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6.1.2.5 Analytical Goals for P–Bilirubins

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ABSTRACT

Analytical goals for P-Bilirubins(total) were assessed on the basis of biological variation and "medical needs". Goals for analytical accuracy were from 0.01 to 0.18 expressed as relative deviations. Goals for analytical precision were 0.11-0.12 expressed as relative standard deviations. Using a reference method, we found that the average values of clinical laboratories deviated from 0.03 to 0.10 from reference method values. The average intra-laboratory precision was 0.088, i.e. within the goal limits.

INTRODUCTION

Analytical goals for P-Bilirubins(total) in the context of diagnosis of liver disease are considered. The applied models correspond to those used for P-Creatinine (1).

ANALYTICAL GOALS FOR ACCURACY

Using the model based on "medical needs", we derive the goal as outlined in Figure 1. The value for a clinically important change or deviation, Δ_{MED} , has been obtained from Skendzel et al. (2). Using the state of art analytical precision of 0.088 in Denmark and the intra-individual biological variation of 0.23, the maximum allowable inaccuracy (ΔSE_c) is computed to 0.018 (relative value).

This accuracy goal may be compared with the goal:

$$2\ CV_a = 0.18$$

as suggested by Stamm (3), and

$$0.20$$

which has been used in proficiency test programs (4).

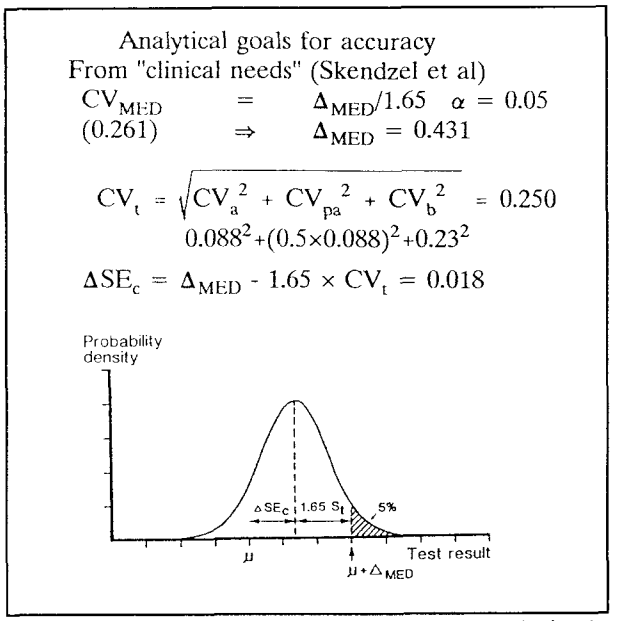

Figure 1. Analytical goals for accuracy derived from "medical needs".

ANALYTICAL GOALS FOR PRECISION

The traditional goal based on intra-individual biological variation is 0.12 as shown in Figure 2. The goal derived from "medical needs" has about the same value, 0.11.

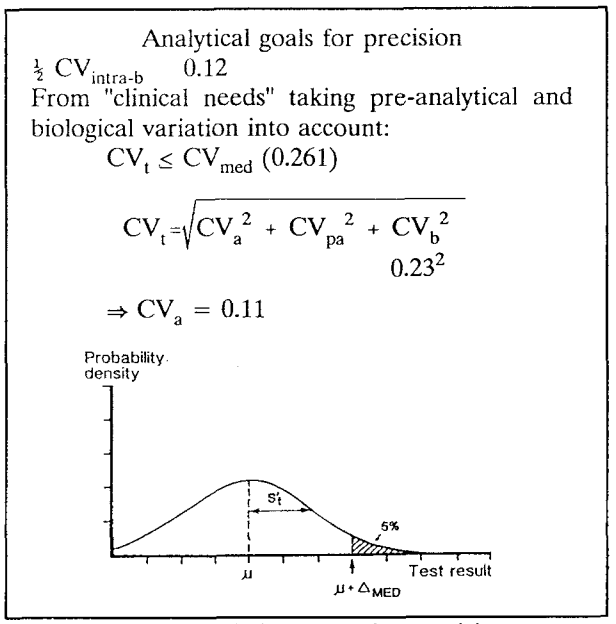

Figure 2. Analytical goals for precision.

ANALYTICAL QUALITY FOR P–BILIRUBINS EVALUATED

In order to evaluate the current analytical quality for P-Bilirubins(total) in Denmark the reference method described by Doumas BT et al. (5) was established. Table 1 displays the relation between reference method values and averages of about 50 clinical laboratories, which each has performed 3 determinations of the human, liquid sera distributed by the Danish Society for Clinical Chemistry. The relative deviations between reference method values and averages of clinical laboratories range from +0.03 to +0.10. The average intra-laboratory coefficients of variations extend from 0.05 to 0.13.

Table 1. Relation between reference method values and values obtained by clinical laboratories in Denmark for human, liquid serum pools.

Ref.method (μmol/l)	Average of routine methods (N = 160) (μmol/l)	Rel. DEV.	Average $CV_{intra\text{-}lab}$
9.7	10.0	+0.03	0.13
67.5	72.0	+0.07	0.05
33.0	36.4	+0.10	0.06

The conclusion of the evaluation is that accuracy goals are fulfilled according to the limits suggested by Stamm and according to proficiency test limits. Precision goals are fulfilled at elevated serum levels but not at the physiological level. Concerning the question of P-Bilirubin (unconj.) used in the diagnosis of neonatal icterus, the relations are somewhat difficult to evaluate because of lack of data.

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