

BLOOD SPOT TEST SPECIFICATIONS

Free T4

Clinical Information

Thyroxine (T4) is the predominant hormone produced by the thyroid gland. It is an inactive prohormone, which converts to triiodothyronine (T3) within cells. Free T4 is the non-protein-bound fraction of the T4 circulating in the blood, representing about 0.04% of the total circulating T4. ZRT's blood spot assay is a direct assay for free T4, and therefore a reliable indicator of circulating free T4.

Free T4 levels reflect the amount of T4 produced by the thyroid that is available to tissues for local conversion to the active thyroid hormone, T3. Inadequate T4 production can be caused by iodine deficiency, autoimmune reactions, or stress. Low thyroid-stimulating hormone (TSH) combined with low free T4 levels indicates hypothyroidism, while low TSH and high free T4 levels indicate hyperthyroidism. High TSH and low free T4 are signs of a thyroid gland disease, such as autoimmune thyroiditis.

The reference range for free T4 is 0.7—2.5 ng/dL (optimum 1—2 ng/dL).

References:

McDermott MT, Ridgway EC. Subclinical hypothyroidism is mild thyroid failure and should be treated. *J Clin Endocrinol Metab* 2001;86:4585-90.

Gharib H, Tuttle RM, Baskin HJ, Fish LH, Singer PA, McDermott MT. Subclinical thyroid dysfunction: a joint statement on management from the American Association of Clinical Endocrinologists, the American Thyroid Association, and the Endocrine Society. *J Clin Endocrinol Metab*. 2005;90:581-5; discussion 586-7.

Miller GD, Rogers JC, DeGroot SL, Schmitz D. Clinical inquiries: which lab tests are best when you suspect hypothyroidism? *J Fam Pract* 2008;57:613-4.

Iverson JF, Mariash CN. Optimal free thyroxine levels for thyroid hormone replacement in hypothyroidism. *Endocr Pract* 2008;14:550-5.

Assay Method: ELISA

Intra-assay Precision

Intra-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times within the same run. Results are shown below:

Mean Free T4 Concentration (ng/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
1.1	0.16	14.7
1.3	0.08	6.1
3.0	0.29	9.9

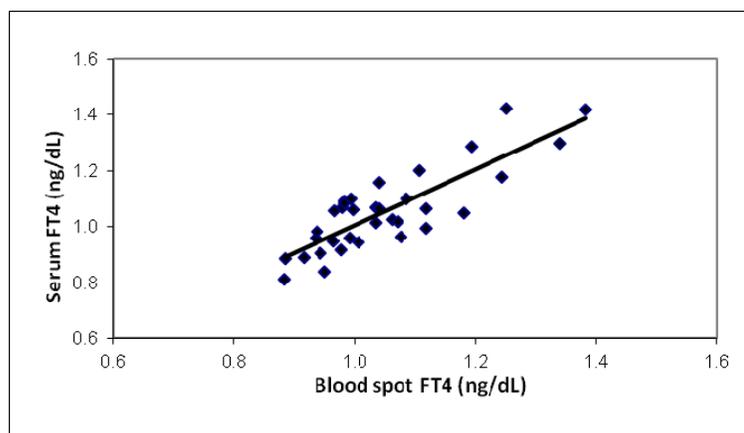
Inter-assay Precision

Inter-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times throughout different runs. Results are shown below:

Mean Free T4 Concentration (ng/dL)	Standard Deviation	Coefficient of Variation (C.V. %)
1.6	0.20	12.7
2.1	0.18	8.8
2.8	0.32	11.4

Accuracy

To test the accuracy of the dried blood spot assay for Free T4, dried blood spot samples collected at the same time as corresponding serum samples were analyzed by linear regression. Resulting correlation data are shown below ($R = 0.84$):



Analyte Stability

The dried blood spot samples are stable for more than 1 month at room temperature.

Specimen Collection

Kits for blood spot collection contain a filter paper collection card, finger lancets, an alcohol prep pad, sterile gauze, a band-aid, easy-to-follow instructions, and a mailer to return the sample for analysis.