

Will standardization assist best practice in thyroid function testing?

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Assays for thyroid function tests (TFT) have been used in the clinical chemistry laboratory for thirty years but external quality assurance schemes reveal that there is still considerable variability in results from different methods. This variability creates difficulty in the transferability of patient data and has caused patient interest groups to question the value and effectiveness of TFT.

Recent international evidence-based guidelines have been prepared to promote best practice and harmonization of the use of TFT. However, the application of such guidelines for TFT is challenged by method dependent differences in results.

The IFCC Working Group on the standardization of thyroid hormones (WG-STFT) has been established to develop new reference materials and reference measurement systems for thyroid hormones and to investigate the use of synthetic or recombinant materials for mass calibration of thyroid stimulating hormone (TSH). With expert direction from Professor Linda Thienpont (University of Gent, Belgium) WG-STFT has overseen the following achievements:

- International clinical thyroid association members have made the clinical case for greater harmonization of TFT results.
- Reference materials and reference measurement procedures have been published to assist the standardization of total thyroxine (TT4) and total tri-iodothyronine (TT3).
- A reference measurement system for free thyroxine (FT4) has been adopted based on equilibrium dialysis and isotope dilution liquid chromatography / tandem mass spectrometry. Forty donor were selected with FT4 results across the normal range and these have had FT4 measured using the reference measurement procedure. Nine IVD manufacturers and two mass spectrometry laboratories also measured FT4 in these specimens. The results confirmed the anticipated between method differences in results but for the first time these could be compared with the results from the reference measurement procedure. Discussion with IVD manufacturers has commenced and it is hoped that this will lead to greater harmonization of FT4 results in the future.
- TSH is a complex, heterogeneous glycoprotein and standardization presents challenges. Measurement of TSH in the forty specimens used for the FT4 project has confirmed the method dependent differences. WG-STFT is currently discussing whether to undertake a primary standardization project and/or development of a reference method procedure.