CE

BabySafe™

TSH Rapid Diagnostic Test

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

DEVICE

INTENDED USE

The BabySafe TSH Rapid test kit is an *in-vitro* diagnostic immunochromatographic assay for the semi-quantitative detection of Thyroid Stimulating Hormone (TSH) in New-Born whole blood samples. This is a screening test.

TEST PRINCIPLE

The BabySafe TSH Rapid Test Cassette (Whole Blood) 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.

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.

INTENDED USER

The test is intended to be performed by a trained user.

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 1.0-2.0 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, Heparin or ACD. Freezing is not recommended. With the help of micropipette transfer 10µl whole blood in to the test cassette 'A' region.

WARNINGS AND PRECAUTIONS:

- Read the instructions carefully before preforming 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.
- 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.

MATERIALS

Materials provided:

A. Individual pouches, each containing:
   1. 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.

B. BUF : Assay buffer vials.

C. Package insert.

PRESENTATION

REF	526030010	526030025
Σ	10 T	25 T

OPTIONAL MATERIAL REQUIRED BUT NOT PROVIDED

i) NBS-RDT Single Channel Pipette (10 µl) (Cat. No.: 10SCPRDT016)
ii) NBS-RDT Micropipette Tips-Tip Box Set (Cat. No.: 10MPTMTB019)

Materials required but not provided:

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 at 4°C to 30°C .
- Do not use beyond the expiration date .
- 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.
- DO NOT FREEZE.

TESTING PROCEDURE

Before testing:

1. When stored in the refrigerator, bring the kit components to ambient temperature.
2. Check that the cassette packaging is not damaged. (If damaged, discard the cassette packaging and use another test).
3. Open the cassette 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 cassette and take another cassette packaging. If the colour of the desiccant does not show any colour change the cassette can be used for the test.
4. Throw the desiccant in the non-sharp disposal container.
5. Take the cassette and place it on the horizontal surface.
6. The cassette will have:
   - A result window (marked as C, R & T)
   - A sample port marked “A”.
   - A circle well marked “B”.
7. Write the patient name or patient identification on the cassette.
8. Put the gloves. Use new pair of gloves for each patient.

Test Procedure

Capillary whole blood 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.

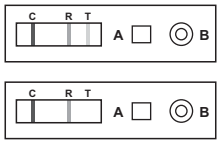
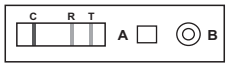
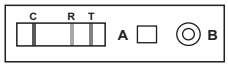
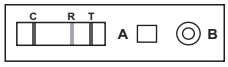
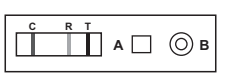
10. Use a new lancet and choose a different puncture site.
11. Collect 10 µl of blood sample with the help of a Micropipette (10 µl) from a large well-formed drop of blood. Take the alcohol swab you put aside (step 5). Press it to the site of pricking to stop the bleeding. After use, put the alcohol swab into the non-sharps disposal container.
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. Do not read and interpret after 25 minutes.
14. Use a separate micropipette tip for each patient to avoid any contamination.

Venous whole blood

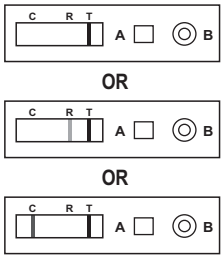
1. Wear Gloves.
2. Collect fresh whole blood by standard venipuncture procedure into tube containing anticoagulant (EDTA or heparin).
3. Mix the tube gently.
4. Perform steps 11 -13 of the previous section ("Capillary whole blood from heel prick").
5. **Storage duration**: If assays are not completed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

INTERPRETATIONS OF THE RESULTS

1. At the end of 25 minutes record the test result as noted in the table below.
2. Where possible have the results confirmed by a second reader within this time frame.
3. Line intensities may vary from faint to strong intensity. Consider the faint lines also as a visible band.
4. Record the test result as noted in the table below:

	**TSH concentration below 10 µIU/ml: T<R & C** Presence of three coloured band at, Reference **'R'**, Control **'C'** and Test **'T'**, where colour intensity of **"T"** is less than **"C"** and **"R"**. Presence of two coloured band at, Reference **'R'**, Control **'C'**, and no Test **"T"** colour band.	**Interpretation:** Presumptive Negative
	**TSH concentration @ 10 µIU/ml: T=R** Presence of three coloured band at, Reference '**R**', Control '**C**' and Test '**T**', provided that colour intensity observed at Test "**T**" is equal than Reference "**R**" it should be inferred as the concentration of TSH in the specimen is @10µIU/ml.	**Interpretation:** Presumptive Negative
	**TSH concentration between 10 to 30µIU/ml: C>T>R** Presence of three coloured band at, Reference '**R**', Control '**C**' and Test '**T**', provided that colour intensity observed at Test "**T**" is more than Reference "**R**" and less than Control "**C**" it should be inferred as the concentration of TSH in the specimen is between 10 to 30µIU/ml.	**Interpretation:** Borderline Range
	**TSH concentration @ 30 µIU/ml: T=C** Presence of three coloured band at, Reference '**R**', Control '**C**' and Test '**T**', provided that colour intensity observed at Test "**T**" is equal than Control "**C**" it should be inferred as the concentration of TSH in the specimen is @30µIU/ml.	**Interpretation:** Presumptive Positive
	**TSH concentration > 30 µIU/ml: T>C** Presence of three coloured band at, Reference '**R**', Control '**C**' and Test '**T**', provided that colour intensity observed at Test "**T**" is higher than Control "**C**" it should be inferred as the concentration of TSH in the specimen is more than 30µIU/ml.	**Interpretation:** Presumptive Positive

Note: All samples tested as Borderline or Presumptive positive; Necessitate Confirmation by Serum Analysis & Correlation with other Clinical Findings (e.g. Sampling Age, Prematurity, Birth Weight, Transient CH status etc.)

	**Invalid Result:** Absence of band in control '**C**' and/ or Reference '**R**' region irrespective of presence or absence of band at Reference '**R**' and '**T**' regions.	

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 Rapid Test Cassette (Whole Blood) 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). BabySafe Rapid TSH is a Screening test; which is a process of Filtration that separates the newborn infants into two groups; one who may have the given disorder or condition from the other group of infants who do not have it. If the screening TSH rapid test results are borderline or presumptive positive, it should be followed by further confirmatory diagnostics tests or additional tests according to the suggested approaches from AAP, ACMG to Treatment Guidelines & Diagnostic algorithm of CH to differentiate Primary and Transient CH. (6). Results must be confirmed using a Serum ELISA test. Presumptive Positive samples needs to be confirmed by Serum analysis and caution must be exercised in correlating test results to clinical status of specimens from new borns less than 48 hours after birth, premature, low birth weight and hospitalized sick new born. (7). Values expressed is in µIU/ml of whole blood. (8). This test does not determine the absolute value of TSH in specimen. (9).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.

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 Endocrinilogy 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	LOT	Batch Number / Lot Number	DEVICE	Device		Do not reuse
	Use by		Consult Instructions for use	Σ	Contains sufficient for <n> tests	EC REP	Authorised Representative in the European Community		Do not use if package is damaged
	Date of Manufacture	REF	Catalogue Number	IVD	*In vitro* Diagnostic Medical Device	BUF	Assay Buffer		This side up

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

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EC REP

CMC Medical Devices & Drugs S.L., Spain.

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