



Parameter	TSH
Intended Use	BabySafe™ TSH Rapid test kit is an <i>in-vitro</i> diagnostic immunochromatographic assay for the semi-quantitative detection of Thyroid Stimulating Hormone (TSH) in New-Born whole blood samples.
Principle	<p>BabySafe™ TSH Rapid test is Semi-Quantitative membrane based immunoassay for the detection of Thyroid Stimulating Hormone (TSH) in whole blood. The conjugate pad contains one component Anti-TSH indicator conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the highly specific antibody for TSH-colloidal gold conjugate complexes with the TSH in the specimen and travels through the membrane due to capillary action. This complexes moves further on the membrane to the test region (T) where it is immobilized by another Anti-h TSH (capture) coated on the membrane leading to formation of purple coloured band. The unbound complex moves further to the absorbent pad.</p> <p>The colloidal gold conjugate to Rabbit IgG moves further to the reference region (R) that contains pre-calibrated Agglutinating sera for goat anti-Rabbit globulin corresponding to 10µIU/ml TSH, immobilized on the membrane. The intensity of the coloured band formed at the reference region (R) corresponds to a TSH concentration of 10µIU/ml. The unreacted Rabbit IgG conjugate, move further on the membrane and are subsequently immobilized by the agglutinating sera for goat anti-Rabbit globulin coated on the membrane at the Control region (C), forming a purple coloured band. The intensity of the coloured band formed at the Control region (C) corresponds to a TSH concentration of 30µIU/ml.</p>
Kit Components	<p>Materials Provided</p> <p>A. Individual pouches, each containing:</p> <ol style="list-style-type: none"> 1. Test Device: Membrane assembly pre-dispensed with TSH (indicator) colloidal gold conjugate Rabbit gold conjugate, Anti-TSH (capture) and Anti-rabbit globulin coated at the respective regions. 2. Desiccant pouch. <p>B. Assay buffer bottle.</p> <p>C. Package insert.</p>
Pack size	10/25 Tests

Key Distinctions

-  Onsite test- Results in 25 minutes at the newborn baby's bed side. Enables bedside testing.
-  Semi-quantitative estimation of analyte concentration.
-  Visual Test that can be performed at Birthing centres, Clinics and Hospital -attached labs.
-  Uses 10 µl heel prick whole blood sample, Minimizes discomfort to the newborn baby, eases sample collection process.
-  Room temperature storage therefore Flexibility of remote distribution and storage.