

1. INTENDED USE

The Biokits TSH Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of Thyroid Stimulating Hormone (TSH) in human serum or plasma. This test is intended for professional use only.

2. INTRODUCTION

Thyroid Stimulating Hormone (TSH) is a glycoprotein hormone secreted by the anterior pituitary gland and plays a central role in the regulation of thyroid function. Abnormal TSH levels are associated with thyroid disorders such as hypothyroidism and hyperthyroidism. Measurement of TSH is widely used as a primary screening tool for assessing thyroid function. The Biokits TSH Rapid Test provides a rapid qualitative result to assist in the evaluation of thyroid disorders.

3. PRINCIPLE OF THE TEST

The Biokits TSH Rapid Test is a lateral-flow immunochromatographic assay with a two-line detection system consisting of a test line (T) and a control line (C). TSH present in the specimen binds to colloidal gold-conjugated anti-TSH antibodies and migrates along the nitrocellulose membrane by capillary action. The antigen-antibody complexes are captured by immobilized anti-TSH antibodies at the test line region, producing a visible colored line when TSH concentrations are ≥ 5 IU/mL. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of TSH concentration, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched TSH Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.
4. Do not use if the pouch is damaged or the seal is broken.

5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid testing hemolytic, lipemic, or icteric specimens.
4. Use separate droppers or pipette tips for each specimen to prevent cross-contamination.
5. Wear gloves and adhere to standard laboratory biosafety practices.
6. Do not eat, drink, or smoke in the testing area.
7. Dispose of all used materials as per biomedical waste regulations.
8. Ensure all reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not provide an exact TSH concentration.
2. TSH levels below 5 IU/mL may not be detected.
3. TSH levels may be influenced by pregnancy, medications, or non-thyroidal illness.
4. Clinical decisions should not be based solely on this test; results must be interpreted in conjunction with clinical findings and other thyroid function tests.
5. The test is validated only for human serum or plasma.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Use appropriate PPE such as gloves, lab coat, and eye protection.
3. Clean spills thoroughly with suitable disinfectants.
4. Dispose of used test components according to biomedical waste disposal guidelines.
5. Do not pipette by mouth.

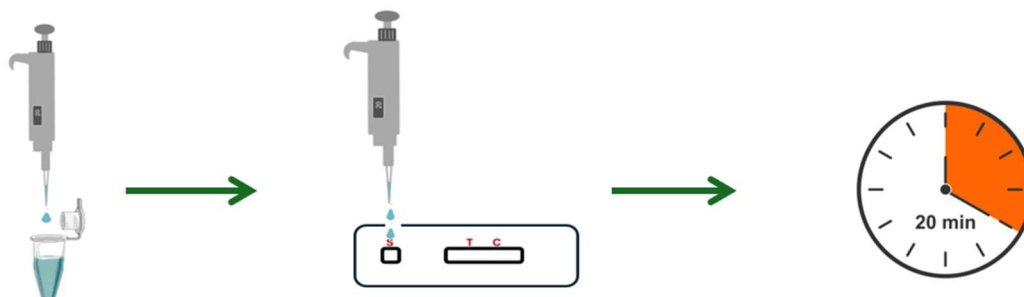
9. REFERENCES

1. Garber JR, et al. *Clinical practice guidelines for hypothyroidism in adults*. Endocrine Society. Journal of Clinical Endocrinology & Metabolism. 2012;97(8):2543–2565.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Whole blood (finger prick or venous) ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Finger prick or venous blood using standard procedures ✓ For serum: allow to clot, then centrifuge ✓ For plasma: centrifuge anticoagulated blood
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, freeze serum/plasma at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE



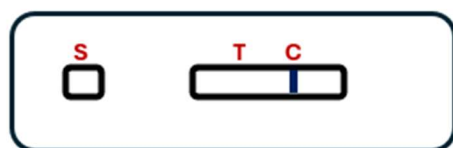
Add 60 ul Serum /Plasma (OR) 100 ul Whole Blood Sample into the Dilution Buffer

Mix Well and Transfer 100 ul of Diluted Sample into the Sample Well (S)

Read Results at the end of 20 Minutes

Note: Do not read results after 20 min- it may give incorrect results !

RESULT INTERPRETATION



TSH is Lesser than 5 IU/ml



TSH is higher then 5 IU/ml



Invalid Test Pattern