

BLOOD SPOT TEST SPECIFICATIONS

Thyroid-Stimulating Hormone

Clinical Information

Thyroid-stimulating hormone (TSH) is produced by the pituitary and acts on the thyroid gland to stimulate production of thyroxine (T4). Higher than normal TSH can indicate a disorder of the thyroid gland, while low TSH can indicate over-production of T4, which acts in a negative feedback on the pituitary to reduce TSH production. Low TSH can also be caused by problems in the pituitary gland itself, which result in insufficient TSH being produced to stimulate the thyroid (secondary hypothyroidism). Thyroid disease or dysfunction is notoriously under-diagnosed. Population studies such as the Colorado Thyroid Disease Prevalence Study indicate that up to 10% of Americans may have thyroid dysfunction, defined as abnormal levels of TSH. Overt hypothyroidism, with its characteristically high TSH and low circulating T4 levels, or hyperthyroidism, with low TSH and high T4 levels (most commonly manifested as Graves' Disease), are relatively easy to recognize clinically. But an elevated TSH associated with normal thyroid hormone levels, defined as "subclinical" hypothyroidism, is thought to be present in 4-10% of the general population and in up to 20% of women over 60 years old, while a low TSH and normal thyroid hormone levels, or subclinical hyperthyroidism, occurs in about 2% of the population. Reference range levels of TSH are between 0.5 and 3.0 $\mu\text{U/mL}$ (optimum 0.5—2.0 $\mu\text{U/mL}$).

References:

Canaris GJ, Manowitz NR, Mayer G, Ridgway EC. The Colorado thyroid disease prevalence study. *Arch Intern Med* 2000;160:526-34.

Gharib H, Tuttle RM, Baskin HJ, et al. 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.

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

Meier C, Trittbach P, Guglielmetti M, et al. Serum thyroid stimulating hormone in assessment of severity of tissue hypothyroidism in patients with overt primary thyroid failure: cross sectional survey. *BMJ* 2003;326:311-2.

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 TSH Concentration ($\mu\text{U/mL}$) | Standard Deviation | Coefficient of Variation (C.V. %) |
|---|--------------------|-----------------------------------|
| 0.7 | 0.10 | 13.1 |
| 1.8 | 0.14 | 7.6 |
| 3.3 | 0.20 | 6.1 |

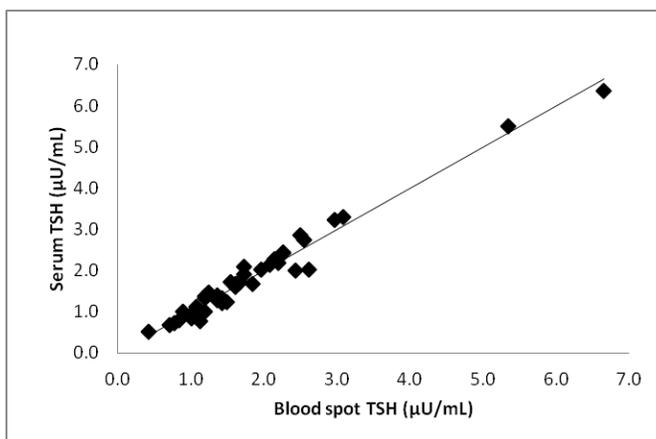
Inter-assay Precision

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 TSH Concentration ($\mu\text{U/mL}$) | Standard Deviation | Coefficient of Variation (C.V. %) |
|---|--------------------|-----------------------------------|
| 0.9 | 0.08 | 9.2 |
| 2.3 | 0.25 | 10.9 |
| 5.4 | 0.51 | 9.3 |

Accuracy

To test the accuracy of the dried blood spot assay for TSH, 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.