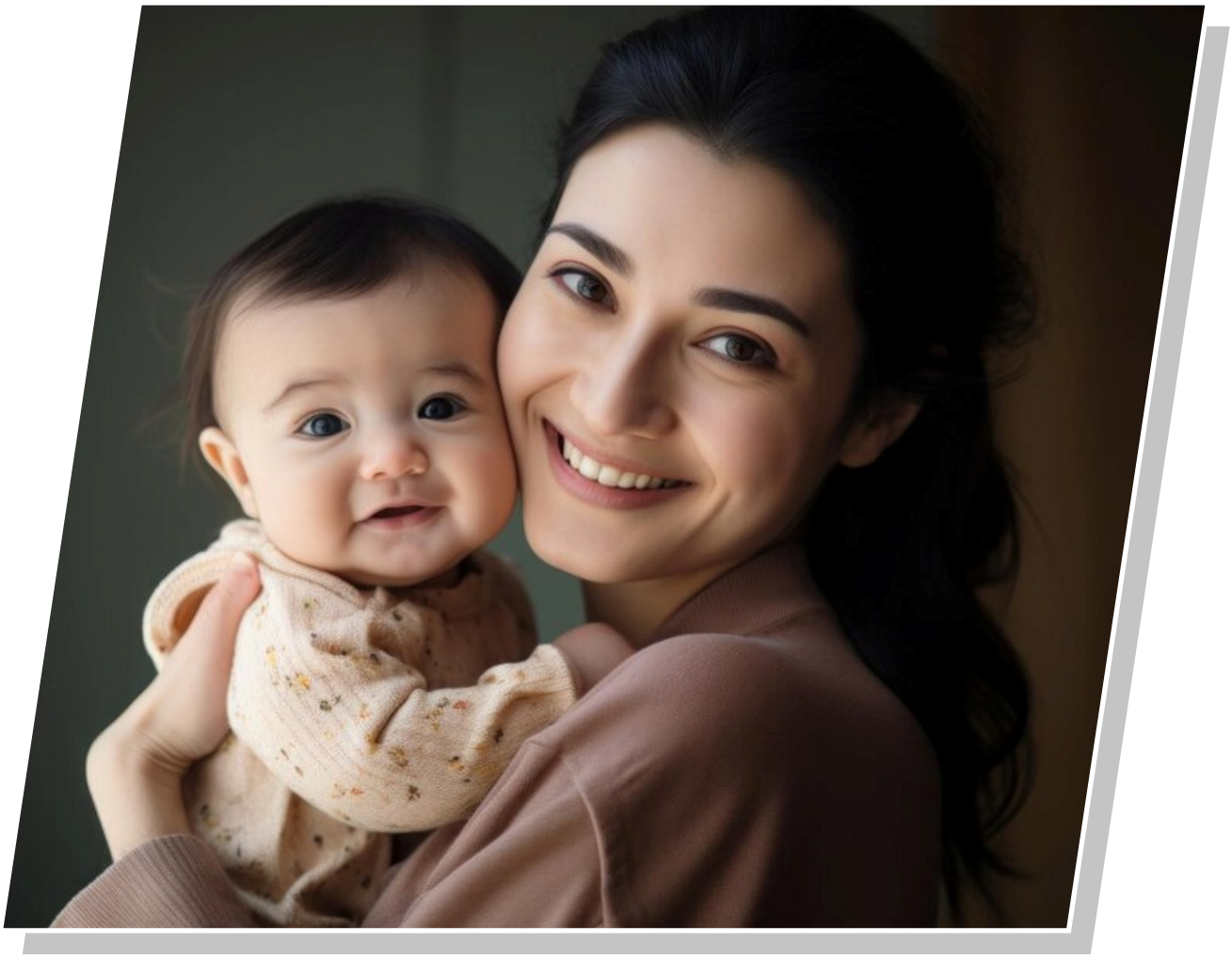
# “Every Parent Deserves a Healthy Child”
# “Every Child Deserves a Healthy Life”



Though births in developing countries contribute to more than half of the total births globally, newborn screening (NBS) is not yet implemented in most developing countries. As a result, many babies with serious metabolic, endocrine, or blood-related genetic disorders go undetected and thus suffer lifelong, irreversible intellectual, physical disabilities and/or death.

## Timely newborn screening can protect babies from irreversible damages.

## Global Scenario

- Around 132 million babies are born in the world every year.
- The global birth prevalence of IEM (Endocrine, Metabolic & Blood Condition) to be **50.9 per 100000** live births.
- In developing countries 5 million babies die in the first month post birth due to Inborn Errors of Metabolism.
- 4 million babies face serious congenital disorders, 25 to 30 % of these have IEMs.

## Indian Scenario

- Approximately 24 million babies are born in India every year.
- In India, the birth prevalence of Inborn Errors of Metabolism (IEM), including endocrine, metabolic, and blood conditions, is approximately **1 in 2,467 live births.***
- The incidence of Congenital Hypothyroidism (CH) is about 1 in 2,500 to 1 in 2,800 live births.*
- A screening cohort of 104,066 newborns in India reported the incidence of Congenital Adrenal Hyperplasia (CAH) as 1 in 5,762 live births.*
- Nearly 390,000 infants are born annually with Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency. (Indianpediatrics)*

**The National Neonatology Forum (NNF)** recommends universal newborn screening for three core disorders (Congenital Hypothyroidism, Congenital Adrenal Hyperplasia & Glucose-6-Phosphate Dehydrogenase Deficiency) and **FOGSI** supports inclusion of these tests as a part of essential newborn care in routine postnatal checkups.

**Newborn Screening** is important as it helps to identify babies with serious medical conditions, before appearance of the symptoms and thus aids in early medical intervention and corrective treatment. Most babies with these conditions if identified at birth and treated early, are able to grow up healthy with normal development.

## Current Challenges

- Lack of Awareness
- Accessibility of New Born Screening tests.
- Logistical problems associated with the current screening technology.
- Economic constraints

## What needs to be done?

- Awareness about IEMs.
- Every newborn should be screened for IEM for early diagnosis to identify disorders before any signs or symptoms appear.

## Why mass screening?

- All newborn babies are suspected for IEMs.
- Early diagnosis and treatment within the narrow window of 72 hours post birth.

## Need of the hour

- Convenient and easy to perform with small heel stick puncture.
- Bedside point of care testing with fresh whole blood.
- Affordable, advanced technology.
- Immediate results.

**A screening system which can be performed on site or offsite & delivers results in <30 minutes .**

*Reference will be available on request.

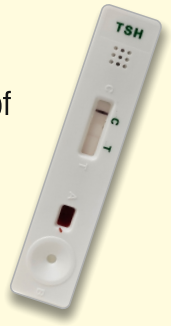
*Tulip Introduces* **BabySafe™**

# A Unique Rapid Immunoassay Test for Newborn Screening

**BabySafe™ is a unique range of Rapid Immunoassay Test for NBS which works with BabySafe™ Analyzer for reading and interpretation of test results detecting the most important core panel analytes**

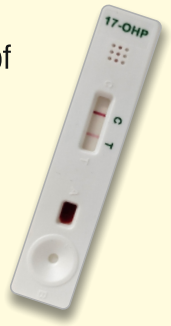
## BabySafe™ Parameters

### BabySafe™ TSH




- Lateral flow immunochromatographic test for the detection of TSH in Newborn Whole blood.
- Quantitative assay.
- Measuring range - 1-60µIU/ml.
- Sample type - 10µl Whole blood ( Venous or Heelprick).

### BabySafe™ 17-OHP




- Lateral flow immunochromatographic test for the detection of 17 α-OHP in Newborn Whole blood.
- Quantitative assay.
- Competitive Inhibition assay.
- Measuring range - 1-60ng/ml.
- Sample type - 10µl Whole blood ( Venous or Heelprick).

### BabySafe™ G6PD


- Lateral flow immunochromatographic colorimetric assay for the detection of severe G6PD deficiency in Newborn whole blood.
- Qualitative assay.
- Biochemical test.
- Sample type - 2µl Whole blood ( Venous or Heelprick).

## BabySafe™ Analyzer


- *Light Reflection based Rapid NBS test card Reader*
- *Lot specific calibration through QR code*
- *Quick, Simple & user friendly software*
- *Portable and Compact: Easy to carry and use anywhere*
- *Provides test results in less than 30 minutes.*

## KEY FEATURES AND BENEFITS

### Core panel recommended by NNF

- Congenital hypothyroidism (CH) • Congenital Adrenal Hyperplasia (CAH) • Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency.

### Accessible

- Rapid Immunochromatography format.
- All birthing centres, hospitals and labs can perform.

### Affordable

- No investment in expensive instruments.
- Small pack size.

### Bed Side Test

- Portable instrument.
- Rapid test format.

### Ease of use

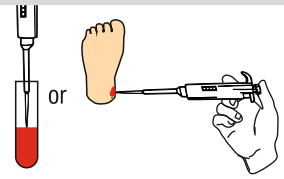
- Venous blood and Heel prick samples.
- No need of DBS samples.
- Smart calibration through QR code.
- Even single sample can be tested at a time.

### Rapid

- Overall test timing of <30 minutes.
- User friendly.

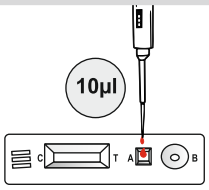
## SIMPLE 4-STEP PROCEDURE

**STEP 1**



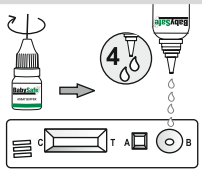

Collect 10 $\mu$l of blood sample with the help of a Micropipette from heel prick or whole blood tube.

**STEP 2**




Dispense the 10 $\mu$l of blood into the Sample port (A) of the Test device.

**STEP 3**




Open Assay Buffer vial. Dispense **4 drops** of Buffer into the Buffer port **(B)** of the Test device.

**STEP 4**


Read the results at 25 mins.

*For BabySafe TSH and 17-OHP Rapid Tests.*

## Let's give every Baby a Safe start with Newborn Screening.

ISO 13485 Certified Company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