

Free Thyroxine (T4)

Method:	Access Chemiluminescent Immunoassay
Kit Manufacturer:	Beckman Coulter, Fullerton, CA
Description:	<p>The hypothalamic-pituitary-thyroid axis controls thyroid hormone synthesis, release, and action. Thyrotropin-releasing hormone (TRH) secreted from the hypothalamus stimulates the synthesis and release of thyrotropin or thyroid-stimulating hormone (TSH). TSH, in turn, stimulates the synthesis, storage, secretion, and metabolism of thyroxine (T4) and triiodothyronine (T3). Both free and bound forms of T4 and T3 are present in the blood. More than 99% of the T4 and T3 circulate in the blood bound to carrier proteins, leaving less than 1% unbound. It is this level of unbound or free hormone that correlates with the functional thyroid state in most individuals.^{1,2}</p> <p>Free T4 and free T3 regulate normal growth and development by maintaining body temperature and stimulating calorogenesis. In addition, free T4 and free T3 affect all aspects of carbohydrate metabolism as well as certain areas of lipid and vitamin metabolism. Fetal and neonatal development also require thyroid hormones.</p> <p>Clearly elevated free T4 levels support the clinical findings of a diagnosis of hyperthyroidism while clearly low free T4 levels coupled with appropriate clinical findings, can establish a diagnosis of hypothyroidism. Measurement of free T4 levels along with other thyroid tests and clinical findings can establish borderline hyperthyroid and hypothyroid diagnoses.</p> <p>The Access Free T4 assay is a two-step enzyme immunoassay. Monoclonal anti-Thyroxine (T4) antibody coupled to biotin, sample, buffered protein solution, and streptavidin-coated solid phase are added to the reaction vessel. During this first incubation the anti-T4 antibody coupled to biotin binds to the solid phase and the free T4 in the sample. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Next, buffered protein solution and triiodothyronine (T3)-alkaline phosphatase conjugate are added to the reaction vessel. The T3-alkaline phosphatase conjugate binds to the vacant anti-T4 antibody binding sites.</p> <p>After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is inversely proportional to the concentration of free T4 in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.</p>

Collection and Performance Characteristics

Tube type:	Preferred: SST Alternate: Heparin Plasma					
Minimum Volume:	0.5 mL					
Special Processing Considerations	Thaw samples only once.					
Lowest Reportable Value:	0.25 ng/dL					
Dynamic range:	0.25 – 6.0 ng/dL					
Precision:	Intra-assay variation is 3.9 – 4.0% Inter-assay variation is 2.8 – 4.0%					
Reference Range:			95% Reference Limit (ng/dL)	95% CI for Lower Limit (ng/dL)	95% CI for Upper Limit (ng/dL)	
	Healthy Adults	316	0.61-1.12	0.54-0.67	1.07-1.24	

		1st Trimester Females	131	0.52-1.10	0.47-0.57	1.08-1.27	
		2nd Trimester Females	120	0.45-0.99	0.40-0.48	0.80-1.08	
		3rd Trimester Females	121	0.48-0.95	0.45-0.51	0.83-1.23	