

BLOOD SPOT TEST SPECIFICATIONS

Thyroid Peroxidase Antibodies

Clinical Information

Thyroid peroxidase (TPO) is an enzyme used by the thyroid gland in the manufacture of thyroxine. In patients with autoimmune thyroiditis, the body produces antibodies to TPO, which mount a direct attack on the thyroid gland itself, resulting in reduced thyroxine production and consequent hypothyroidism. Levels of TPO antibodies in blood spot can indicate the presence and extent of autoimmune thyroiditis.

The most predominant form of autoimmune thyroiditis is known as Hashimoto's disease, which is also the most common cause of overt hypothyroidism; 95% of such patients are positive for TPO antibodies. Testing for TPO antibodies has also been found to help diagnose thyroid disease in patients with abnormal thyroid-stimulating hormone and/or mild thyroid symptoms.

The reference range for TPO antibodies is 0–150 IU/mL, while 70–150 IU/mL is borderline for the presence of autoimmune thyroiditis.

References:

Baskin HJ, Cobin RH, Duick DS, Gharib H, Guttler RB, Kaplan MM, Segal RL; AACE. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hyperthyroidism and hypothyroidism. *Endocr Pract.* 2002;8:457-69.

Bjøro T, Holmen J, Krüger O, Midthjell K, Hunstad K, Schreiner T, Sandnes L, Brochmann H. Prevalence of thyroid disease, thyroid dysfunction and thyroid peroxidase antibodies in a large, unselected population. The Health Study of Nord-Trøndelag (HUNT). *Eur J Endocrinol* 2000;143:639-47.

Sakaihara M, Yamada H, Kato EH, Ebina Y, Shimada S, Kobashi G, Fukushi M, Fujimoto S. Postpartum thyroid dysfunction in women with normal thyroid function during pregnancy. *Clin Endocrinol (Oxf)* 2000;53:487-92.

Diez JJ. Hypothyroidism in patients older than 55 years: an analysis of the etiology and assessment of the effectiveness of therapy. *J Gerontol A Biol Sci Med Sci* 2002;57:M315-20.

Assay Method: EIA

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 TPO antibody Concentration (IU/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
47	3.3	7.0
53	5.1	9.6
62	6.7	10.8

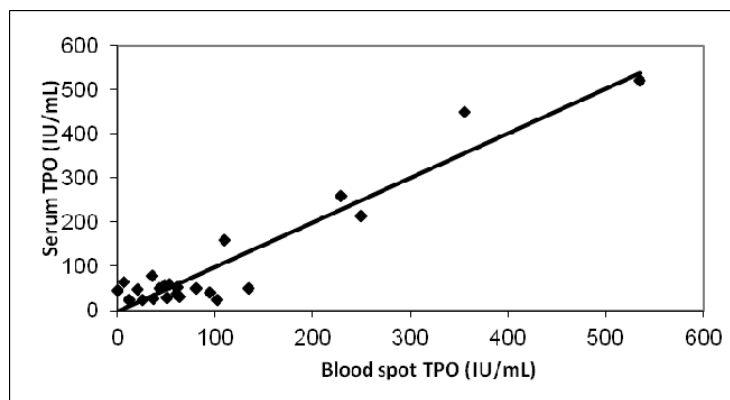
Inter-assay Precision

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 TPO antibody Concentration (IU/mL)	Standard Deviation	Coefficient of Variation (C.V. %)
36	5.3	14.6
41	4.7	11.5
371	51.1	13.8

Accuracy

To test the accuracy of the dried blood spot assay for TPO antibodies, dried blood spot samples collected at the same time as corresponding serum samples were analyzed by linear regression. Resulting correlation data are shown below ($R = 0.95$):



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.