Biological Variation and Point-of-Care Testing

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Harmonization

- Laboratory results
- Within and between institution
- POCT and Lab method
A reliable measurement
Starts with a good meter
A reliable measurement and POCT

- A good meter
- Education of the performer
- Control of meter and performer
Guidance

• Companies
  ✓ CE/IVD directive
  ✓ ISO 15197

• Laboratories
  ✓ EA accreditation according to ISO 15189 and 22870
  ✓ EQAS
IVD directive

- Traceability to reference systems
- 80 category A analytes
- JCTLM defines reference methods and reference materials
Metrological Traceability of Laboratory Test Results
The Complete Traceability Chain

Fig. 1 Diagram adapted from EN ISO 17511

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October 4 2012
Allowable variation

• Reference method targets
• Variance limits based on biological variance
Biological variation
Biological variation

- CVw within-person variation
- CVb between-person variation
- CVa desirable analytical variation
  \[ CVa = 0.5 \times CVw \]
- B maximum allowable bias
  \[ B = 0.25 \sqrt{(CVw^2 + CVb^2)} \]
- TE total allowable error
  \[ TE = 1.65 \times CVa + B \]
Biological variation glucose

CVw  5,8%
CVd  2,9%
Bias  2,2%
TEa  6,9%
Mean glucose 9,0 mmol/L

- Biological variation (5.8%): 8,0 – 10,0
- Lab TE 2.5% added: 7,8 – 10,3
- TEa 7% added: 7,2 – 10,8
- Present ISO 20%: 6,1 – 11,9
- Future ISO 15%? 6,6 – 11,4
ISO meter glucose

First measurement 8.4 mmol/L
Second measurement 7.2 mmol/L

Decrease? Adjust insuline?
ISO meter glucose

First measurement 7.2 mmol/L
Second measurement 8.4 mmol/L

Increase? Adjust insuline?
Future ISO meter
15%

First (true 7.0):  5.2 – 8.8
Second (true 9.0):  6.6 – 11.4

Decrease? Increase? Insuline?
increase or decrease?

5.6 = 8.4 (7)
7.2 = 10.8 (9)
SKML Quality

- Traceability
- ISO 15197
- Test using biological variation concept
- Tests on interfering substances
A reliable measurement and POCT

- A good meter
- Education of the performer
- Control of meter and performer
Multidisciplinary standardized courses

- Professionals
- Industry
- Nurses
Better a good neighbor than a distant friend

-Dutch proverb
Figure 1—The deviation in glucose concentrations of the first (A) and second (B) drops of blood when the patient had not washed the hands vs. control measurement. (A high-quality color representation of this figure is available in the online issue.)
A reliable measurement and POCT

• A good meter
• Education of the performer
• Control of meter and performer
POCT meter control

- ISO 15189 and 22870 accredited laboratory
- Obligatory course and CPD of performers
- Regular test of meter against lab method
- Lab method tested using Category 1 EQA
Category 1 EQA

• Commutable samples
• Reference method target values
• Biological variation based tolerance limits
Glucose

![Graph showing glucose levels and deviations from normal.](image-url)
Harmonization?

Four Evangelists
Jordaens 1625, Louvre
Gospel Harmony

- Diatesseron
- Tatian, 2nd century
Harmony in music
Harmonization

The good message, the good music for POCT and clinical laboratory results
Harmonization for the safety of patients
Harmonization in Europe