Concerns about the accuracy and reliability of thyroid function tests, especially free thyroxine (FT4), have been stated by the clinical laboratory community for many years. Thyroid function tests are the most used tests in the U.S. and are the only means to detect and treat diseases of the thyroid. The consequences of inadequate thyroid hormone levels can be severe and are easily preventable and treatable with early detection. In response to these concerns, the CDC CSP has partnered with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and created a standardization program for FT4 based on the IFCC reference system. The CDC program aims to improve the accuracy, reliability, and comparability of current methods and, thus, improve the diagnosis, treatment, and prevention of thyroidal illnesses. There were no commutable, certified serum-based FT4 reference materials (RMs) available to assess the accuracy and reliability of FT4 assays. CDC has developed an accurate and sensitive reference measurement procedure (RMP) to assign reference values to individual donor sera. Assay manufacturers and research and clinical laboratories can use these sera to assess the analytical performance of their
measurements, and monitor performance over time. In addition, the CDC’s FT4 RMP is used to assign reference values to materials used in EQA/PT programs to verify that standardization efforts at the developer level translate to the end-user level. The CDC FT4 RMP uses equilibrium dialysis (ED), based on an internationally recognized ED procedure, followed by solid-phase and solvent extractions before analysis by LC-MS/MS. Certified primary RM IRMM468 is used as calibrators. The intra- and inter-day imprecision of the CDC RMP are 3.0% and 1.1%, respectively. The CDC RMP measurement range is 3.02–258 pmol/L, which is suitable for analysis of hypo- and hyperthyroid patients. Based on an IFCC comparison study between four FT4 RMPs, the CDC RMP’s bias was within 2.5% of the all-labs mean. CDC CSP is currently conducting a comparison to further define the differences among various types of commercially available FT4 assays. A set of 40 serum RMs value assigned with the FT4 RMP are now available via the Phase 1 of the Hormone Standardization (HoSt) Program. These materials can be used for calibration and verification by assay developers. CDC CSP is currently working to develop a Phase 2 of the HoSt Program for FT4 to assist developers with certification of FT4 assays. Based on the needs and requests from the clinical community, programs for new biomarkers, such as thyroid-stimulating hormone, are also being developed.

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