

Size : 137 x 218 mm



**Rapid test for detection of human Thyroid stimulating Hormone (TSH)
in Human whole blood**

DEVICE

INTENDED USE

The **BabySafe™ TSH** kit is an *in-vitro* diagnostic immunochromatographic assay for the detection of Thyroid Stimulating Hormone (TSH) in Human Whole Blood samples. This is a screening test. **BabySafe™ TSH** test results of new born whole blood samples can be quantified using **BabySafe™ Analyzer**.

SUMMARY

A TSH (Thyroid-Stimulating Hormone) test is a blood test that measures the level of TSH, a hormone produced by the pituitary gland to regulate the thyroid. It is used to evaluate thyroid function and diagnose conditions like an underactive thyroid (hypothyroidism) or overactive thyroid (hyperthyroidism). High TSH levels can indicate hypothyroidism, while low levels may point to hyperthyroidism or a pituitary issue.

A TSH (thyroid-stimulating hormone) test is a key part of newborn screening (NBS) to check for congenital hypothyroidism, which is a deficiency of thyroid hormone essential for brain development. The test is performed on a blood sample, usually collected from a heel prick, after 24 hours of age to minimize the effects of a temporary, normal surge in TSH that occurs shortly after birth. The primary goal is to enable early detection and treatment to prevent irreversible brain damage.

BabySafe™ TSH is a screening test wherein the test results can be quantified using **BabySafe™ Analyzer**.

TEST PRINCIPLE

The **BabySafe™ TSH** is a membrane based immunoassay for the quantitative determination of Thyroid Stimulating Hormone (TSH) in new-born whole blood sample. 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.

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.

PRESENTATION

REF	526030008	526030024
△	8 T	24 T

REAGENTS AND MATERIAL SUPPLIED

BabySafe™ TSH Kit contains:

- Individual pouches, each containing:
 - 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.
 - Desiccant pouch.
- BUF** : Assay buffer bottle.
- QR Code card for calibration.
- Package insert.

MATERIAL REQUIRED BUT NOT PROVIDED

- BabySafe™ Analyzer** (Cat. No.: 853BSA00002)
 - Micropipette, Micropipette Tips, Gloves, Alcohol swab, Sterile blood lancet (0.85 mm- 2 mm max depth) and stopwatch.
- ** For premature neonates, a lancet depth of 0.85 mm is recommended.

TEST KIT STORAGE AND STABILITY

- Store the sealed pouches and assay buffer at 4°C to 30°C. DO NOT FREEZE.
- The test kit is stable until the expiration date marked on the RDT box and /or the packaging of the individual components when stored as specified.

WARNINGS AND PRECAUTIONS

- Read the instructions carefully before performing the test.
- For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use only.
- Do not use the kit beyond expiry date and do not re-use the test device.
- Do not intermix reagents from different lots.

Colour	C	M	Y	K
Black	0	0	0	100
Green	100	20	100	10

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- Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to minimum. Inhalation / swallowing may cause harm.
- Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
- Scan QR code card specific to the lot you are using.
- Assay buffer contains Sodium Azide(0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing system and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.

SPECIMEN REQUIRED

Capillary Whole Blood Sampling by Heel Prick:

- Blood samples should ideally be collected between the third and fifth day of baby's life (48 to 120 hrs after birth) by Heel prick. However, in some screening programs the sampling timing may vary. Consult local regulations for appropriate timing for specimen collection.
- Blood from the new-born's Heel should be collected **ONLY** from the medial (closest to the body center-line) or lateral portion (furthest from the body center-line) of the planter surface (walking surface).
- Clean the skin with an alcohol swab and allow to air-dry.
- Puncture the infant's Heel with a sterile lancet to the depth of approximately 0.85 mm - 2.0 mm. Puncturing deeper than 2.0 mm on small infants may cause bone damage. (Reference: WHO Guidelines for Paediatric and Neonatal patients sampling).
- Puncture infant's heel with one quick, continuous and deliberate stroke, to achieve a good flow of blood and to prevent the need to repeat the puncture.
- Wipe away the first drop of blood because it may be contaminated with tissue fluid or debris (sloughing skin). Collect 10 µl of blood sample with the help of a Micropipette (10 µl) from a large well-formed drop of blood.
- Avoid squeezing the heel too tightly because this dilutes the specimen with tissue fluid (plasma) and increases the probability of haemolysis.
- When the blood collection procedure is complete, apply firm pressure to the site to stop the bleeding.

Venous blood:

- Fresh whole blood collected in EDTA. Freezing is not recommended. With the help of micropipette transfer 10µl whole blood in to the test device 'A' region.

ASSAY PREPARATION

Before testing:

1. To calibrate the **BabySafe™ TSH** kit, scan the QR code card provided with the kit.
2. When stored in the refrigerator, bring the kit components to ambient temperature.
3. **BabySafe™** Test device should be used within 30 mins once the foil pouch is opened.
4. Check that the device packaging is not damaged. (If damaged, discard the device packaging and use another test).
5. Open the device packaging by tearing along the notch indicated and check the desiccant. (If it shows saturation i.e. colour changed from blue to pink or colourless), discard the device and take another device packaging. If the colour of the desiccant does not show any colour change the device can be used for the test.
6. Throw the desiccant in the non-sharp disposal container.
7. Take the device and place it on the horizontal surface.
8. The device will have:
 - A result window (marked as C & T)
 - A sample port marked "A".
 - A circle well for buffer marked "B".
9. Write the patient name or patient identification on the device.
10. Put the gloves. Use new pair of gloves for each patient.

TESTING PROCEDURE

Capillary whole blood Sample from Heel prick

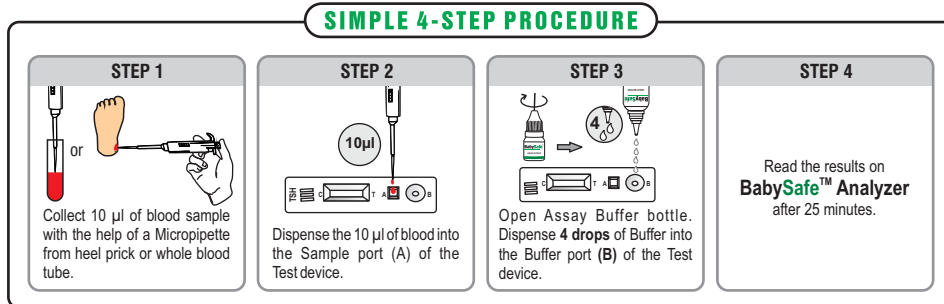
1. Wear gloves.
2. Open the packaging of the alcohol swab. Take out the alcohol swab. Do not throw away the empty packaging (wrapper) but keep it aside.
3. Wipe the complete area to be pricked with the alcohol swab.
4. Wait until the area has completely dried (minimum 30 seconds).
5. Place the alcohol swab in the wrapper and set it aside (you will use it again to stop the bleeding after you collected the blood).
6. Take the safety-seal lancet.
7. Detach the cap of the lancet. Puncture the infant's Heel (from medial or lateral portion of plantar surface) with a sterile Lancet (0.85 mm-2 mm) . Dispose the lancet immediately into the sharps box.
8. Make sure a well-formed drop of blood is present.
9. If there is no well-formed drop of blood, repeat the prick at some other area.
10. Use a new lancet and choose a different puncture site.
11. Collect 10 µl of blood sample with the help of a Micropipette (10 µl) from a large well-formed drop of blood. Take the alcohol swab you put aside (step 5). Press it to the site of pricking to stop the bleeding. After use, put the alcohol swab into the non-sharps disposal container. Use a separate micropipette tip for each patient to avoid any contamination.

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12. Dispense 10 µl blood sample in the sample port 'A', followed by the addition of 4 drops of the Assay buffer in port 'B' (**Do not move the devices after addition of Assay buffer**).
13. Read the result in 25 minutes on **BabySafe™ Analyzer**. Do not read and interpret after 25 minutes.

Venous whole blood

1. Wear Gloves.
2. Collect fresh whole blood by standard venipuncture procedure into tube containing anticoagulant (EDTA).
3. Mix the tube gently.
4. Perform steps 11 -13 of the previous section ("Capillary whole blood from heel prick").
5. **Storage duration:** If assays are not completed immediately, Whole blood samples should be stored at +2°C to +8°C no longer than 24 Hours.



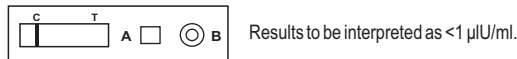
Quantitative result interpretation using BabySafe™ Analyzer:

The test results can be read and quantified using **BabySafe™ Analyzer** (Cat. No.: 853BSA00002). Please refer the User manual of **BabySafe™ Analyzer** for procedural details.

Results	Interpretation
<10 µIU/ml	Presumptive Negative
10-30 µIU/ml	Borderline Positive
>30 µIU/ml	Presumptive Positive

NOTE: The device measuring range is between 1.0 µIU/ml – 60 µIU/ml

No Test Line:



Invalid Result:



PERFORMANCE CHARACTERISTICS

Internal Evaluation: In an in-house study, the performance of **BabySafe™ TSH** was evaluated using a total 100 samples collected from the locally available tertiary care center and were tested in parallel on ELISA system. Out of which 1 was clinically TSH positive, 3 borderline positive and remaining 96 were known Negative specimens. The results of the evaluation are as follows:

SPECIMEN DATA	TSH	BabySafe™ TSH	BornSafe™ TSH
No. of specimens tested	100	100	100
No. of positive specimens	01	01	01
No. of Borderline positive specimens	03	03	03
No. of negative specimens	96	96	96

Based on this evaluation **BabySafe™ TSH** has 100% correlation with licensed reference system, BornSafe™ Neonatal TSH.

External Evaluation: In a NABL accredited reputed reference laboratory in India, **BabySafe™ TSH** (Device) were evaluated with 100 nos. of whole blood samples derived from new born. Results were obtained as below:

SPECIMEN DATA	TSH	BabySafe™ TSH	BornSafe™ TSH
No. of specimens tested	100	100	100
No. of positive specimens	2	2	2
No. of negative specimens	98	98	98

Size : 137 x 218 mm

Based on this evaluation **BabySafe™ TSH** have 100% correlation with licensed reference system, BornSafe™ Neonatal TSH.

LIMITATIONS OF THE PRODUCT

1. The test procedure, precautions and interpretation of results for this test must be followed while testing.
2. The **BabySafe™ TSH** is for in vitro diagnostic use only. The test should be used for the detection of TSH in whole blood specimens only.
3. Test kit directly exposed to sunlight and heat can lead to wrong results.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Values expressed is in µIU/ml of whole blood.
6. This test does not determine the absolute value of TSH in specimen.
7. Screening based on the Primary Determination of TSH constitutes the most sensitive index for the detection of Primary Hypothyroidism. However, it should be noted that babies with Secondary Hypothyroidism, TBG Deficiency, very low birth weight with a delayed elevation of TSH level can be missed in Primary TSH based Screening. Confirmatory Serum Analysis must be carried out as per various national & international CH advocacy groups for the confirmation of Hypothyroidism.

REMARKS

1. **BabySafe™ TSH** is a first-line screening test. If the result is negative but symptoms develop later, positive results should be confirmed with more sensitive and confirmatory assays.
2. In cases of IEMs, toxic metabolites and by-products can only be detected biochemically about 12 hours after the baby's first feed.
3. Infants screened before 24 hours of life should be re-screened by 2 weeks of age to detect possible missed cases.
4. Screening performed between 2 and 7 days of age provides the earliest results, allowing initiation of specific therapy or special elimination diets if the baby tests positive.
5. Cord blood is not suitable for newborn Screening since it is taken before the baby takes first breast milk.
6. Use of hemolyzed samples can produce reddish background which can interfere with results interpretation.
7. All samples tested as Borderline or presumptive positive, necessitate confirmation using more sensitive confirmatory assays & further correlation with other clinical findings (e.g Sampling age, Prematurity, birth weight, sick infants etc.)
















WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1). WHO Guidelines for Paediatric and Neonatal patients sampling. (2). Juliane Leger et al. European Society for Paediatric Endocrinology Consensus Guidelines on Screening, Diagnosis and Management of Congenital Hypothyroidism. J Clin Endocrinol Metab. Feb 2014;99(2):363-384. (3). Data on file: Zephyr Biomedicals.

SYMBOL KEYS

 Temperature Limitation	 Manufacturer	 Batch Number / Lot Number	 Device	 <small>HARMFUL</small> Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
 Use by	 Consult Instructions for use	 Contains sufficient for <n> tests	 Assay Buffer	
 Date of Manufacture	 Catalogue Number	 This side up	 Do not reuse	
 In vitro Diagnostic Medical Device	 Do not use if package is damaged			


Manufactured by:

Zephyr Biomedicals

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