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Belgian Nuclear Research Centre

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Getting the most out of your PT Results

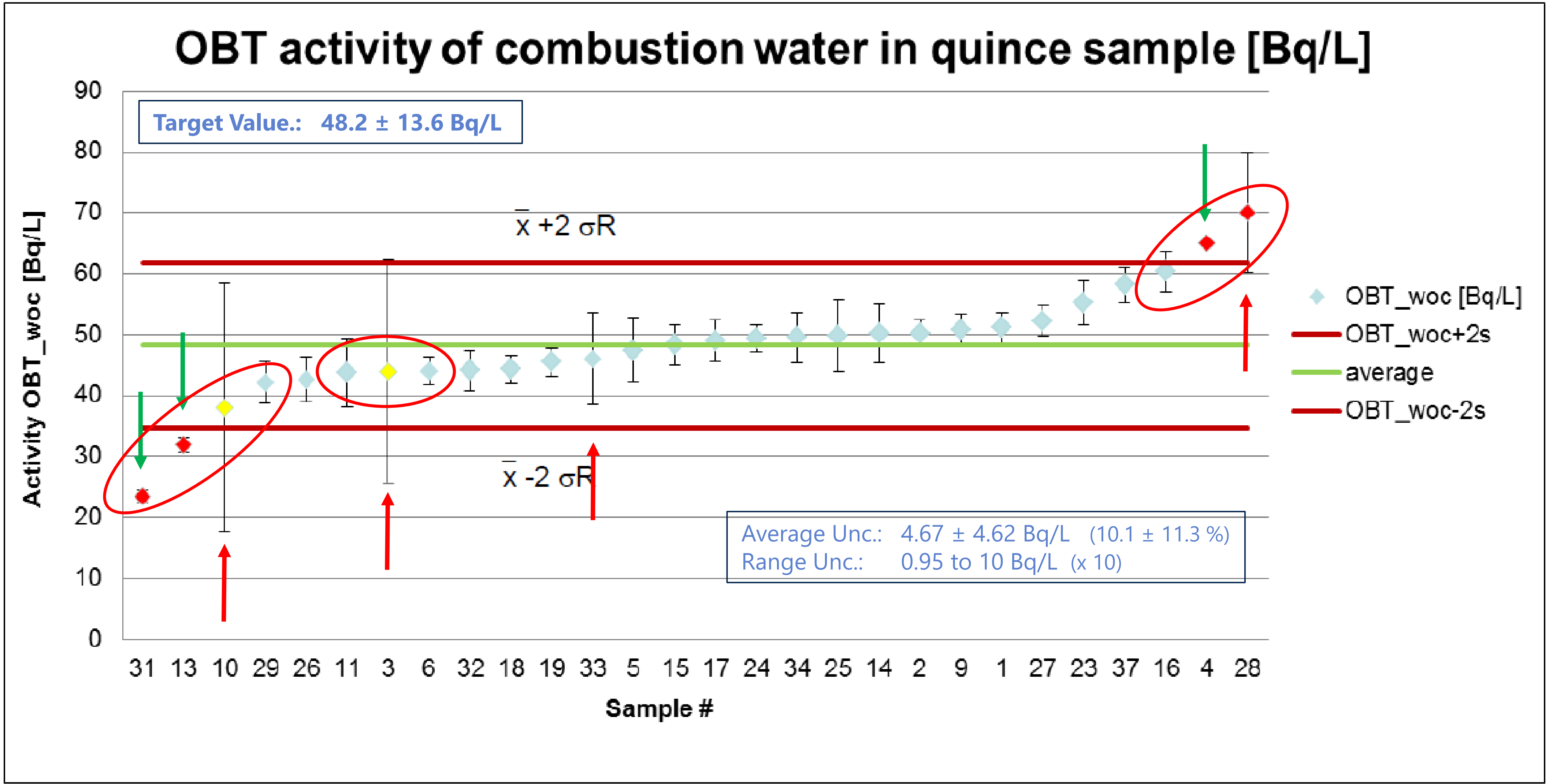
Contents

- Why participate in proficiency tests?
- How to evaluate the results?
- How to implement the evaluation in your QA management system?

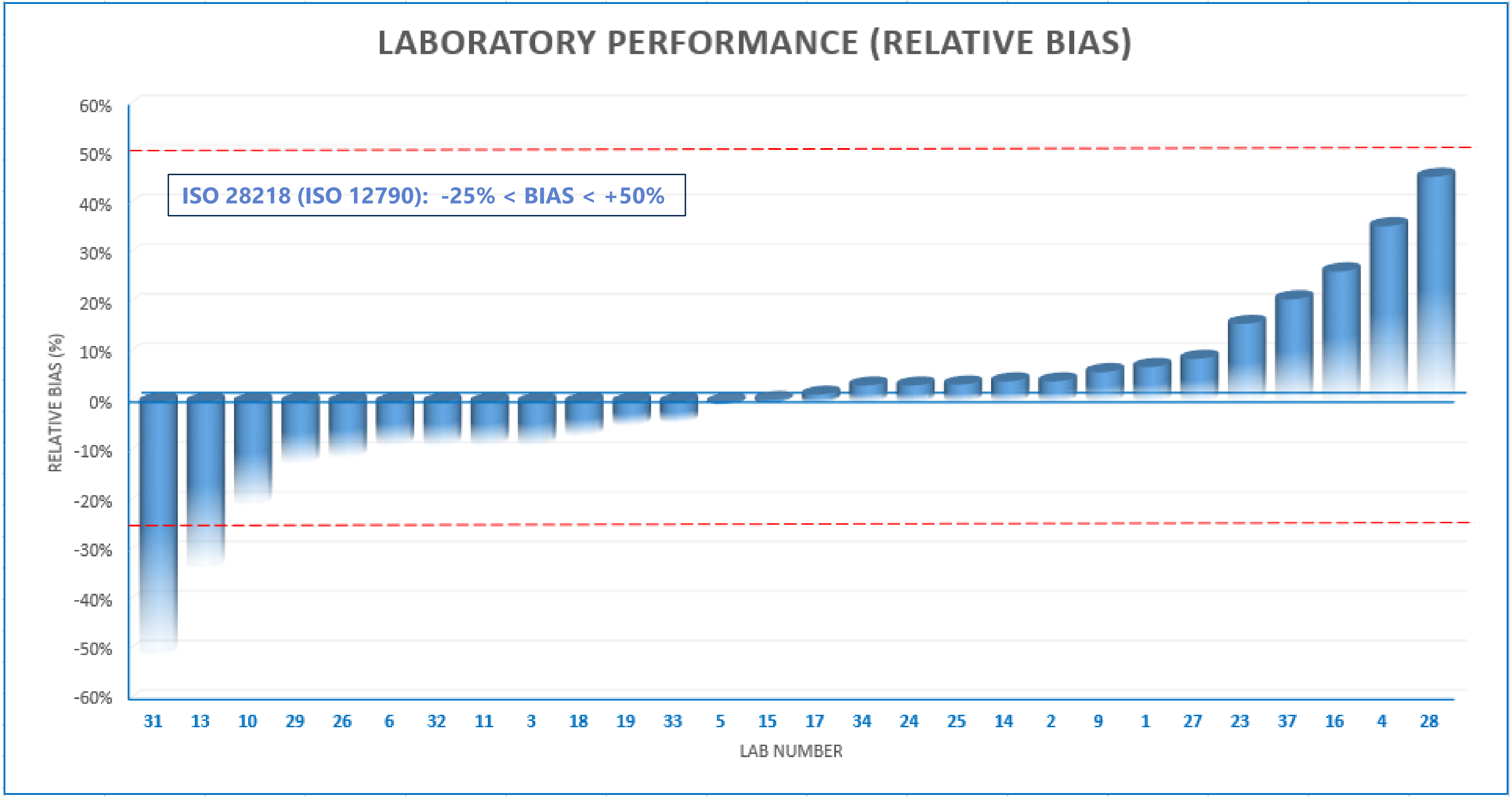
Clever use of PT results can save time

- Quality Assurance Management Systems (such as ISO-17025, ISO-9001, ISO-15189 and others) impose strict requirements to:
  - Method validation
  - Method verification
  - Uncertainty budget
- General guidelines on method validation (such as Eurochem Guide ‘Fitness for Purpose’) specify a number of parameters:
  - Selectivity
  - Limit of Detection or Limit of Quantification
  - Linearity and Working Range
  - Trueness
  - Precision (Repeatability and Reproducibility)
  - Uncertainty
  - Ruggedness
- Clever use of PT results can provide information for a number of these parameters

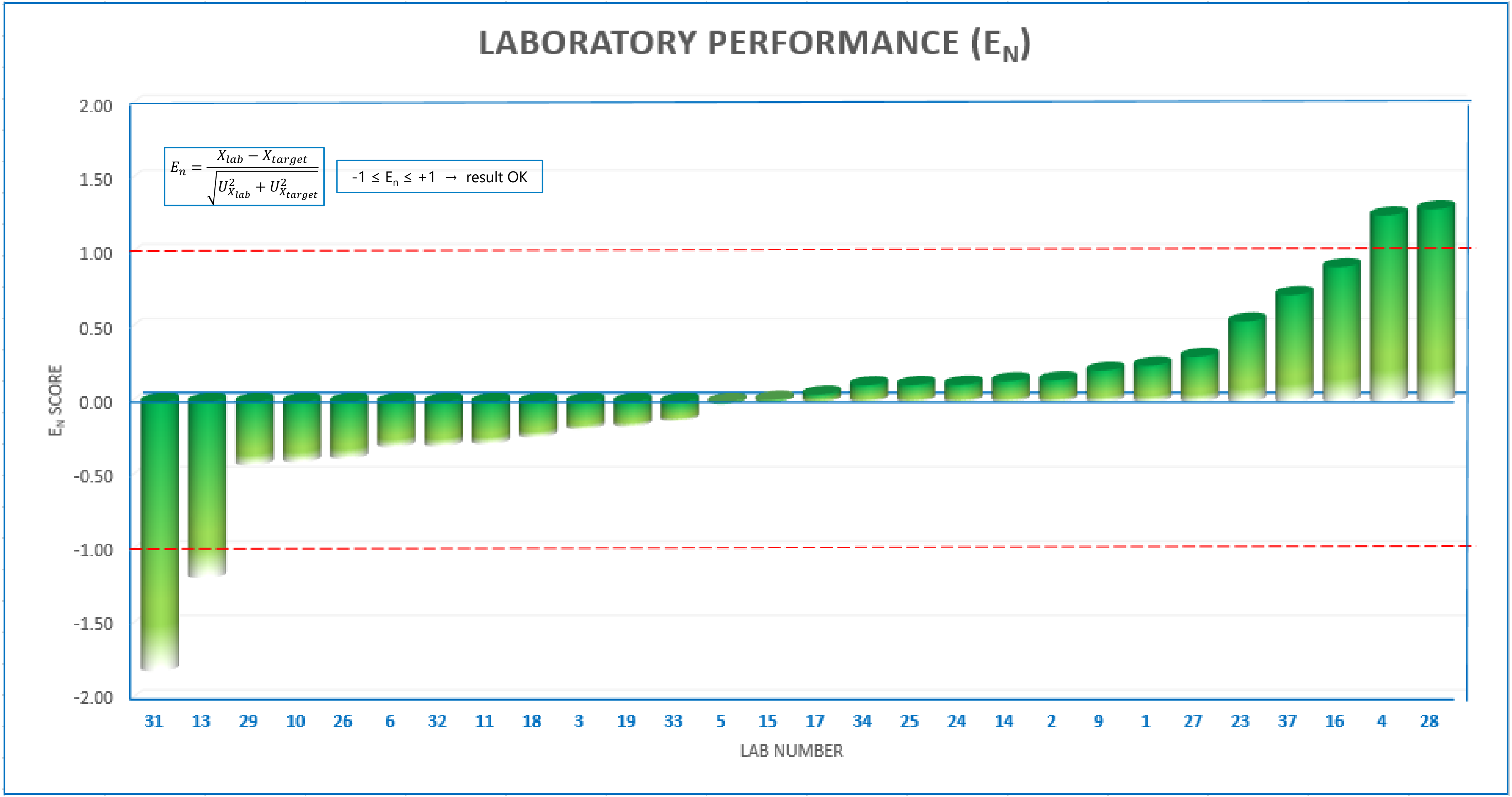
OBT PT #6: Large variation in the reported uncertainty



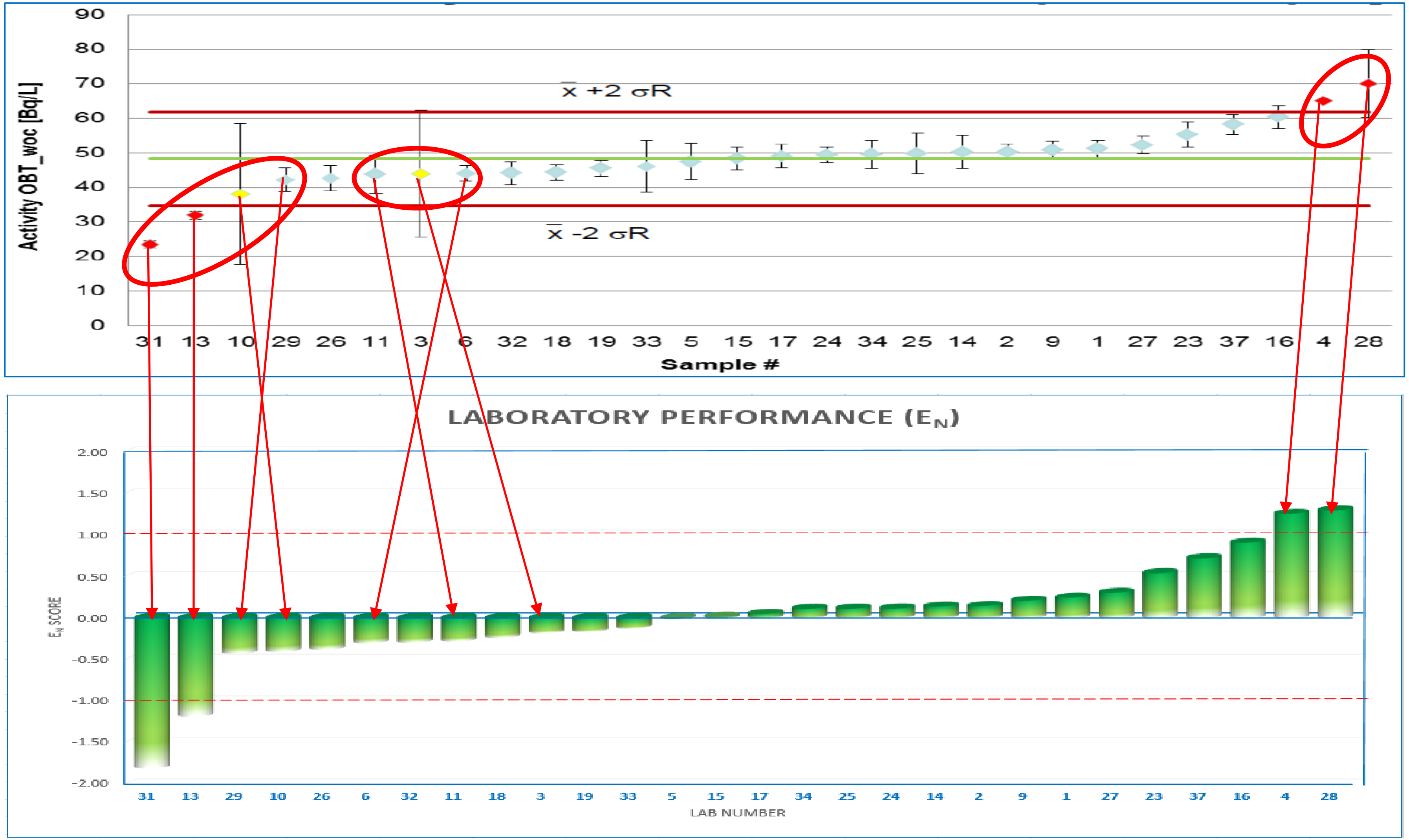
Investigating the possible bias of your result



Using your lab performance score (zèta, U, E_n, …)



Effect of uncertainty on performance indicator E_n



Getting more out of Proficiency Test results

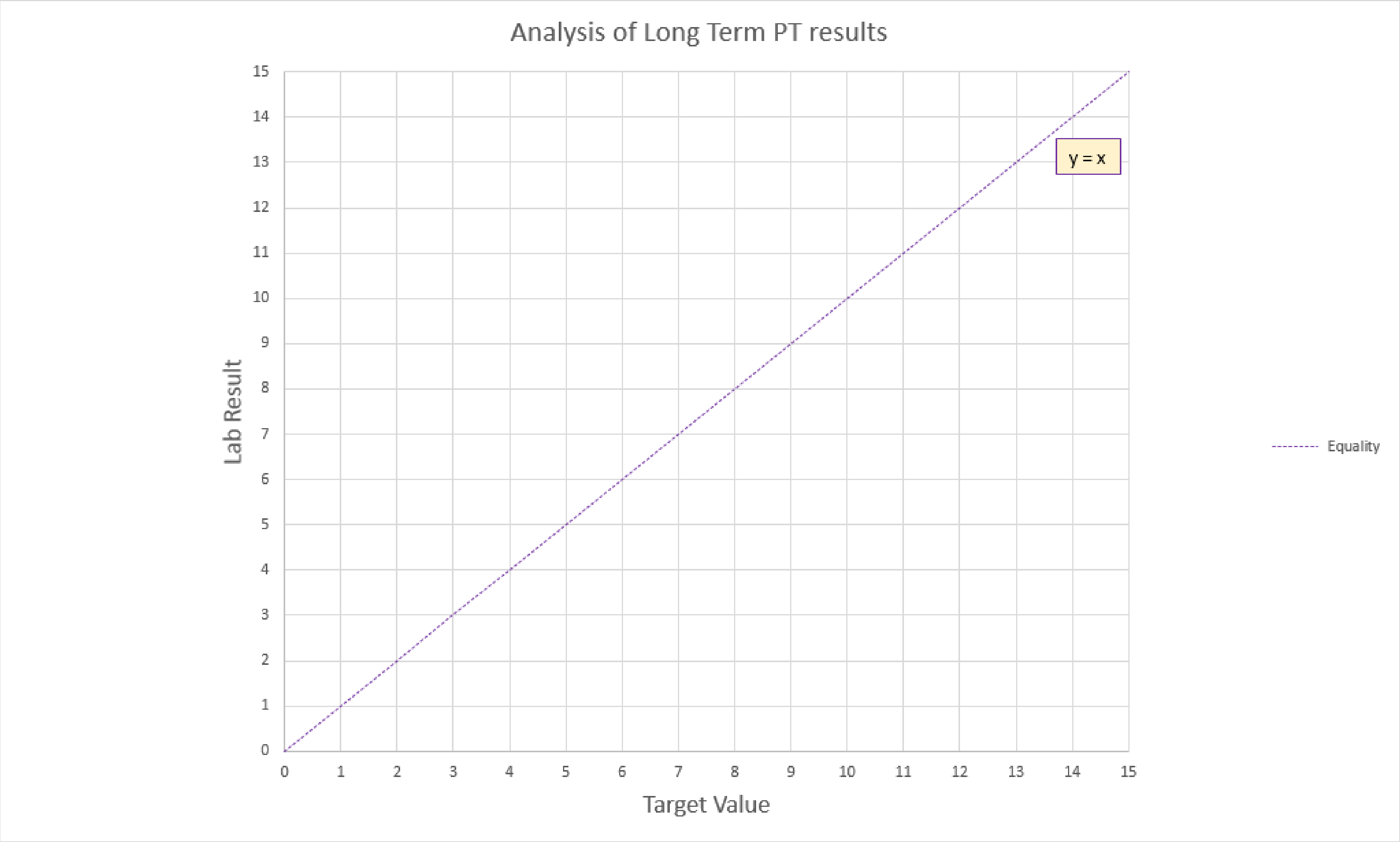
- How to verify if your lab results …
  - … are correct
  - … have a realistic estimation of uncertainty
  - … are reproducible
  - … are not biased

- An alternative method was proposed by Meijer et al. (*) in 2002, based on the long term analytical performance of a laboratory in various proficiency tests (LTUM: Long Term Uncertainty Method). This method was applied by Matar er al (**) in 2015.

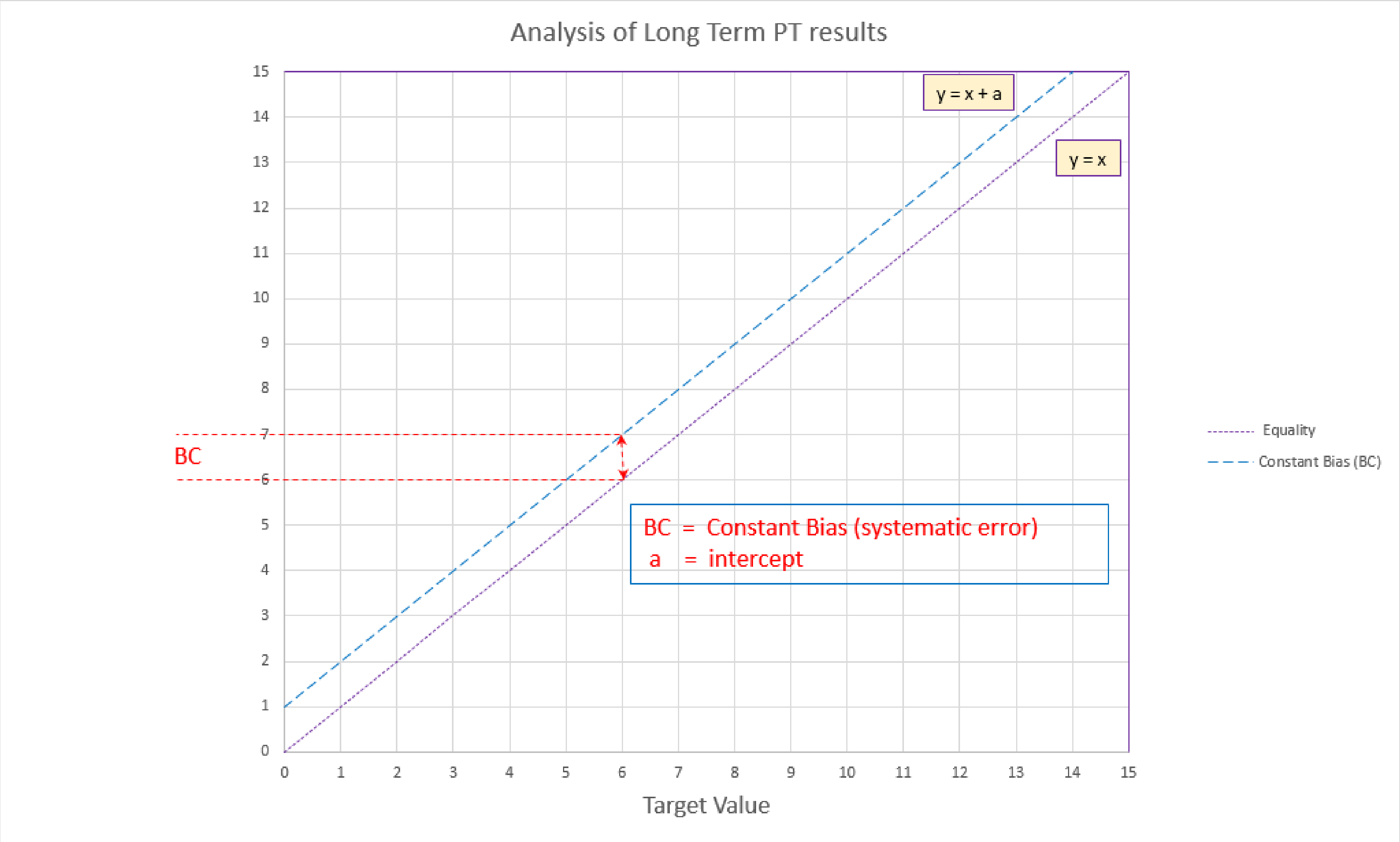
(*) Meijer P., de Maat M.P., Kluft C., Haverkate F. and van Houwelingen H.C.; "*Long-term analytical performance of hemostasis field methods as assessed by evaluation of the results of an external quality assessment program for antithrombin.*"; Clin. Chem.; 2002; **48**: 1011-5.

(**) Matar G., Poggi B., Mely R., Bon C., Chardon L., Chikh K., Renard A.C., Sota C., Eynard J.C., Cartier R. and Cohen R.; "*Uncertainty in measurement for 43 biochemistry, immunoassay, and hemostasis rou)ne analytes ecaluated by a method using only external quality assessment data*."; Clin. Chem. Lab. Med.; 2015; **53** (11); 1725-36.

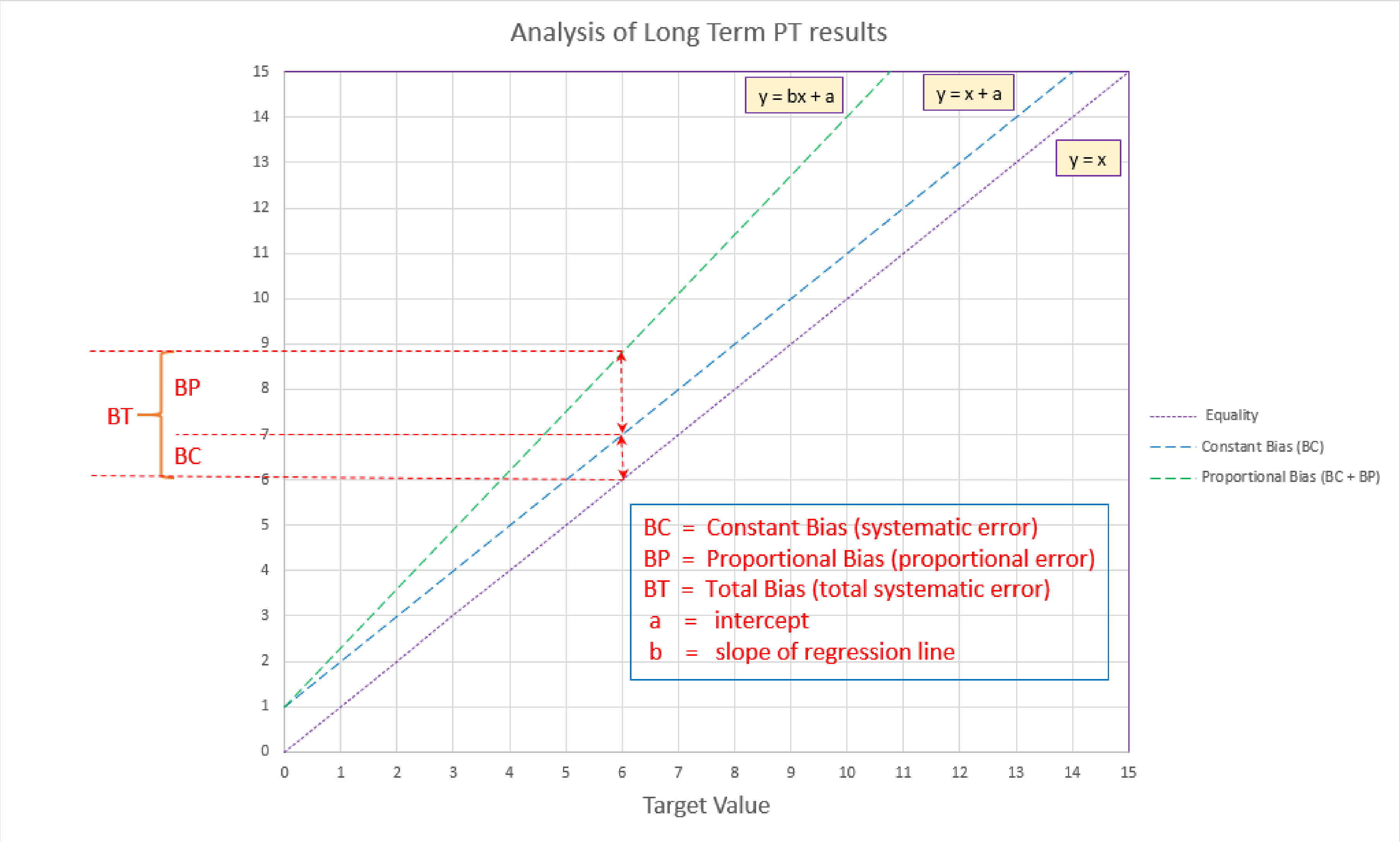
The ‘perfect’ lab: equality



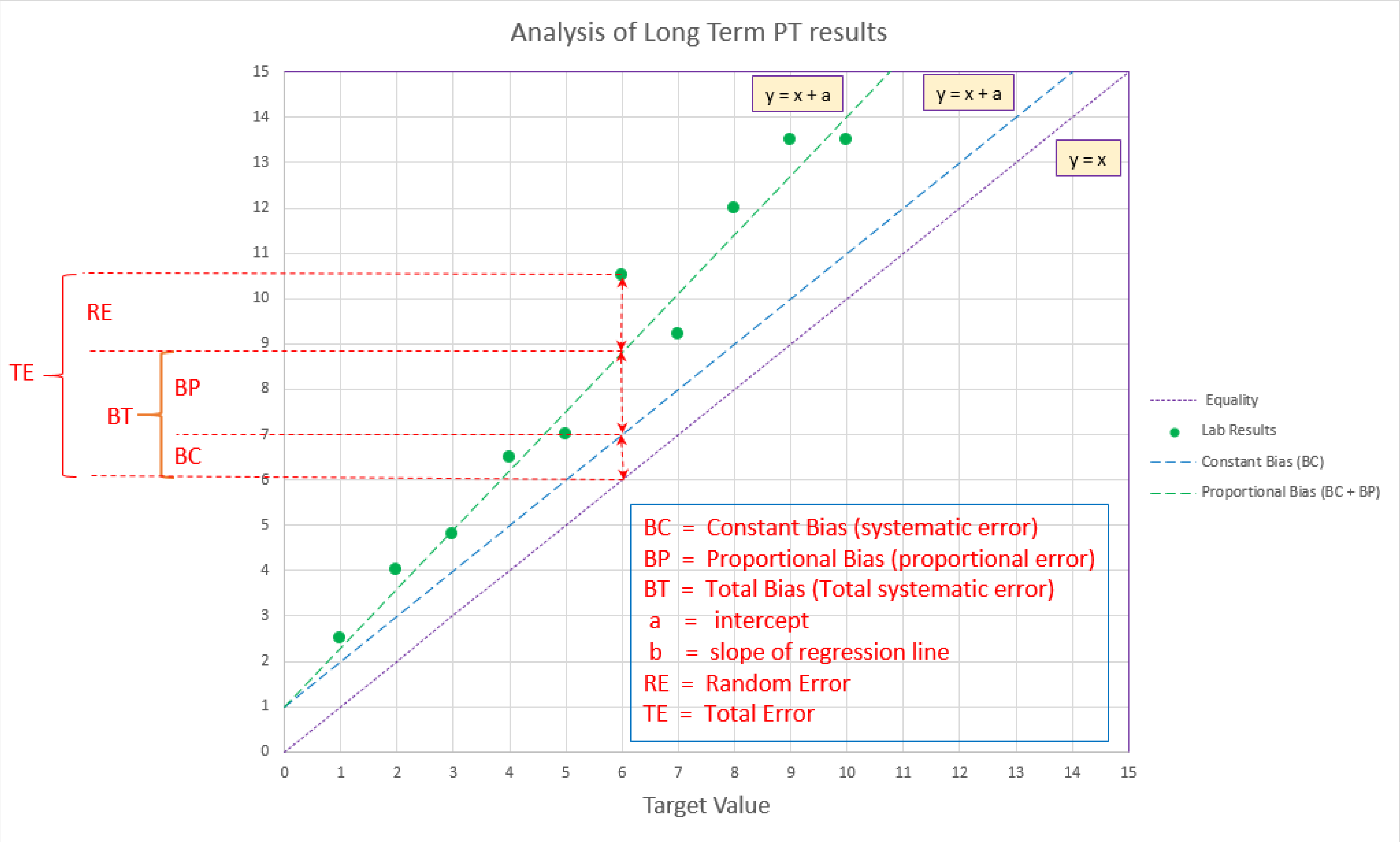
Effect of a constant bias



Effect of a proportional bias



The 'real' lab: combined (total) uncertainty



The mathematics behind the analysis

$$TE = \sqrt{LTCV^2 + BT^2}$$

'sum of squares'

$$BT = \sqrt{BC^2 + BP^2}$$

$$BC = \sqrt{(\bar{y} - \bar{x})^2} = a$$

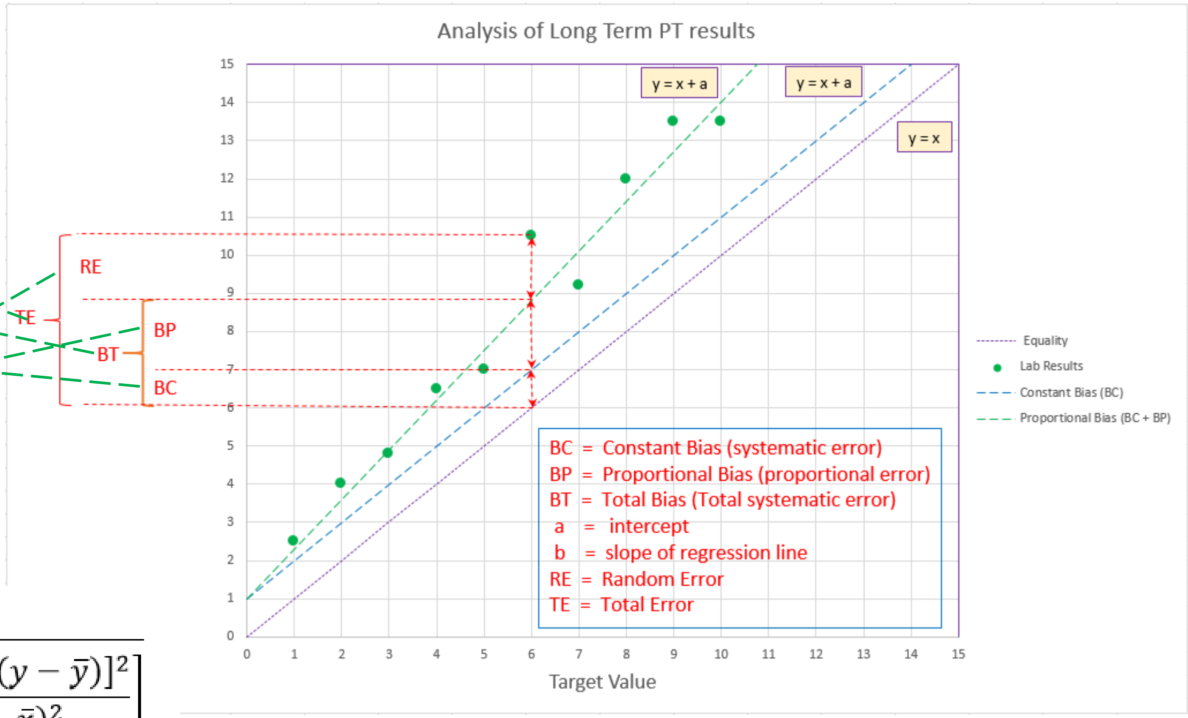
~ intercept

$$BP = \sqrt{\frac{(n-1)}{n} \times (b-1)^2 \times S_x^2}$$

~ slope

$$RE = \sqrt{\frac{(n-2)}{n} \times S_{\frac{y}{x}}^2}$$

$$S_{\frac{y}{x}} = \sqrt{\frac{1}{(n-2)} \times \left[\sum (y-\bar{y})^2 - \frac{[\sum (x-\bar{x})(y-\bar{y})]^2}{\sum (x-\bar{x})^2}\right]}$$



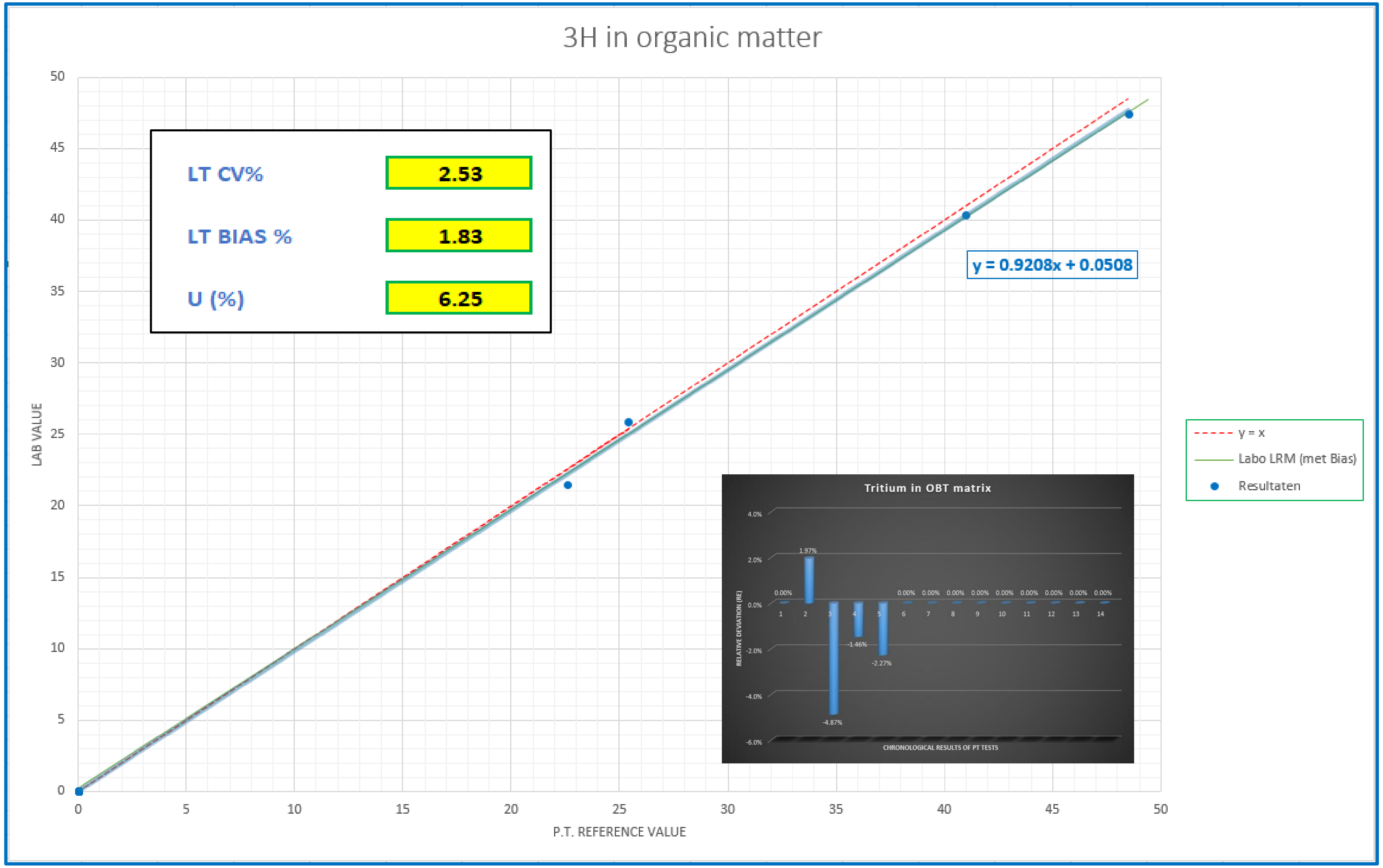
Long term analytical error

Residual standard deviation (variability of the regression line)

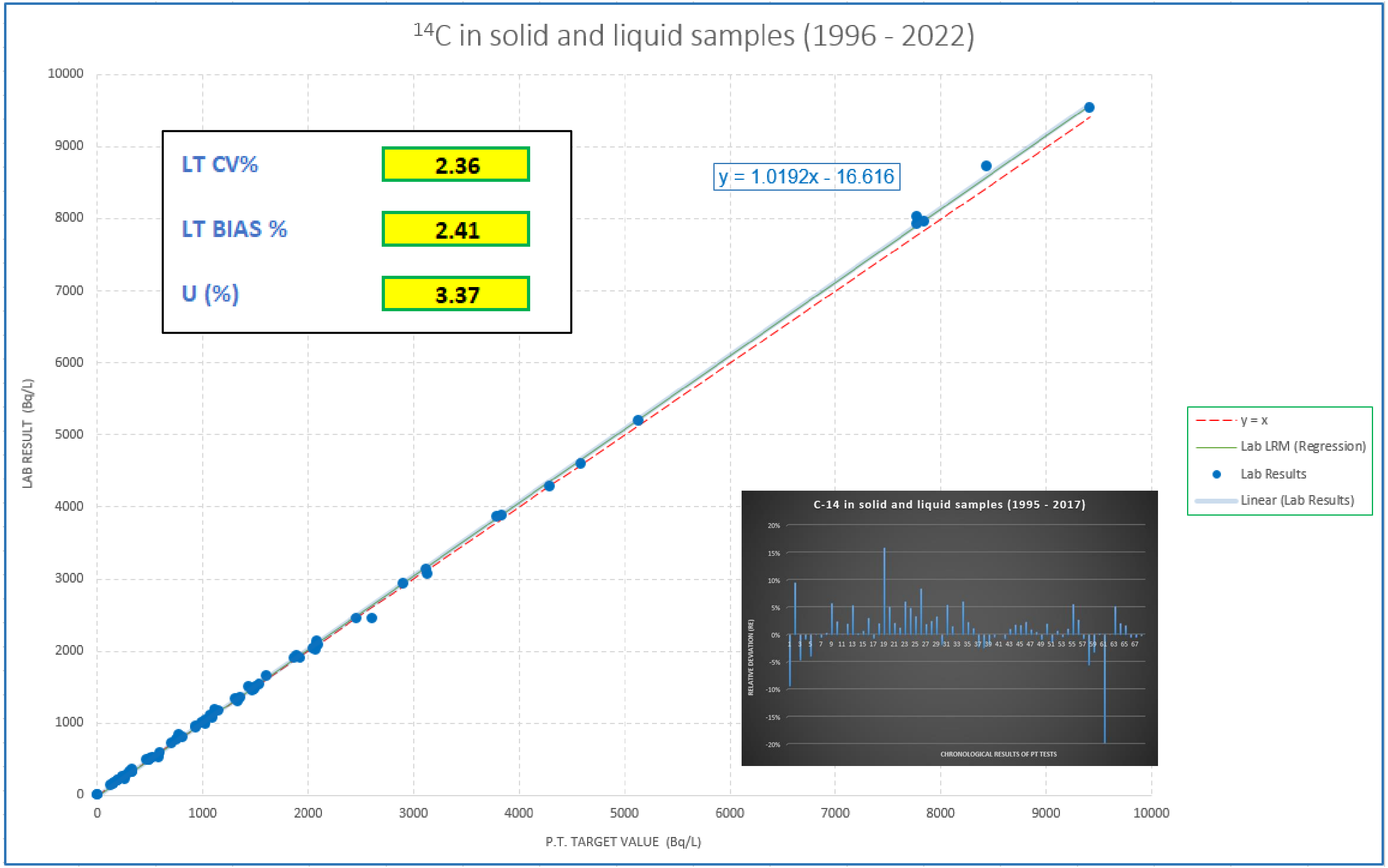
$$LTCV = \frac{S_{\frac{y}{x}} / b}{\bar{x}} \times 100$$

Long term coefficient of variation (CV)

Liquid Scintillation Counting: ^{3}H in OBT



Liquid Scintillation Counting: ^{14}C in various matrices



Conclusion: PT results provide excellent validation and verification data

- Easy to use method based on simple regression analysis
- Directly compare the performance of your lab with other labs
- Good estimate of long term stability ($\Rightarrow$ Reproducibility)
- Good estimate of linearity (and possibly range)
- Good estimate of bias (both constant and proportional)
- Confirmation of calculated uncertainty budget
- Confirmation about trueness and precision
- Possible information about method ruggedness

Questions?

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