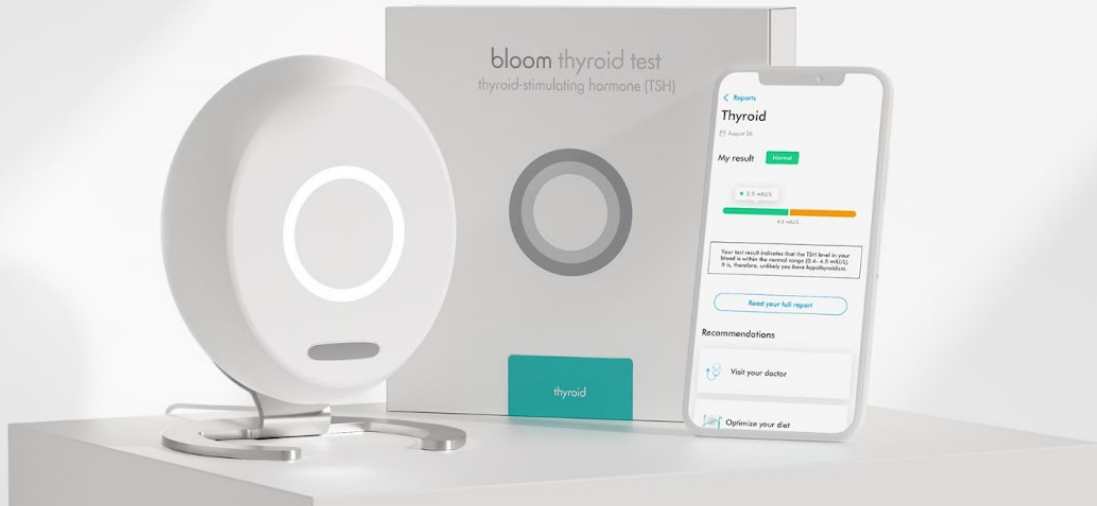




bloom

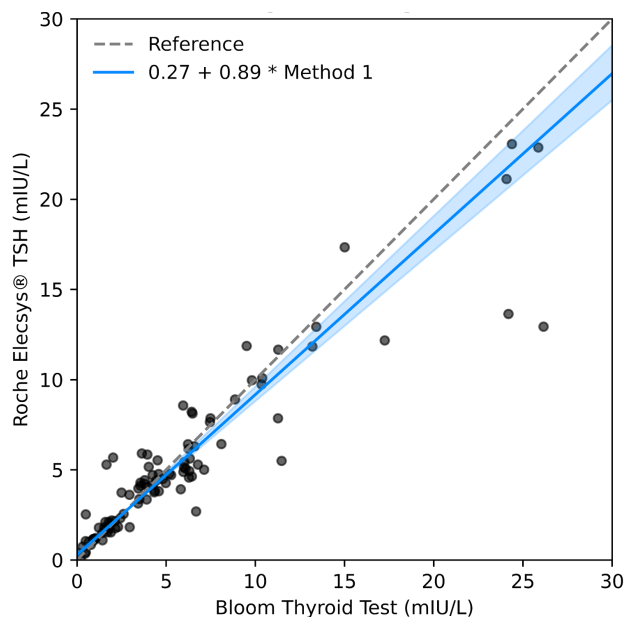
Bloom Thyroid Test Info Sheet



Bloom System

The Bloom System is a medical testing system intended to be used in a home, store or professional setting. It provides screening and monitoring of target markers and medical guidance. The Bloom System is CE mark approved for the EU and Switzerland. It combines lateral flow immunoassays (Bloom Test strips), an established diagnostics technology, with an electronic reader for test strip analysis (Bloom Lab) and an app for displaying and interpreting results (Bloom App).

Passing-Bablok Regression



Results are automatically generated by the Bloom App using a batch specific four parameter logistic calibration curve determined from 10 calibration measurements.

Indication

Thyroid stimulating hormone (TSH) is produced by the pituitary gland, a small gland located in the brain. TSH stimulates the thyroid to release thyroid hormones triiodothyronine (T3) and thyroxine (T4). These thyroid hormones play an important role in the function of tissues and organs and are also involved in the regulation of body temperature and metabolism. As the release of TSH is very sensitive to small changes of thyroid hormone levels, a TSH test can be used to assess the status of the thyroid.

Intended Use

The Bloom Thyroid Test is a single-use self-testing kit for manual in-vitro diagnostic quantitative measurement of thyroid stimulating hormone in capillary blood, used to screen for hypothyroidism. It is intended for self and near patient testing for individuals 18 years old and above.

Test time 10 minutes

Test principle Lateral flow immunoassay

Sample 50µl capillary whole blood

Application Add 1 drop of chase buffer

LOD 1.5 mIU/L

Quantifiable range 2.6 - 30.0 mIU/L

Precision (CV) 12.4 - 16.4 %