



Parameter	Neonatal TSH
Intended Use	The Born Safe™ Neonatal TSH Screening ELISA is an enzyme immunoassay for the quantitative determination of thyroid stimulating hormone in dried blood samples spotted on Whatman S&S 903 filter paper. This kit is particularly suitable for screening for primary hypothyroidism in newborns. Elevated results indicate the need for further study to assess congenital hypothyroidism.
Principle	<p>Born Safe™ Neonatal TSH Screening ELISA is an immunoenzymatic assay to quantitate human thyroid stimulating hormone (TSH) in newborn dried blood spots.</p> <p>Born Safe™ Neonatal TSH Screening ELISA is a sandwich ELISA. The essential reagents required for a sequential immunoenzymatic assay include high affinity and specificity antibodies (enzyme conjugated and immobilized), with different and distinct epitope recognition, in excess, and native antigen. Upon mixing of dried blood spots with Elution Reagent, reaction results between the eluted antigen and immobilized anti-TSH antibody to form an antigen-antibody complex.</p> <p>After a suitable incubation period, unreacted reactants and remnants are washed off via wash step. Another antibody (directed at a different epitope) labeled with an enzyme is added. Another interaction occurs to form an enzyme labeled antibody-antigen- antibody complex on the surface of the wells.</p> <p>Excess enzyme is washed off via a wash step. A suitable substrate is added to produce color measurable with the use of a microplate ELISA reader. The enzyme activity on the well is directly proportional to the TSH concentration in the dried blood spot. By utilizing several different dried spots of known antigen concentration, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.</p>
Kit Components	<p>Reagents</p> <ul style="list-style-type: none"> ● TSH Calibrators –Dried Blood Spots in Aluminium pouch (One row of six spots levels - 1 x 6): Six (6) levels of TSH Antigen in dried blood spots at approximate concentrations of 0(C0), 5(C1), 25(C2), 50(C3), 105(C4) and 150(C5) µIU/ml spotted on S&S Whatman 903 filter paper. Store at 2-8°C. Desiccant is included. <ul style="list-style-type: none"> Note 1: The Lot Specific calibrators are whole human blood based, were calibrated against the WHO (NIBSC) 3rd, International Standard (81/565) and 5th ISNS Reference Preparation for Neonatal Screening (5th ISNS-RPNS), RIVM, Bilthoven, Netherlands. Note 2: The exact TSH values are printed on the lot specific quality control certificate included in the kit.(values mentioned here are for illustration purpose only) ● TSH Controls –Dried Blood Spots in Aluminium pouch (One row of two spots – 1 x 2): Two levels of whole human blood controls with different concentrations of TSH antigen spotted on S&S type 903 filter paper. Store at 2- 8°C. Desiccant is included. <ul style="list-style-type: none"> Note 1: The controls are whole human blood based, were manufactured to fall within significant clinical ranges using WHO 3rd, international standard (81/565). Note 2: The exact controls values are measured and printed on the lot specific quality control certificate included in the kit. (values mentioned here are for illustration purpose only) ● TSH Enzyme Reagent – 14.0 ml <ul style="list-style-type: none"> One vial containing enzyme labelled monoclonal antibody to human TSH in buffer, and preservative. Store at 2-8°C. ● Extraction Reagent – 14.0 ml <ul style="list-style-type: none"> One vial containing protein, stabilizers and surfactant in buffer, and preservative. Store at 2-8°C.

TSH

- Coated Microwells: One 96-well microplate coated with anti-TSH antibody and packaged in an aluminium bag with a drying agent. Store at 2-8°C.
- Wash Solution (40X) – 22.0 ml
One (1) vial containing a surfactant in buffered saline. A preservative has been added. Store at 2-30°C.
- Substrate Solution – 15.0 ml
One (1) vial containing tetramethylbenzidine (TMB) and hydrogen peroxide (H₂O₂) in buffer. Store at 2-8°C.
- Stop Solution – 7.0 ml
One vial containing a mineral acid. Store at 2-8°C.
- Plate sealers – 3 nos
- Product Instructions– Details of the Kit and have testing methodology.

Pack size 96 Tests

Linearity 0-180 µIU/ml

Key Distinctions

👣 Born Safe TSH is Indian FDA approved, ISO certified. 👣 Comprehensive External Clinical Evaluation, exclusively on neonatal population: >3200 samples. 👣 Absolute Compliance with Lab QMS trend (e.g. CDC-PT/QC). 👣 Born Safe TSH Calibrators are traceable to international CRMs e.g. 5th ISNS-RPNS, WHO-NIBSC/ are validated by CDC samples. 👣 Excellent correlation to other commercial Colorimetric & Fluorometric assays and CDC target values. 👣 Born Safe kits are available both in smaller (96T) and in larger pack sizes (192T) suitably fitting into the requirements of every NBS Lab. 👣 Manufactured in India Plant, hence efficient management of supply & logistics across country.