

## Monitoring the stability of the standardization status of FT4 and TSH assays by use of daily outpatient medians and flagging frequencies.

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#### Abstract

Clinicians diagnose thyroid dysfunction based on TSH and FT4 testing. However, the current lack of comparability between assays limits the optimal use of laboratory data. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) gave a mandate to the Committee for Standardization of Thyroid Function Tests (C-STFT) to resolve this limitation by standardization. Recently, the Committee members and their partners felt ready to set the step towards the technical recalibration. However, before implementation, they were furthered by the Food and Drugs Administration (FDA) to develop a tool to assess the sustainability of the new calibration basis. C-STFT began to use 2 online applications, i.e., the "Percentiler" and "Flagger", with the intention to assess their utility for this purpose. The tools monitor the course of instrument-specific moving medians of outpatient results (Percentiler) and flagging rates (Flagger) from data of individual laboratories grouped by instrument/assay peer. They additionally document the mid- to long-term medians, hence, are quality indicators of stability of performance of both laboratories and peers/assays. Here, the first experiences built up in the pre-standardization phase are reported. They suggest the suitability of both applications to document the sustainability of the calibration basis in the post-standardization phase.

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**KEYWORDS:** Committee for Standardization of Thyroid Function Tests; International Federation of Clinical Chemistry and Laboratory Medicine; Median; Outpatient; Population variation; Quality indicator

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