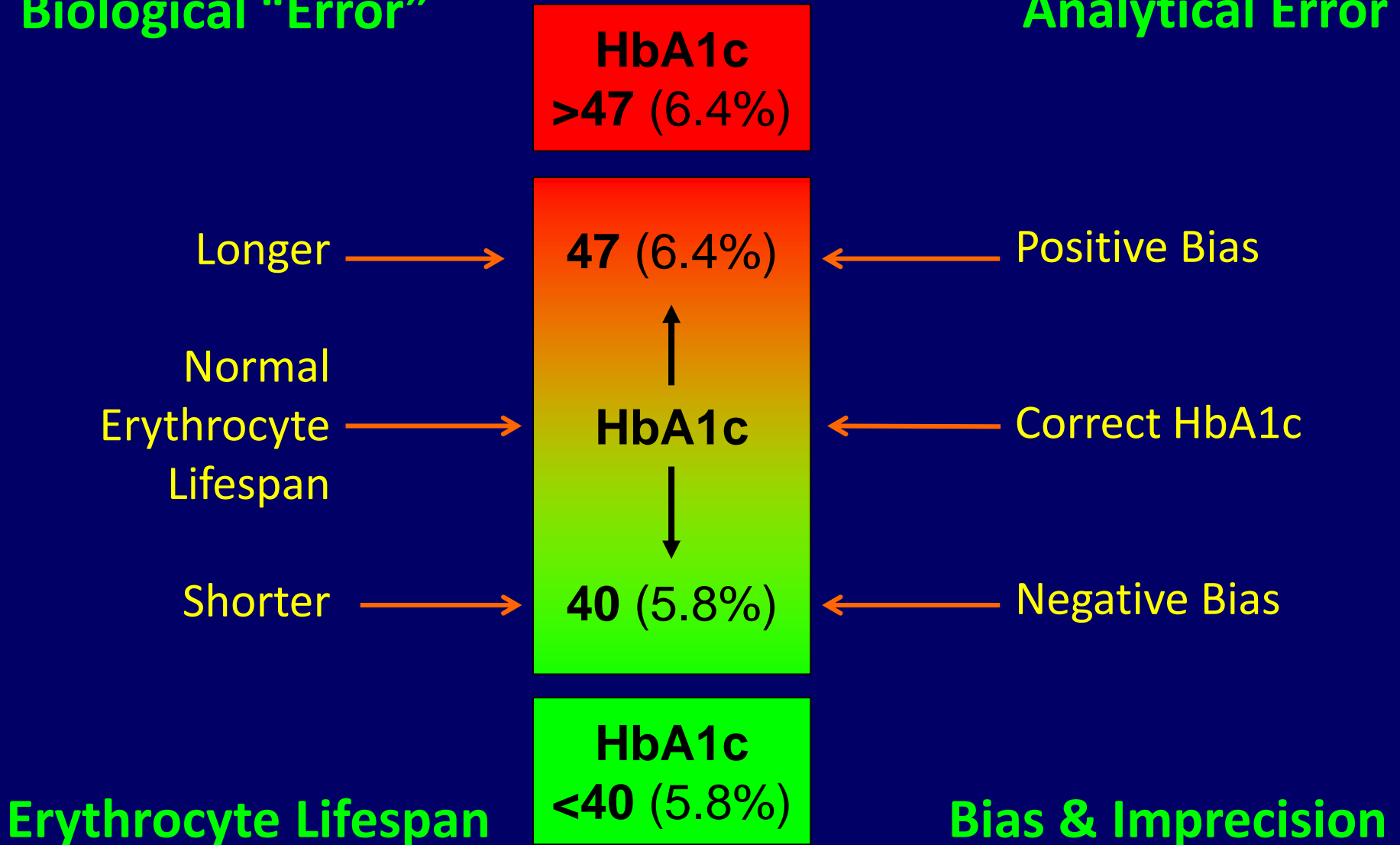
Analysis

- Blood collected any time of the day
- Sample is stable
- Fasting not necessary
- “Well standardized” assay

Interpretation HbA1c: Impact Error

Biological "Error"

Analytical Error



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POCT for Diagnosis?

Conditionally
Yes

Diabetes	HbA1c >47 (6.4%)	Professional Handling?
Increasing Risk Diabetes	47 (6.4%)	Internal QC?
	↑ HbA1c	External QC?
	↓	Batch Management?
	40 (5.8%)	IFCC/NGSP certified?
Low Risk	HbA1c <40 (5.8%)	Throughput/Expiry Date?

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