

BLOOD SPOT TEST SPECIFICATIONS

Thyroglobulin

Clinical Information

Thyroglobulin is a protein synthesized only in the thyroid gland. It is rich in the amino acid tyrosine, which forms conjugates with the iodine that is actively transported into the thyroid gland via the sodium-iodide symporter. The iodine-enriched thyroglobulin, the source material for synthesis of the thyroid hormones T3 and T4, is stored in the lumen of the thyroid gland. When activated by thyroid-stimulating hormone (TSH), the iodinated thyroglobulin is translocated into the follicular cells of the thyroid where it is hydrolyzed to release T4 and T3 into the bloodstream. When there is insufficient iodine intake for normal thyroid hormone synthesis, thyroglobulin is poorly iodinated and leaks into the bloodstream, raising the blood levels above normal. While very elevated blood levels of thyroglobulin are used as a marker for thyroid cancer, moderately elevated levels are a good indicator of an individual's average exposure to iodine over a period of weeks. Urinary iodine can fluctuate depending on variations in daily consumption of iodine-containing foods, therefore blood spot thyroglobulin is a better indicator of longer term iodine status. Thyroglobulin levels are also raised in autoimmune thyroiditis (Hashimoto's disease) as the destruction of thyroid tissue releases thyroglobulin into the circulation. The reference range for thyroglobulin is 3–40 ng/mL (optimum 3–10 ng/mL).

References:

van den Briel T, West CE, Hautvast JG, et al. Serum thyroglobulin and urinary iodine concentration are the most appropriate indicators of iodine status and thyroid function under conditions of increasing iodine supply in schoolchildren in Benin. *J Nutr.* 2001;131:2701-6.
Zimmermann MB, Moretti D, Chaouki N, Torresani T. Development of a dried whole-blood spot thyroglobulin assay and its evaluation as an indicator of thyroid status in goitrous children receiving iodized salt. *Am J Clin Nutr.* 2003;77:1453-8.
Zimmermann MB, de Benoist B, Corigliano S, et al. Assessment of iodine status using dried blood spot thyroglobulin: development of reference material and establishment of an international reference range in iodine-sufficient children. *J Clin Endocrinol Metab.* 2006;91:4881-7.

Assay Method: Chemiluminescent Immunoassay

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 Thyroglobulin Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
25.8	2.38	9.2
18.7	1.56	8.3
7.8	1.07	13.6

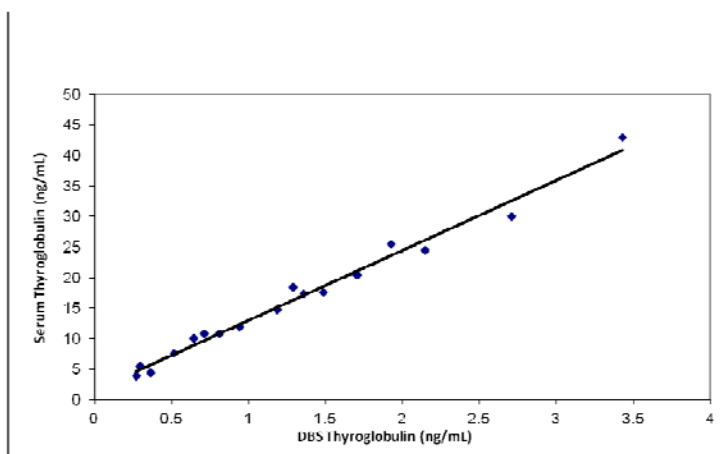
Inter-assay Precision

Inter-assay precision was determined by choosing three samples spanning the reference range, and analyzing them multiple times throughout 10 different runs. Results are shown below:

Mean Thyroglobulin Concentration (ng/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
42.8	0.27	0.6
14.4	1.09	7.5
6.4	1.23	19.3

Accuracy

To test the accuracy of the dried blood spot assay for Thyroglobulin, dried blood spot samples collected at the same time as corresponding serum samples were analyzed by linear regression. Resulting correlation data are shown below ($R = 0.98$).



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.