

Praxistauglichkeit: Evaluierung über einen Ringversuch - Grundsätze der Vergleichbarkeit

Practicality: Evaluation via interlaboratory study - principles of reproducibility

04.02.2026

Dr. Carsten Fauhl-Hassek

Head of Department Reference Centre for Food and Feed Analysis BfR

What is an interlaboratory method validation study?

Systematic investigation of the performance of an analytical method conducted by multiple laboratories

Demonstration that the method is:

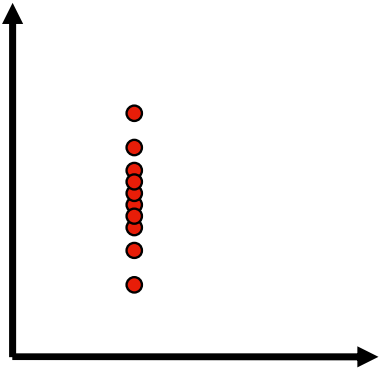
- suitable
- reliable
- reproducible
- well described

Basis for quality-assured analytical studies

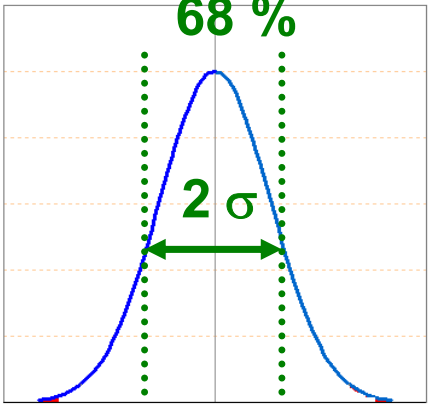
Analytical chemistry



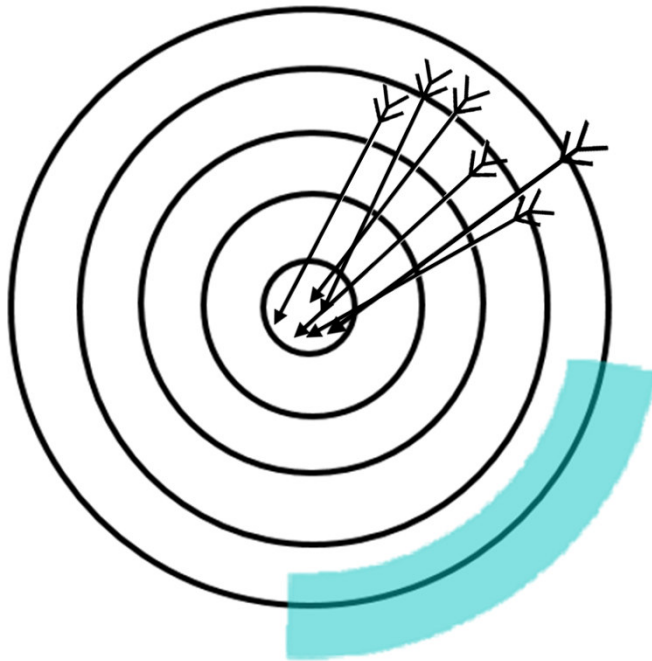
◆ Test result varies !



10
± 2



Accuracy of the method (precision and trueness)



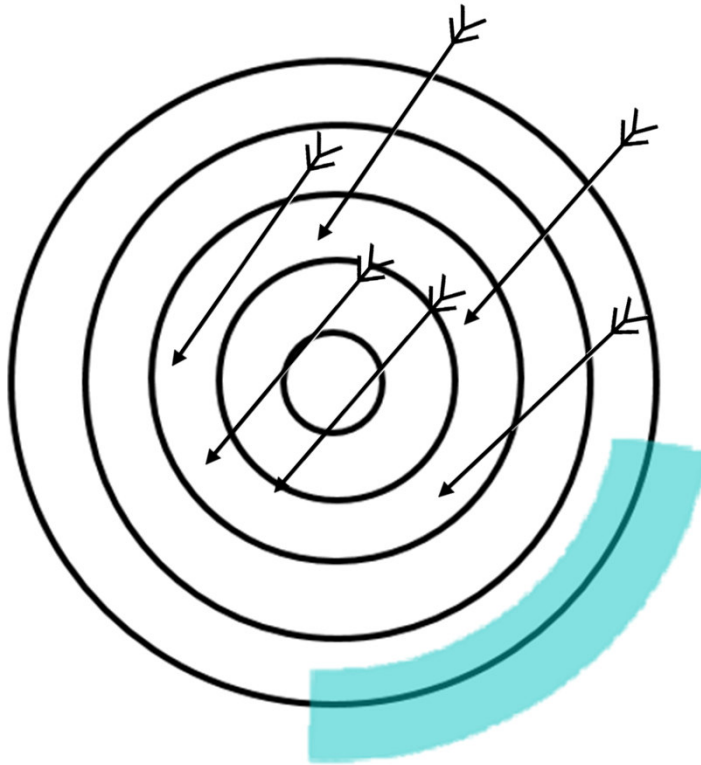
- Close to the true value
- and high precision

Accuracy of the method (precision and trueness)



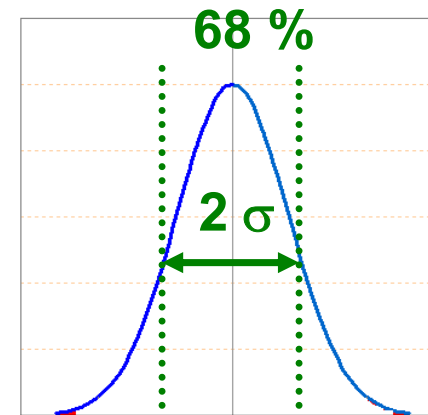
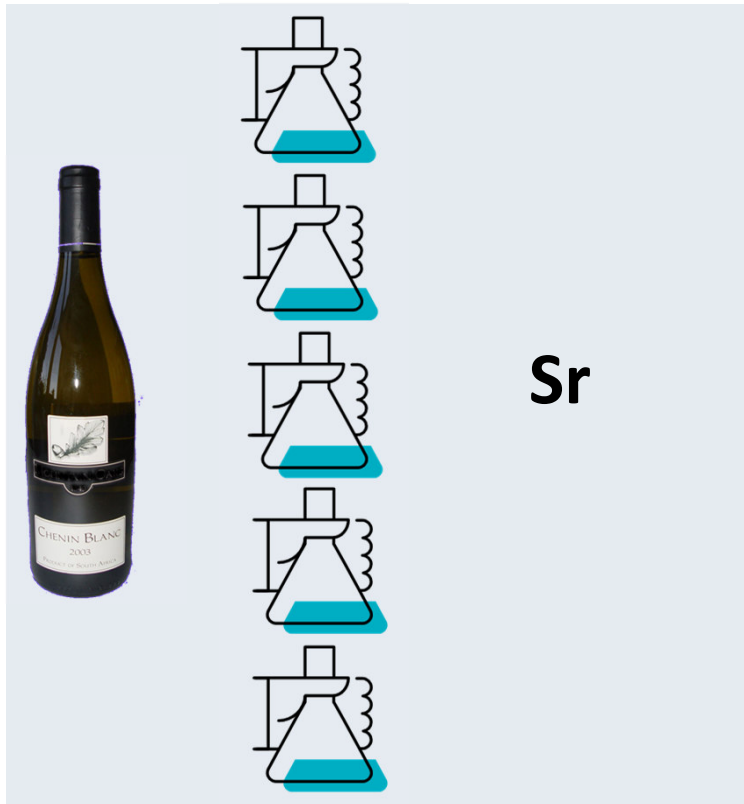
- High precision
- but far away from the true Value

Accuracy of the method (precision and trueness)



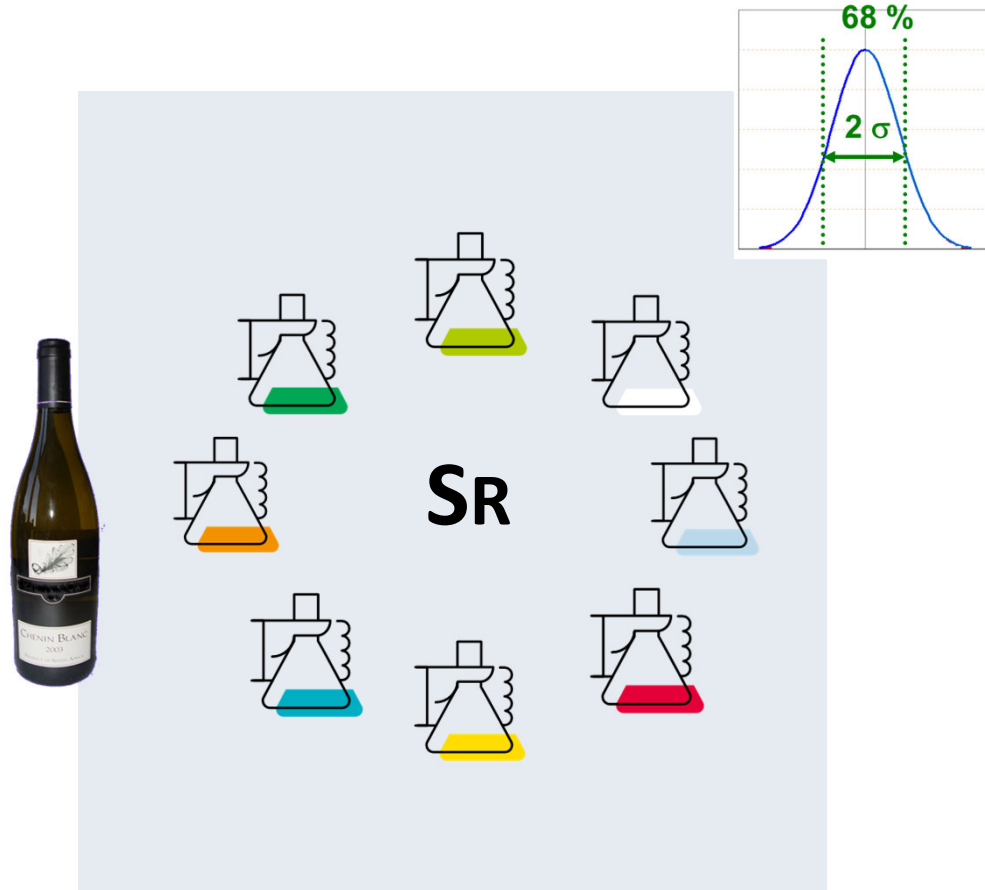
- Close to the true value
- but low precision

Precision: Repeatability of a method



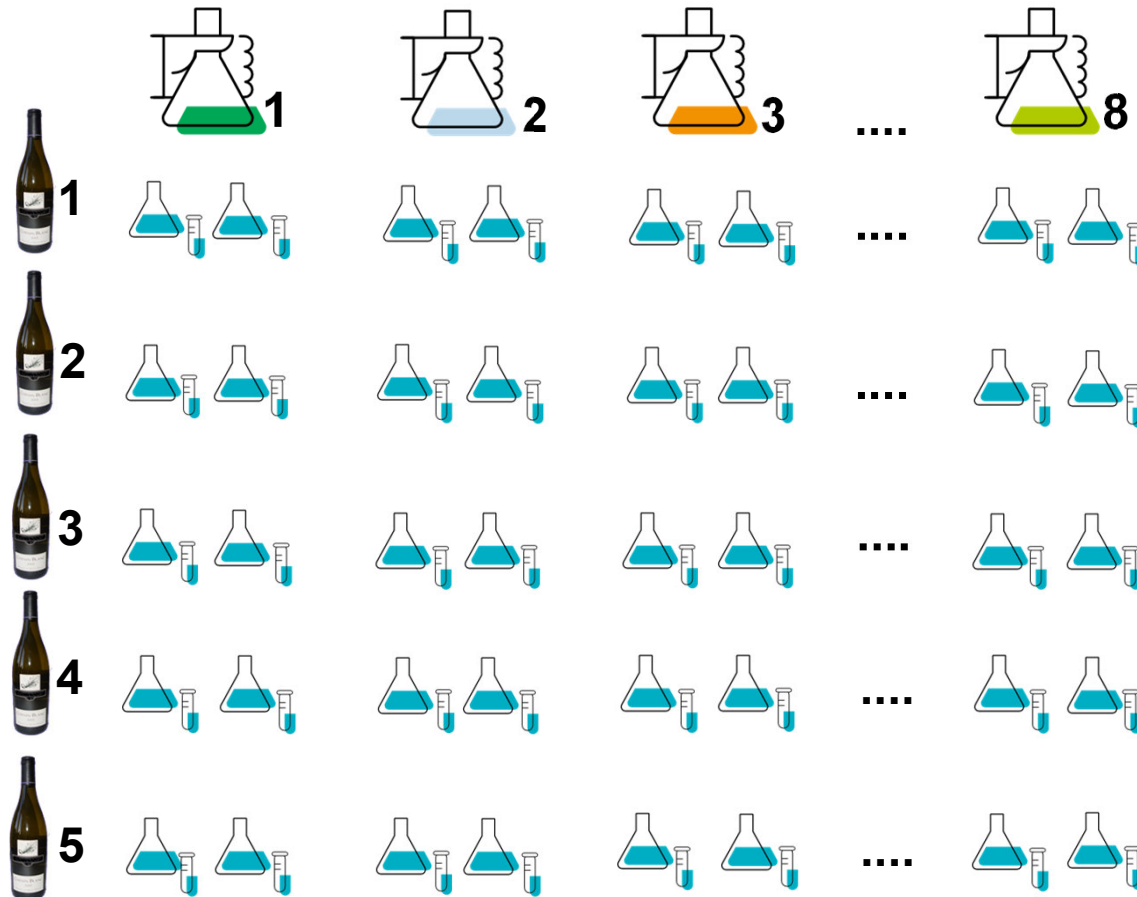
- Testing the precision under intra-lab conditions
- same method

Precision: Reproducibility of a method



- Testing the precision under reproducible conditions
- same method
- different laboratories
- preferably on international level rather than on national level

Typical Study Design (analytical chemistry)... ISO 5725 1 - 6



Standard Deviation of Repeatability S_r

Standard Deviation of Reproducibility S_R

Interlaboratory studies

Proficiency tests

- Estimate the accuracy of participating laboratories results
 - Proficiency of the laboratories
- ISO 17043
- ISO 13528

Method validation

- Estimate the accuracy of a measurement method
 - Fitness for Purpose of Analytical Methods
- ISO 5725 1 - 6

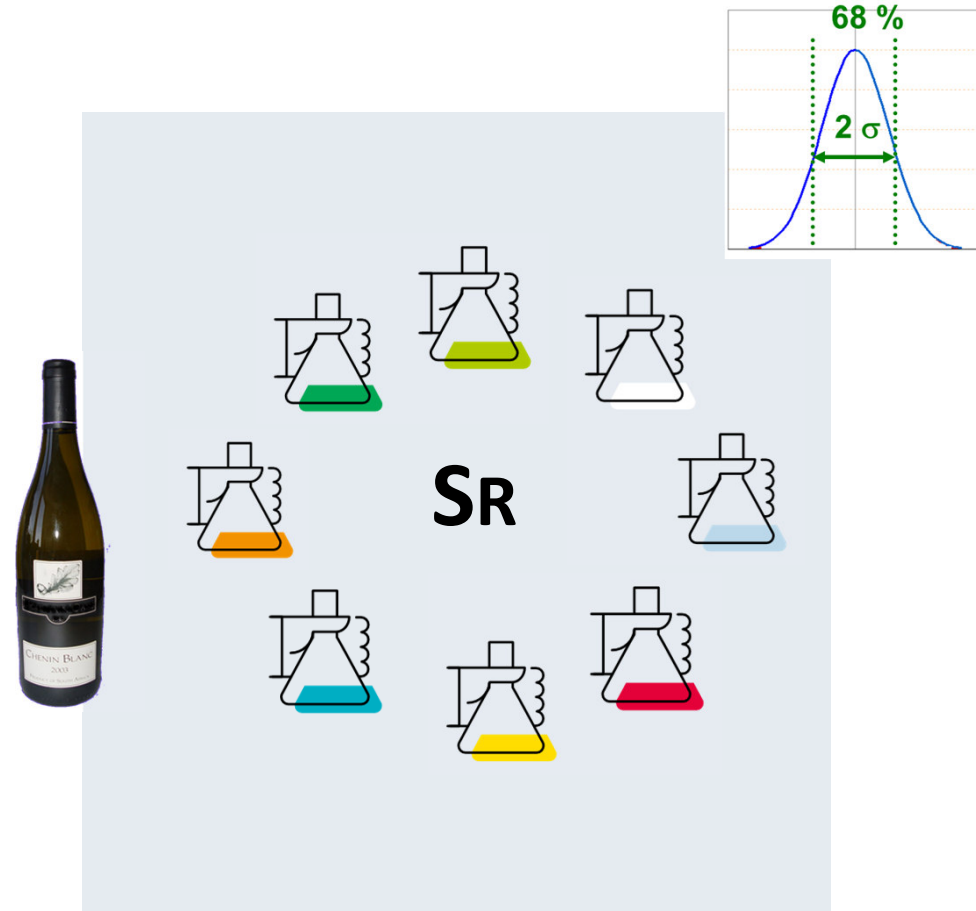
What is a interlaboratory method validation study?

Characterized validation parameters:

- Accuracy (trueness & precision)
- Precision (repeatability & reproducibility)
 - Selectivity / Specificity
 - Linearity & working range
 - Limit of Detection (LOD)
 - Limit of Quantification (LOQ)
 - Robustness

Reproducibility of a method

- Testing the precision under reproducible conditions
- same method
- different laboratories
- preferably on international level rather than on national level



Fitness for Purpose of Analytical Methods

How to decide if a method is fit for purpose?

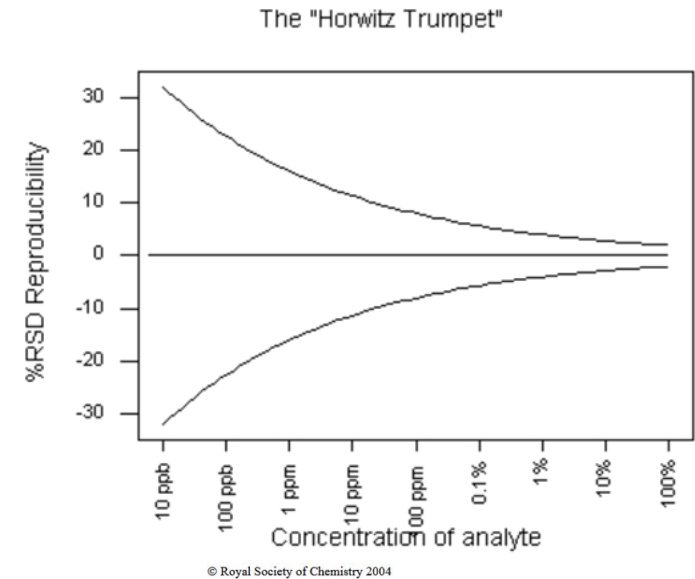
Calculate reproducibility standard deviation S_R
and relative reproducibility standard deviation RSD_R (%)
From data \rightarrow **Observed RSD_R (%)**

Calculate the concentration-dependent theoretical expected
relative reproducibility standard deviation

$PRSD_R$ (%)
(Horwitz function) \rightarrow

$$HorRat = \frac{\text{Observed } RSD_R(\%)}{\text{Predicted } PRSD_R(\%)}$$

HorRat: 0.5 - 2 \rightarrow Generally acceptable range for inter-laboratory studies



Advantages of a Interlaboratory Method Validation Study

- Proof of method reliability
- Assurance of correct measurement results
- Clear understanding of the method and methodological limitations
- Reduction of measurement errors
- Improved data quality
- Comparability of results
- Fulfilment of regulatory requirements (e.g. ISO, ICH, GMP)



R package ilab for ISO conform evaluation of interlaboratory studies

Developed and validated at Reference Centre for Food and Feed Analysis - BfR

Carsten Fauhl-Hassek
T +49 30 18412-75000
Carsten.fauhl-hassek@bfr.bund.de

German Federal Institute for Risk Assessment
bfr.bund.de/en











valid for texts produced by the BfR
images/photos/graphics are excluded unless otherwise indicated

BfR | Identifying Risks –
Protecting Health

Consumer health protection to go
BfR2GO – the BfR Science Magazine

bfr.bund.de/en/publications/bfr2go/

Follow us

-  [@bfrde](#) | [@bfren](#) | [@Bf3R_centre](#)
-  [@bfrde](#)
-  youtube.com/@bfr_bund
-  social.bund.de/@bfr
-  linkedin.com/company/bundesinstitut-f-r-risikobewertung
-  podcast.bfr.bund.de
-  threads.net/@bfrde
-  bsky.app/profile/bfrde.bsky.social