LGC Standards

Excellence through measurement

Determining the standard deviation for proficiency assessment (SDPA) in microbiology

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Topics

- Microbiological testing
- Methods for setting SDPA values
  - According to ISO 13528
  - In practice
- Impact of SDPA on performance assessment?
- Is microbiology any different?
- Discussion

What do we test?

Total counts or indicator organisms

Spoilage organisms

Pathogens

Challenges of testing…….

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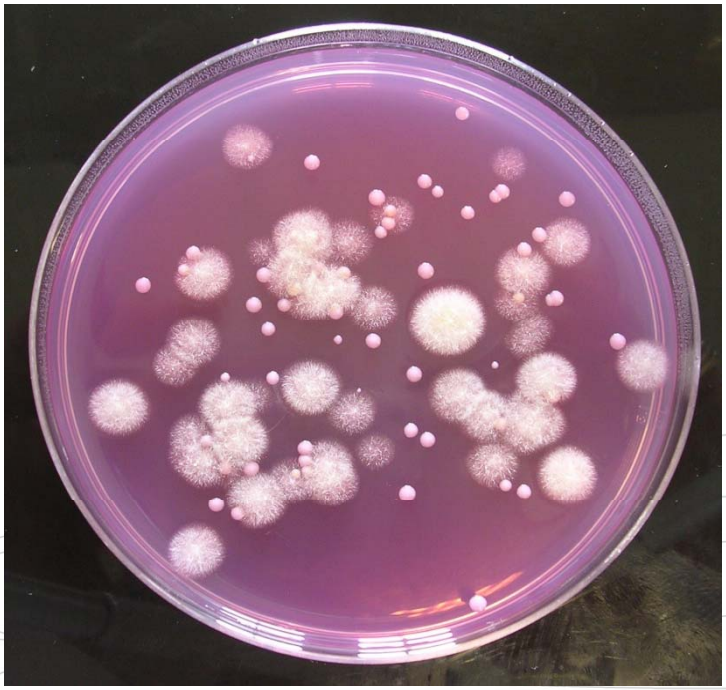
- Difficult, expensive and time-consuming
- Inaccurate
  - -How to count a billion
  - -Living organisms
  - -Colony-forming unit
  - -Identification & enumeration
- Method limitations
  - -Selective agar
  - -Only finds what looking for…?



More challenges of testing?

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- Usual causes of error & variation

-Sampling

-Analyst

-Matrix

-Media

-Equipment

-Environment

Reasons for testing?

- Validation of risk assessment & process control
- To meet requirements of legislation/regulation
- To show compliance with specifications
- Commercial reasons
- It's better than not testing….!

Microbiology PT

- Over 40 schemes listed on EPTIS
- Qualitative and quantitative schemes
- Mostly cover food, water and clinical microbiology
- Majority specific to bacteria, some virology
- Based on principles of ISO 17043 and ISO 13528
- Widespread use of z-scores

$$z\ score = \frac{(x - X)}{SDPA}$$

Acceptable variation in microbiology??

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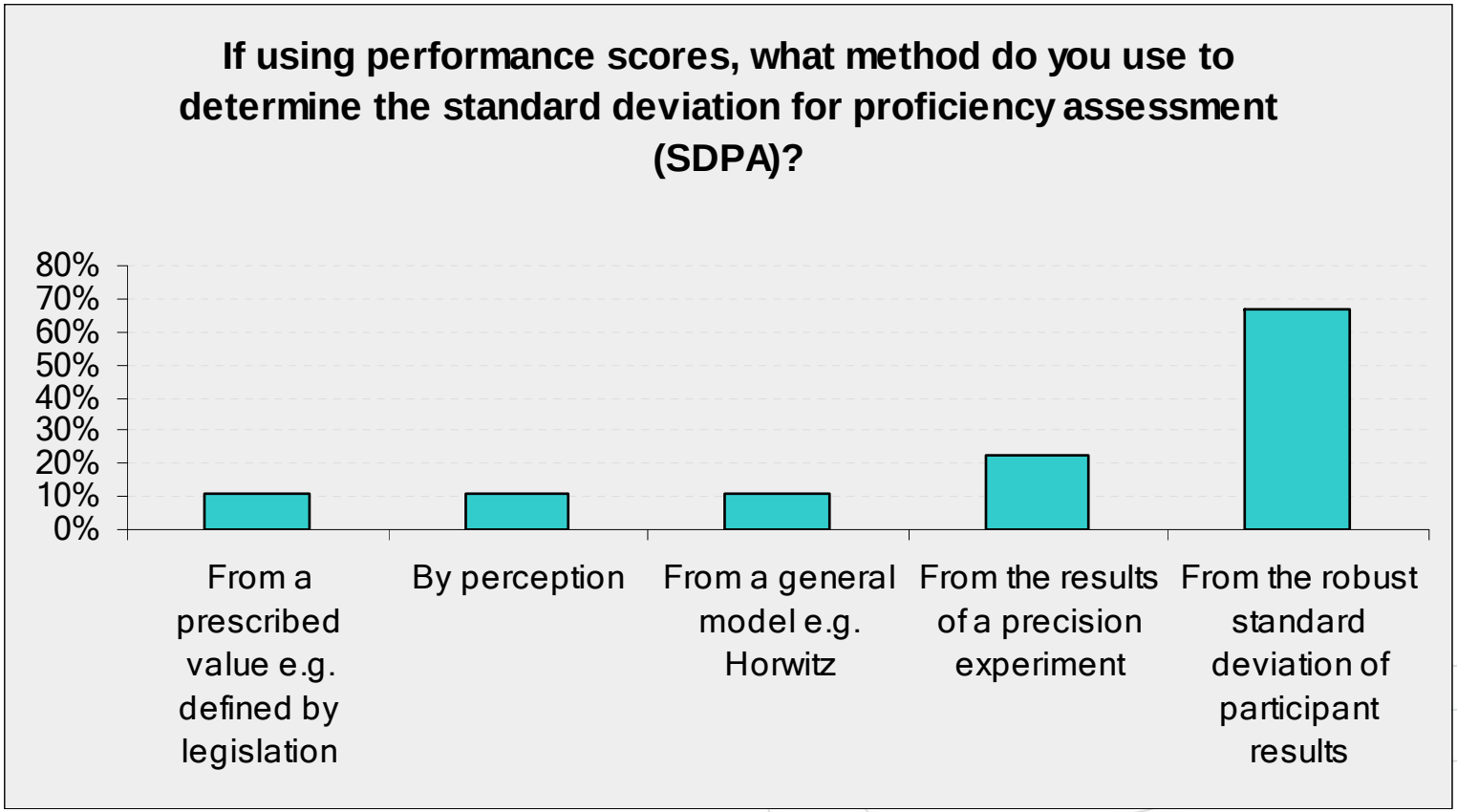
- ISO standard
  e.g. BS EN ISO 4833 (2003)
  For TVC at 30^0C, r = 0.25 $\log_{10}$, R = 0.45 $\log_{10}$
  Acceptable range for count of 100,000 $cfug^{-1}$ would be 36,000 to 280,000 $cfug^{-1}$

- Collaborative trials
  e.g. Jarvis et al (2007)
  Augustin and Carlier (2006)

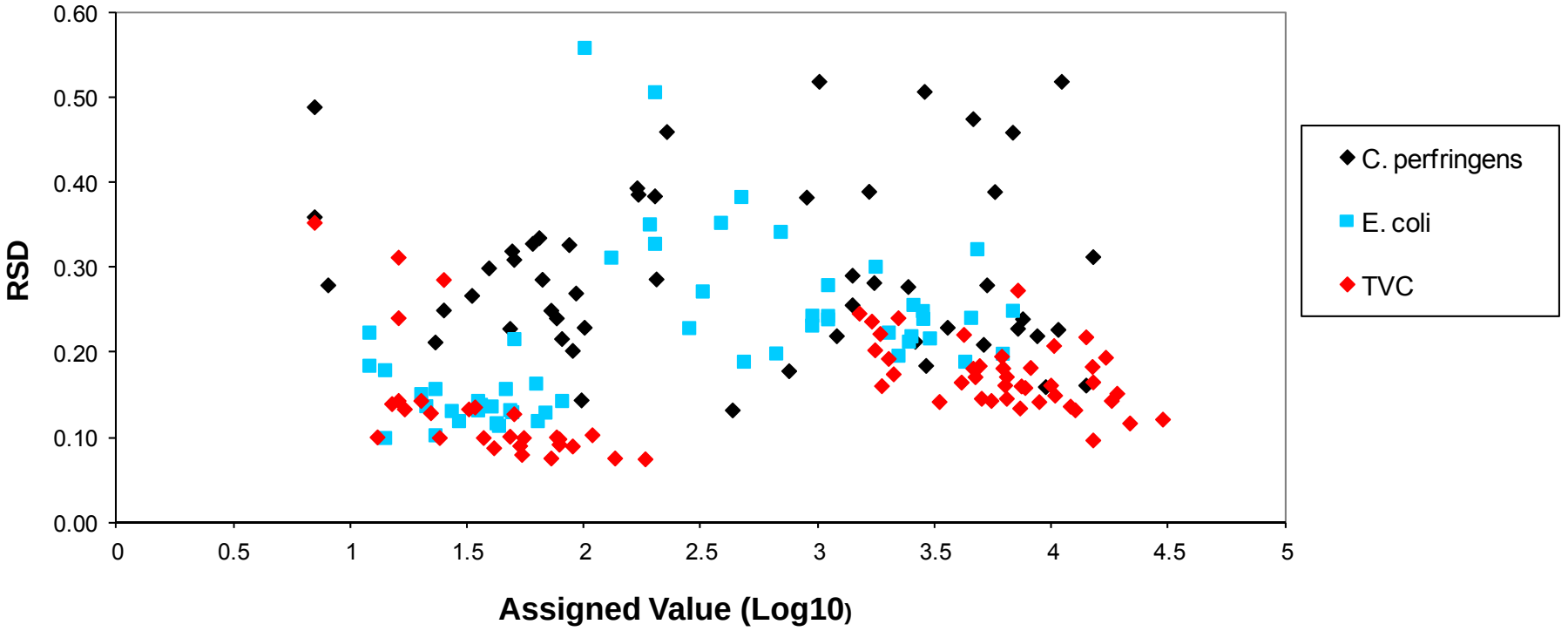
In some cases, reproducibility found to be as high as 82%
i.e. no significant difference between count of 10 to 10,000 cfu^{-1}

Determining the SDPA

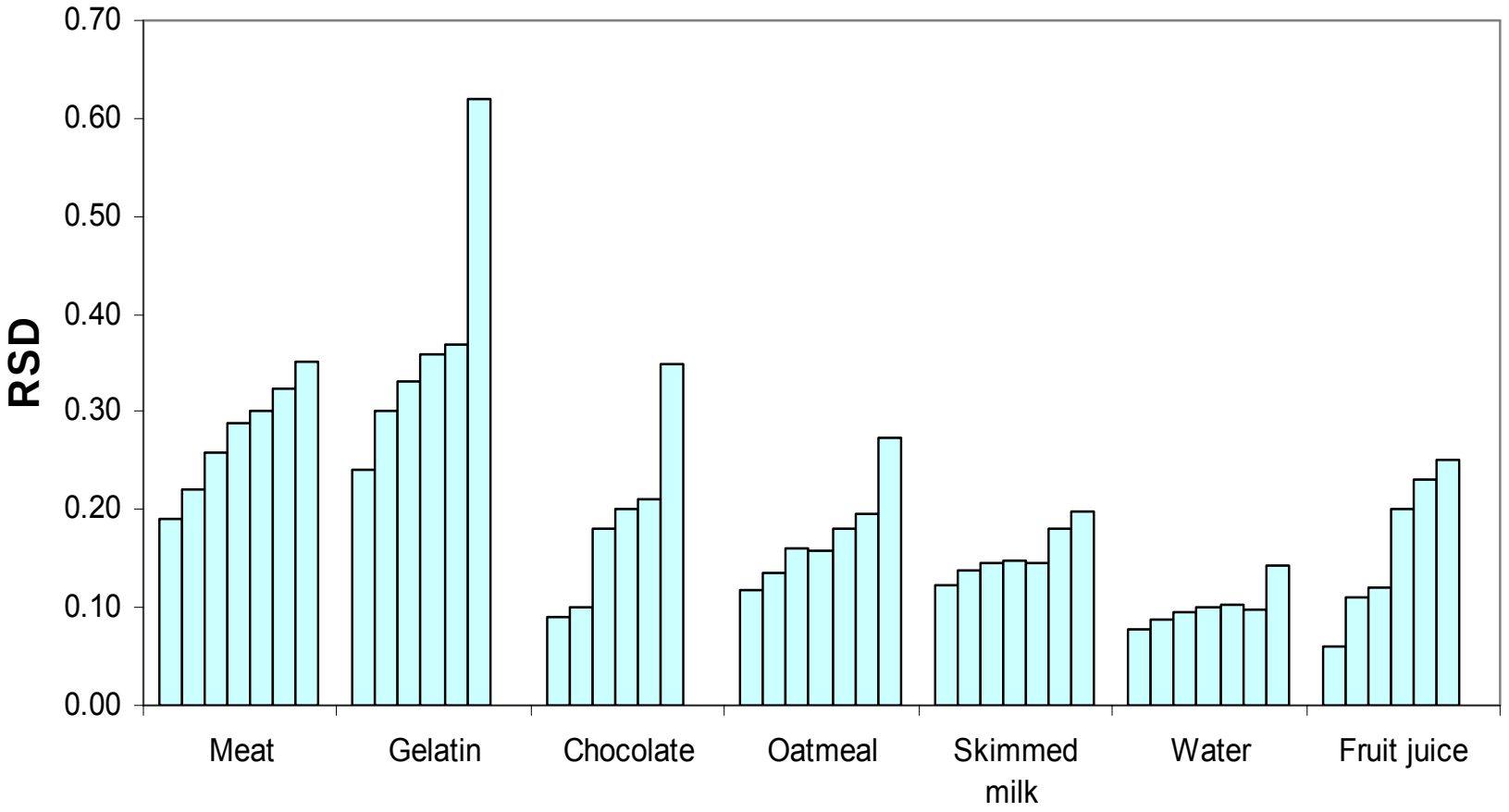


Robust SD by organism

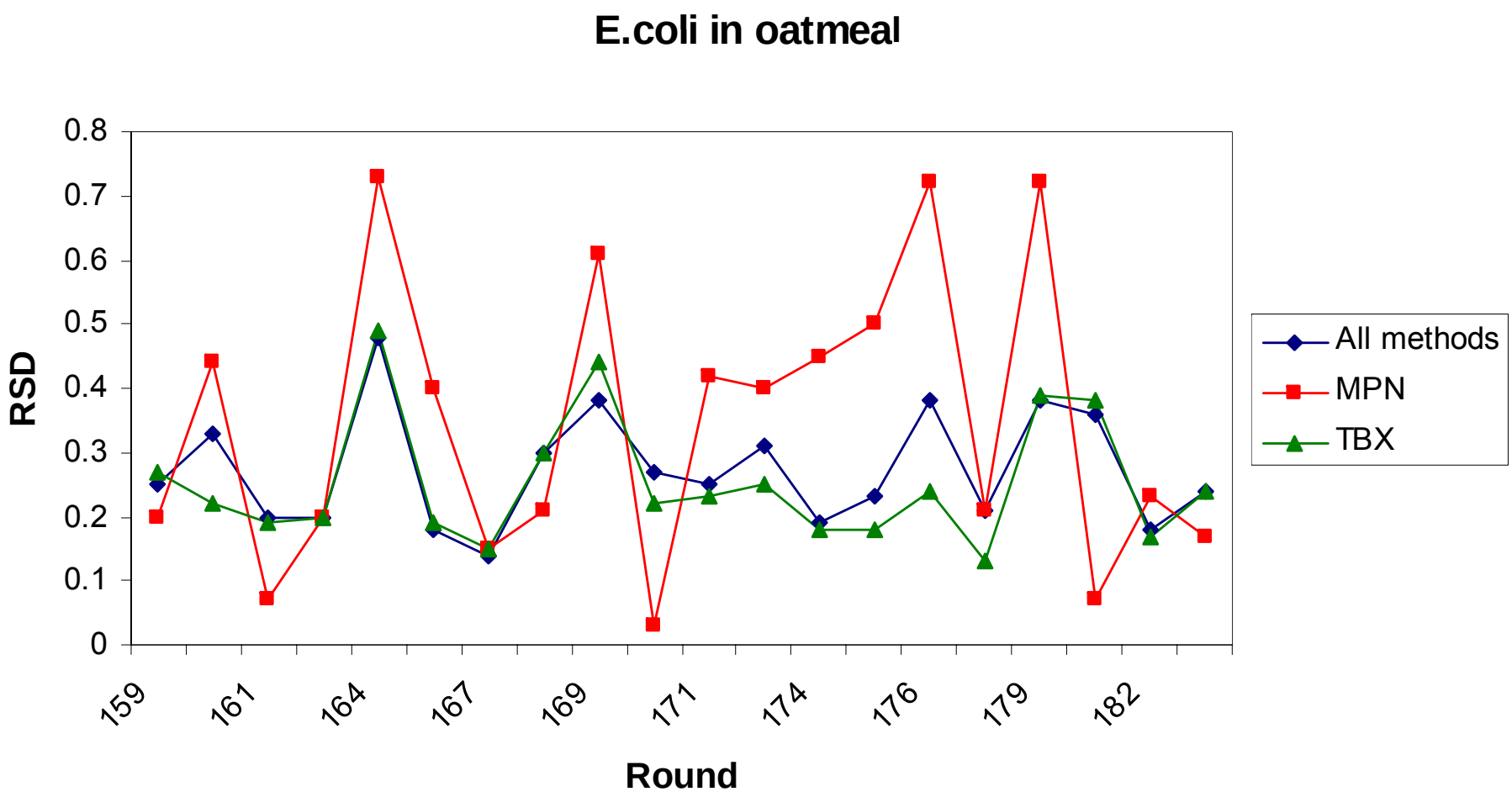
TVC 0.18
E.coli 0.28
C.Perfringens 0.32



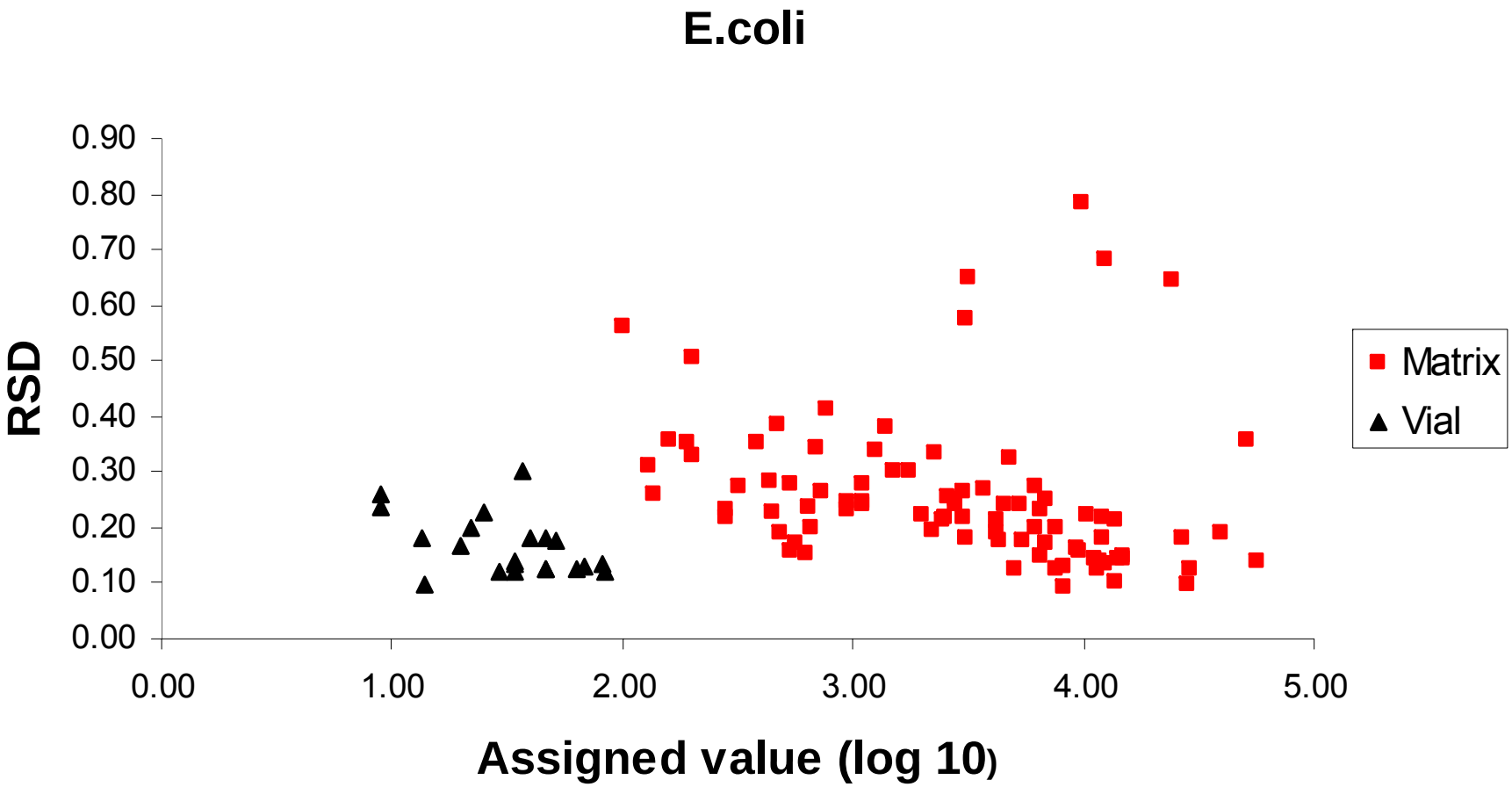
Robust SD by Matrix



Robust SD by Method

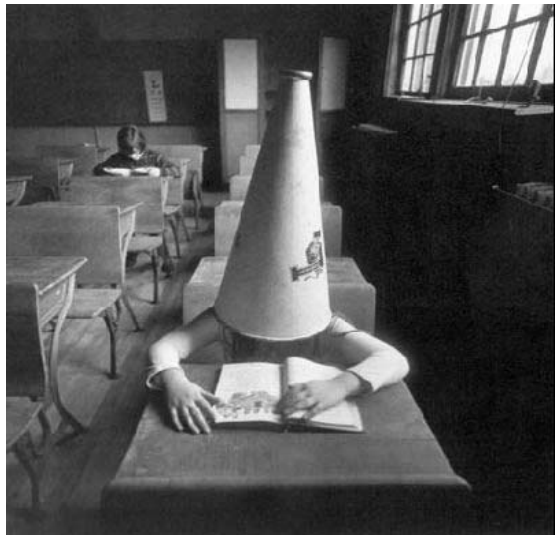


Robust SD by inoculum level



Fixed vs Variable SDPA

Score 90% to pass



Score 50% to pass

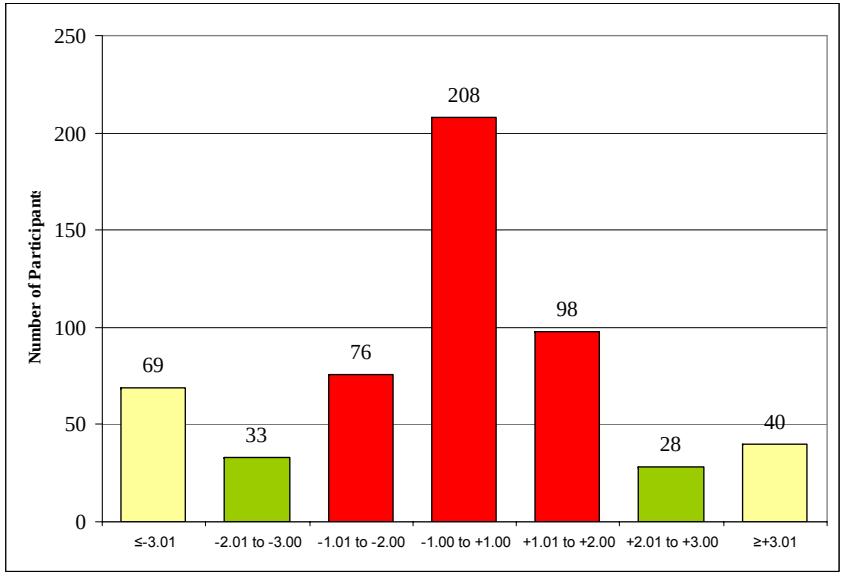
C/D

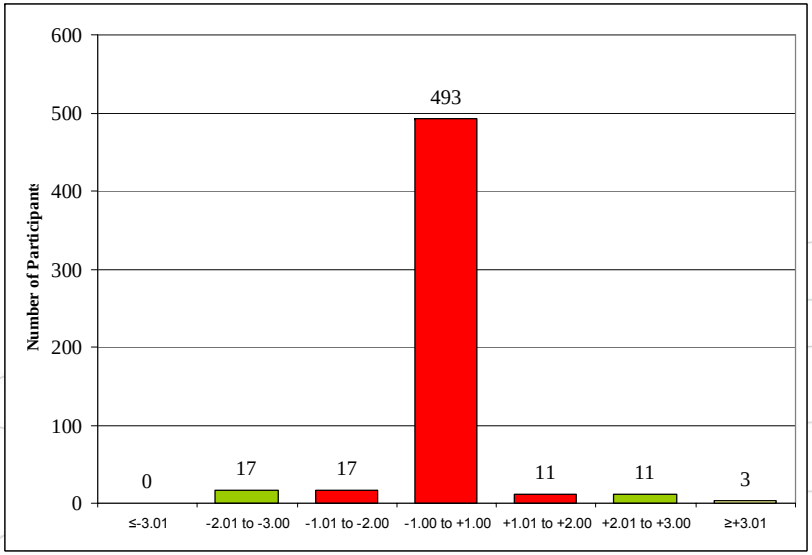
Score 65%

A

Using a fixed SDPA

SDPA	0.10	0.20	0.30	0.40	0.50
% Satisfactory	69	86	91	93	94
% Questionable	11	4	3	4	5
% Unsatisfactory	20	9	7	2	1
Satisfactory range	3849 to 9668	2428 to 15323	1532 to 24285	967 to 38488	610 to 61000





How accurate does the count need to be?

Satisfactory total count $<10^6$ $cfug^{-1}$

Is microbiology any different?

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- COEPT Project 2003 to 2005
- PT schemes for food, water, soil
- Showed large differences between SDPA for number of analytes e.g. protein in milk ranged from 0.09 to 0.85
- Harmonisation in some fields

Discussion

- Should SDPA be based on how precise we need to be, not how precise we can be…..
- Use Robust SD but with minimum and maximum limits
- Let participants define acceptable performance in relation to their own requirements……?
- More emphasis on performing the correct test, and identification and interpretation
- More emphasis on long-term performance over time