

# Thyroid Stimulating Immunoglobulin (TSI)

MDL Test Number: 664

Methodology: Immunoassay

CPT Codes: 84445



## Specimen Collection Platform:

Serum in Serum Separator Tube (SST)

## Turnaround Time:

24 - 72 hours

## Stability:

Room temperature

## Test Additions\*:

30 days to add tests

## Specimen Collection:



1. Immediately after blood collection, invert the tube(s) gently 5 times to ensure mixing of clot activator.



2. Allow the tube to rest upright for at least 30 minutes after collection to ensure proper clotting.



3. Centrifuge for at least 15 minutes at 2200-2500 RPM within one hour of collection.



4. Do not remove the stopper or pour off serum.



## What is Thyroid Stimulating Immunoglobulin (TSI)?

Thyroid stimulating immunoglobulins are antibodies the immune system makes by mistake against the body's own thyroid. Instead of damaging the gland, they lock onto the switch that the pituitary, a small gland at the base of the brain,

normally uses to control it, and turn the thyroid on. Because the antibody is not under the body's control, the thyroid keeps producing hormone whether or not any is needed. This is what causes Graves' disease, the commonest reason for an overactive thyroid.

Healthy people carry essentially none of these antibodies, so this is not a test with a normal range in the usual sense. What it has instead is a level above which a result counts as positive. The amount present tends to follow how active the disease is, falling with treatment, which is why the test is used at diagnosis and again later. Just as usefully, the antibody is absent in the other conditions that make a thyroid overactive, so a negative result points the diagnosis elsewhere.

## Why test for Thyroid Stimulating Immunoglobulin (TSI)?

This test answers a specific question: is an overactive thyroid caused by Graves' disease or by something else? It is commonly ordered to:

- **Confirm Graves' disease as the cause of an overactive thyroid**, and separate it from a nodule producing hormone on its own and from a temporarily inflamed gland leaking it. These are treated in completely different ways.
- **Reach that answer without a thyroid scan**, which matters when a scan is unsuitable or unwanted, as in pregnancy and breastfeeding.
- **Support the diagnosis where thyroid eye disease is present or suspected**, since the same antibody acts on tissue behind the eye.
- **Help judge the risk of the disease returning before antithyroid tablets are stopped**, since a level that has not settled makes a relapse more likely.
- **Follow a woman through pregnancy who has Graves' disease now or has had it in the past**. The condition often quiets as pregnancy goes on and can flare again afterwards, and professional guidance recommends measuring the antibody during pregnancy.



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IH0343 Rel.: 9.2026

## Special Instructions:

- **Thyroid treatment must be listed:** Antithyroid tablets, radioactive iodine, and thyroid surgery all change the level, and they do not all change it in the same direction or over the same period. What treatment has been given, and when, should be on the request, because the same number means different things before treatment, during it, and years afterward.
- **Blood-thinning medicines should be noted:** The sample has to clot completely before it is spun, and the manufacturer notes that samples from patients on anticoagulant therapy may need longer to do so. Listing these medicines on the request lets the laboratory allow for it.
- **Comparing results over time:** Methods for measuring this antibody are not interchangeable, and the manufacturer's own comparison against a different type of test did not agree on every sample. Repeat testing should be done at the same laboratory whenever possible.

## Limitations:

Every laboratory test has limits. For this test, the main ones are:

- The result is read against a cutoff rather than as a precise measurement, and the manufacturer describes the test as semi-quantitative. It answers whether the antibody is present at a meaningful level, not exactly how much there is.
- A positive result is not unique to Graves' disease, and a negative one does not entirely exclude it. In the manufacturer's study, a small number of people with other autoimmune thyroid diseases tested positive, and a small number of people with Graves' disease tested negative.
- Very high results are approximate. These antibodies differ from person to person, and the manufacturer notes that some samples do not dilute predictably, so a result well above the measuring range should be read as very high rather than as an exact number.
- A sample in which the red blood cells have broken down (hemolysis) may give an unreliable result, and the manufacturer advises that such samples be interpreted with caution.
- Rarely, antibodies that some people carry after routine contact with animals or animal products can interfere with tests built this way and produce a result that does not fit the clinical picture.
- This result is one piece of a larger picture. It is meant to be read together with the patient's symptoms, medical history, thyroid function tests, and other findings — never on its own.

## Reference Range(s):

Results are reported in international units per liter (IU/L). There is no ordinary reference range, because carrying none of this antibody is the healthy state. In a study of 842 apparently healthy adults, all but a small fraction fell below the lowest value the test is able to report, which is 0.10 IU/L. What the manufacturer publishes instead is a decision point, worked out from patients with Graves' disease and patients with other thyroid and autoimmune conditions, above which a result is taken as positive.

- **Adults:** not detectable to **0.55 IU/L**

*A result outside this range is not automatically a problem, and a result inside it does not rule one out. Only the ordering provider can interpret what a given number means for a given patient. Patients should always go by the reference range printed on their own laboratory report.*

| Analyte | Disorder                       | Expected Value* |
|---------|--------------------------------|-----------------|
| TSI     | Normal early pregnancy         | ↑               |
| TSI     | Graves' disease                | ↑↑              |
| TSI     | Thyroid autoimmunity           | <b>N</b>        |
| TSI     | Toxic nodular goiter           | <b>N</b>        |
| TSI     | Subacute (painful) thyroiditis | <b>N</b>        |

\* N – Normal Range, ↑ – Increased, ↑↑ – Markedly Increased.

## What are some references that discuss the medical necessity of testing Thyroid Stimulating Immunoglobulin (TSI)?

1. Kahaly GJ, et al. 2018 European Thyroid Association guideline for the management of Graves' hyperthyroidism. *Eur Thyroid J*, **7**, 167–186 (2018).
2. Ross DS, et al. 2016 American Thyroid Association guidelines for diagnosis and management of hyperthyroidism and other causes of thyrotoxicosis. *Thyroid*, **26**, 1343–1421 (2016).
3. Caturegli P, et al. Hashimoto thyroiditis: clinical and diagnostic criteria. *Autoimmun Rev*, **13**, 391–397 (2014).
4. Korevaar T, et al. American Thyroid Association 2026 guidelines for thyroid disease in preconception, pregnancy, and postpartum. *Thyroid*, **36**, 481–544 (2026).
5. Hollowell JG, et al. Serum TSH, T4, and thyroid antibodies in the United States population (1988 to 1994): National Health and Nutrition Examination Survey (NHANES III). *J Clin Endocrinol Metab*, **87**, 489–499 (2002).



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