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External Quality Assurance Model for Improvement of Specificity and Assuracy of Serum Hormone Determinations in the Nordic Countries

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Previous external quality assurance projects of hormone determinations in the Nordic countries and other areas have shown the wide scatter of results without essential improvement during many years. Reasons for the wide scatter like wrong calibration, unspecific reactions and various factors causing imprecision have been mainly characterized but until now very little has been done to eliminate them. In this project we try to reduce their influence. The purpose of this project is to:

- set up a new quality assurance model for improvement of specificity and accuracy of hormone determinations in the Nordic countries
- to test the model for serum thyrotropin (TSH), free thyroxine (FT_4) thyroxine (T_4), triiodothyromine (T_3) and cortisol (C) determinations
- to define practical goals of accuracy and specificity for these hormone determinations
- to maintain the quality, if acceptable accuracy and specificity are reached by the quality assurance model.

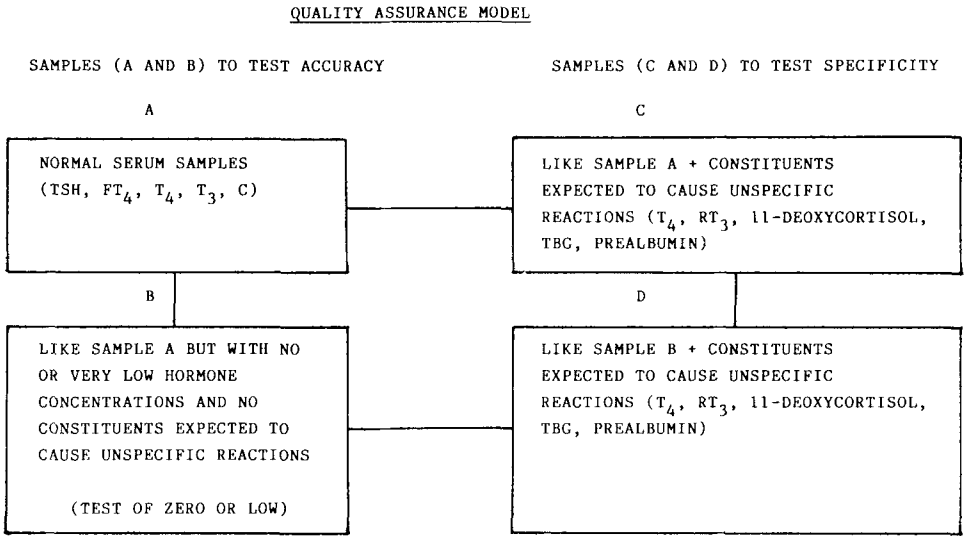
Control material (quality assurance samples and the calibrator) is frozen human serum and its T_4 and C concentrations have been determined by GC-MS. Quality assurance samples are used to evaluate specificity and calibration bias (at three concentration levels) of the analytical method of each laboratory. If needed, the calibrator is used for recalibration.

There are four kinds of quality assurance samples (Fig 1). One of the controls is a normal serum pool (A) with known concentrations of hormones, another is the same pool (B) with no or very low hormone concentrations, the third pool (C) is the same

as pool A, but it also contains constituents expected to cause nonspecific reactions. Samples A and B are used to test accuracy and samples C and D to test specificity.

In result reports quality goals have been defined and comments are given on reproducibility, linearity, specificity and bias of the methods of each laboratory. This project is carried out after the protein project.

Fig 1.



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