Data treatment

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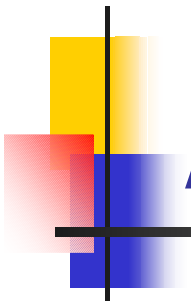
Controls

- 5 control samples:
  - CAL: Serum pool, target values for most components established by reference methods
  - X: Serum pool from men
  - P: Serum pool from women using contraceptive pills
  - HIGH: Serum pool concentrated by freezing
  - LOW: HIGH diluted 1:2 with calcium/sodium-solution

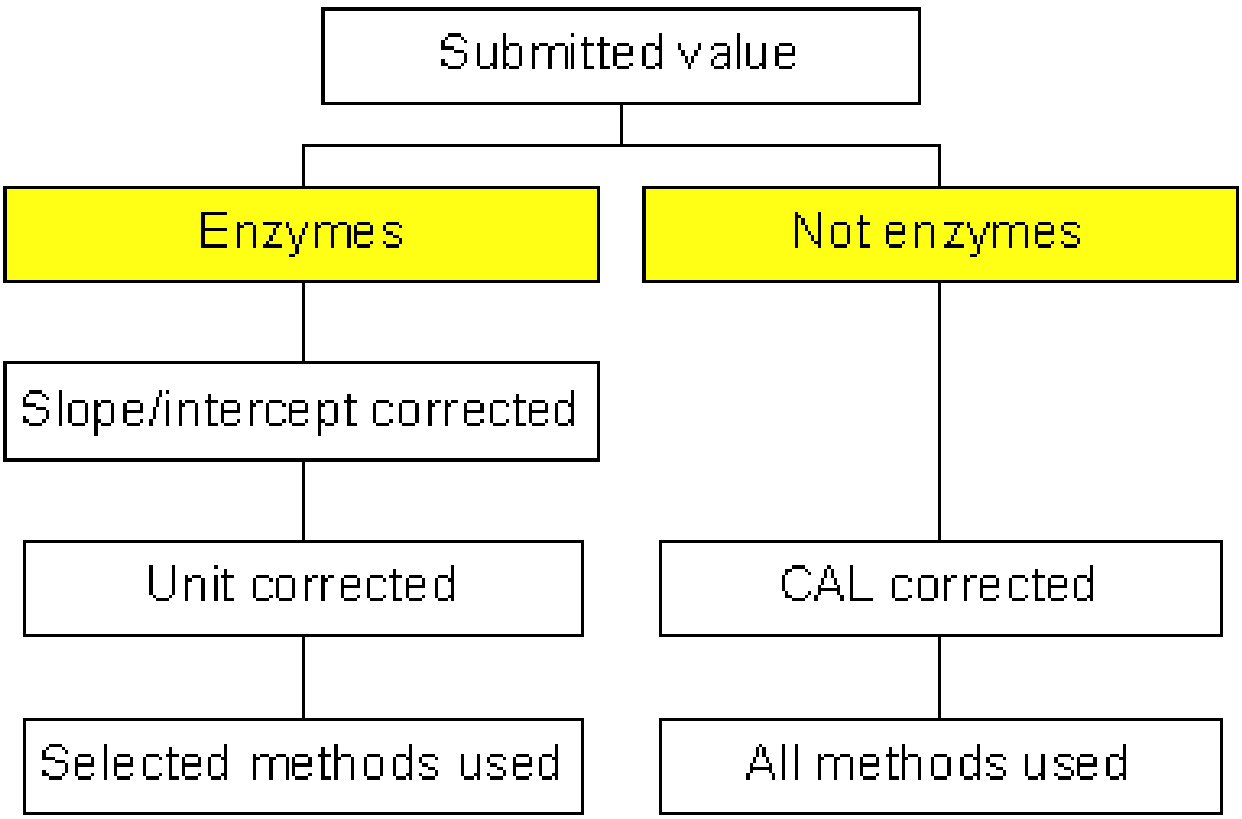


Analysis

Person samples measured together with control samples is defined as one series.

- At least one series should consist of:
  - 10 CAL
  - 3 each of X, P, HIGH, LOW
- other series by:
  - 10 X

Selection/calculation
of reference values



Calculation
except enzymes

- For all components (except enzymes) CAL is the reference standard (calibrator), i.e. all results (with CAL in series) are multiplied by the factor:

  $CAL_{target}/CAL_{mean\ of\ this\ series}$

- Factor for series with only X:

  $X_{target}/X_{mean\ of\ this\ series}$

  where

  $X_{target}=CAL_{target}*median(X_{mean}/CAL_{mean})$
- Results: Creat, etc

Calculation
enzymes

- R - result from lab
- r - result from instrument
- S, I - slope, intercept used by lab as correction parameters according to formula:

  $R = S \bullet r + I$ or $r = (R-I)/S$

  r is converted to common unit (U/L)

Error handling

- Laboratory asked to check registered data by printing report from registration program before submitting data!
- Report
- Person analytical data

  comparison of different materials for same person and component
- Control data

Exclusion of data

- According table with person analytical data, these are the concepts of exclusion:
  - Person (Peter Feldings)
  - Enzymes (Heidi Steenslands)
  - Controls
  - Material (comparison of results from fresh and thawed serum and plasma for same person)
  - Gross errors (missing decimal point, etc)
  - Duplicate

Exclusion of data
Controls

- Quality goals for precision NOT evaluated
- Quality goals for systematic error (bias):
  - optimum: $B < 1/8 \bullet s_B + k \bullet s_A$
  - desirable: $B < 1/4 \bullet s_B + k \bullet s_A$
  - minimum: $B < 3/8 \bullet s_B + k \bullet s_A$

  where

  s_B - interindividual biological variation

  s_A - analytical variation

  k - factor dependent on number of measurements and confidence level

Exclusion of data Controls

- Quotients tested for bias:
  - X/CAL, P/CAL, HIGH/LOW
- Quality goals

  expressed with reference limits (H, L) and log transformed distributions according to

  $CV_B = [\ln(H)-\ln(L)]/4$

  and measurement uncertainty for the quotients, gives the following quality criteria:

  - Optimum

    $B < 1/32 \cdot (\ln H-\ln L) + 2 \cdot (1/i + 1/j)^{1/2} \cdot CV_{CAL}$

  - Desirable

    $B < 2/32 \cdot (\ln H-\ln L) + 2 \cdot (1/i + 1/j)^{1/2} \cdot CV_{CAL}$

  - Minimum

    $B < 3/32 \cdot (\ln H-\ln L) + 2 \cdot (1/i + 1/j)^{1/2} \cdot CV_{CAL}$

Exclusion of data Controls

- Result
  - No of exclusions
  - Effect on calculated reference limit
- Conclusion
  - Exclusion only used for sodium

Exclusion of data
Same person, different materials

- Absolute difference > 1.5 CVb and at least one outside reference limit
- No excluded: 1053 (0.8%)

Exclusion of data Gross errors

- Many such errors corrected by report
- Rest (2-3) deleted

Exclusion of data Summary

- No of results: 126213
- No of results excluded
  - Person 1159 0.9%
  - Enzymes 15939 12.6%
  - Controls 2367 1.9%
  - Material 1053 0.8%
  - Gross errors 2 0.0%
  - Duplicate 1710 1.4%
- Not excluded: 104959

What have we NOT done?

- Frozen plasma
- Multivariate ref.intervals
- Influence of
  - all person parameters
  - sample tubes
  - geography