

FREE THYROXINE

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REFERENCE: Centaur Assay Manual Protocol 111624 Rev. C, 9/98 Chiron Diagnostics.

PRINCIPLE:

The FT4 assay is a competitive immunoassay. FT4 in the sample competes with acridinium ester-labeled T4 for a limited amount of polyclonal rabbit anti-T4 antibody, which is covalently coupled to paramagnetic particles. An indirect relationship exists between the FT4 in a sample and the relative light units detected by the ACS: Centaur.

CLINICAL SIGNIFICANCE:

Thyroxine is a hormone synthesized and secreted by the thyroid gland and it plays an important role in regulating metabolism. Secretion into the circulation is in response to the pituitary hormone TSH and is regulated by a negative feedback mechanism involving the thyroid gland, pituitary gland, and hypothalamus.

In the circulation, 99.95% of T4 is reversibly bound to transport proteins, primarily thyroid-binding globulin (TBG) and to a lesser extent albumin and thyroid-binding pre-albumin (TBPA). The remaining T4 is not bound to transport proteins, but is free in the circulation. This unbound fraction, or free T4 (FT4), is both metabolically active and a precursor to triiodothyronine (T3).

Free T4 levels correlate with T4 secretion and metabolism. In hypo- and hyperthyroidism, FT4 levels parallel changes in total T4 levels. Measuring FT4 is useful when altered levels of total T4 occur due to changes in T4 binding proteins, especially TBG. TBG levels remain relatively constant in healthy individuals, but certain conditions, such as normal pregnancy and steroid therapy, can alter these levels. In these conditions, FT4 levels are unchanged, while total T4 levels parallel the changes in TBG.

REAGENTS: Centaur Ready Pack Cat # 110738 or 110737 - 250 or 50 test pack size.

FREE T4 LITE REAGENT: 5 ml

Acridinium ester labeled T4 in sodium barbital buffer, protein stabilizers, sodium azide, and EDTA. Stable when stored refrigerated 2-8°C until the manufacturer's expiration date or 2 consecutive days on the instrument.

FREE T4 SOLID PHASE REAGENT: 22.5 ml

Polyclonal rabbit anti-T4 antibody covalently coupled to paramagnetic particles in sodium barbital buffer, protein stabilizers, sodium azide, and EDTA. Stable when stored refrigerated 2-8°C until the manufacturer's expiration date or 2 consecutive days on the instrument.

CALIBRATOR A:

A two-point calibrator set for Free T4 in human plasma with sodium azide, microbicides, and protein stabilizers. Concentrations of each analyte will change with lot number

QUALITY CONTROL:

Refer to the general operating procedure for QC instructions.

SPECIMEN:

Refer to the general operating procedure for sample requirements, handling, and storage. The minimum testing volume for the FT4 assay is 25ul plus 50ul of dead space.

PROCEDURE:

Refer to the general operating procedure for operating instructions. FT4 testing does not require any secondary reagents. FT4 master curve calibrations are stable for 21 days.

REPORTING:

1. Results are reported to the nearest tenth in ng/dl. Quality control material is reported to the nearest hundredth.
2. Results reading less than 0.1 or <<< should be reported as less than 0.1 using '0.1'.
3. Results reading from 0.1 to 12.0 should be reported as such.
4. Results reading greater than 12.0 or >>> should be reported as such using '>12.0'.
5. Results exceeding the assay linearity should NOT be diluted.
6. Results reading <<< or >>> on Thyroid Cascade samples (TTC) should be rejected at the A,M,R prompt if results are being monitored under OEM. Results reading <<< should be entered as 0.0 for both FT4C and FT4X under MEM. Sunquest will change the result to <0.1 and will charge a T3. Results reading >>> should be entered as 13.1 for both FT4C and FT4X under MEM. Sunquest will change the result to >13.0. If you modify the result under OEM, the calculations associated with the TTC charge code will not function and the appropriate tests will not be ordered.

NOTES:

1. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values can be observed. Additional information may be required for diagnosis.

REFERENCE RANGE:

0.8-1.8 ng/dl

CALL VALUES:

No call values have been established for this assay.