Method comparison for evaluating new (improved) CD4 and viral load assays for laboratory service

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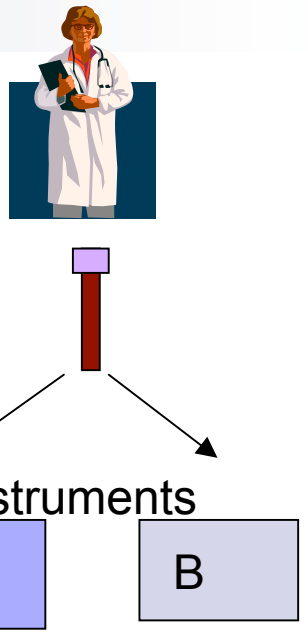
Why perform evaluations?

- **Justify** or **confirm** before routine implementation (result reporting)
- Sensitivity and specificity in local population (VL subtype sequence).
- Performance (reported result: copies/ml, IU/ml, pg/ml, ranges, %CD4 of lymphocytes, single/dual platform).
- Laboratory infrastructure requirements (high/low throughput, footprint, skill/training).
- GCLP (good clinical laboratory practise)
- Applies to equipment, assay, reagent and even sample collection/handling.

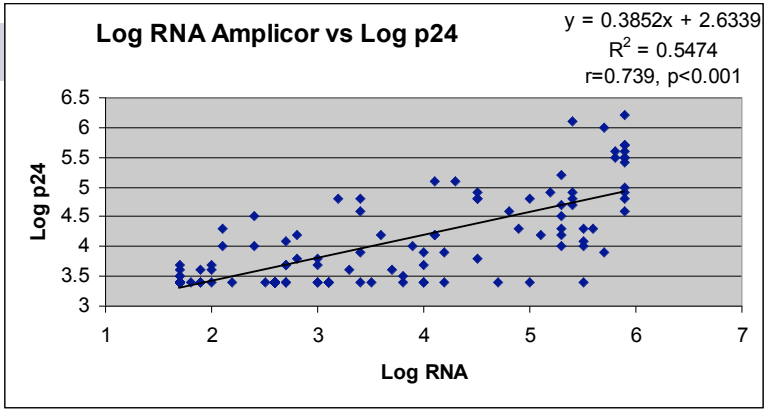
A typical approach to evaluation

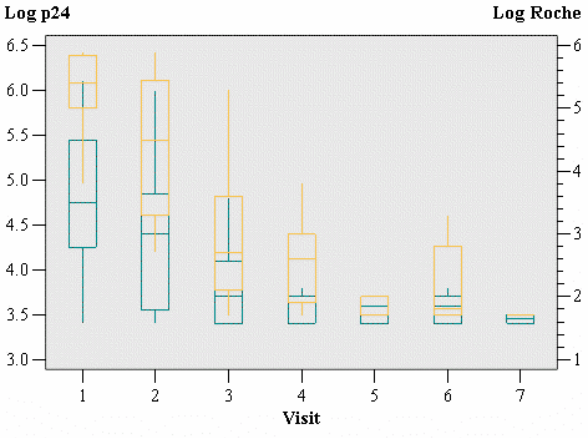


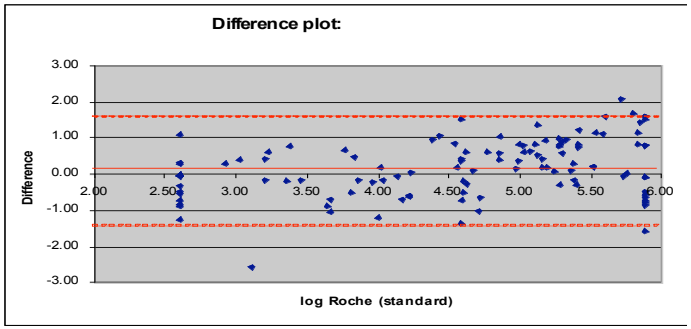
- **Phase I** (background and set up)
  - Select appropriate comparative technology (Gold standard, more than one assay, more than one site, use automation)
- **Phase II (**Design and analysis)
  - Sample size: A balance of cost, risk of taking too few samples to measure lack of agreement.
  - Include reference material and controls
  - Statistical analysis (continuous data – can convert into discrete/bin approach): intra/inter variability=background variability)

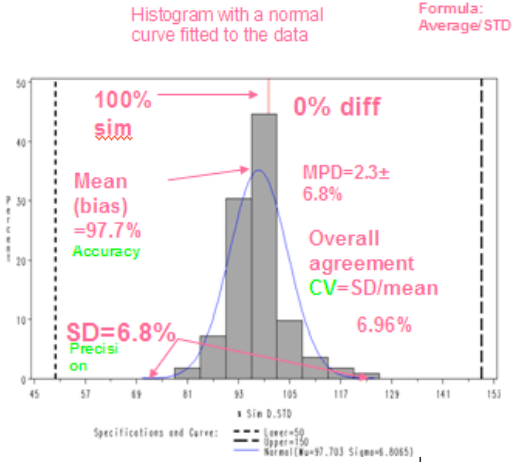
A protocol for method comparison

- **Describe** and **summarize** the data
- **Visualize** the data
- **Choose** the correct **model** for method comparison

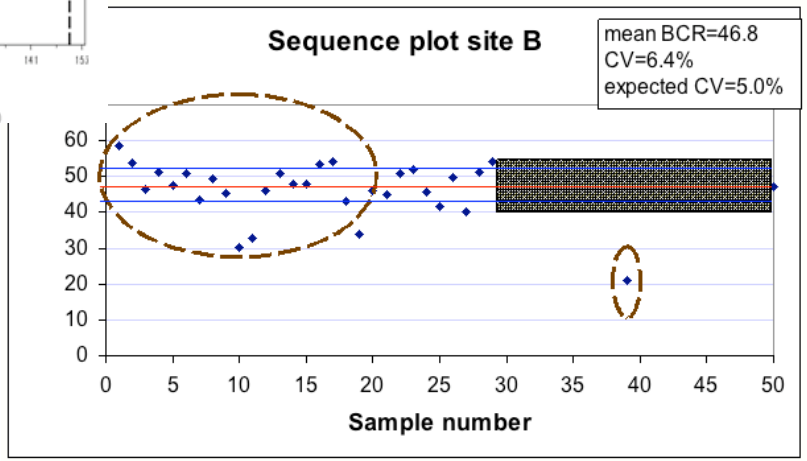








- Analyze the data in **sequence** of sample preparation



- **Phase III (Reporting)**
  - Validation report
  - Good documentation
  - Store everything!!!
  - Take action if deviations

- **Phase IV (Follow-up)**
  - Handle change control
  - Participate in EQA/proficiency testing

Clinically acceptable differences

- **CD4:**
  - ~20cells/ul @ 200cells/ul (NB: data range)
- **Viral load**:
  - 0.3 log copies/ml for intra-variability
  - 0.5 log copies/ml for inter-variability
  - 1.0 log copies/ml = clinical difference/patient mismanagement

Experiences

- CD4:
  - TetraCHROME (Beckman Coulter)
  - Pan*Leuco*gated CD4 (Beckman Coulter)
  - Flow Count (Beckman Coulter)
  - Easy CD4 (Guava Technologies)
  - FACSCount (Becton Dickinson)
  - PointCare/AuRICA (PointCare Technologies)
- Viral load
  - COBAS (Roche) (Ampliprep/Amplicor)
  - TaqMan (Roche)
  - EasyQ (bioMerieux) (miniMAG/easyMAG)
  - LUX assay (WITS, in house)
  - P24 (Perkin Elmer)
  - RT (Cavidi)

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Soon to launch methodcomparison.com