BornSafe™

T.GAL

Parameter	**TGAL**

Intended Use

The Born Safe™ Neonatal Total Galactose Screening Assay is an enzymatic assay for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in neonates using blood spot samples dried on Whatman S&S 903 filter paper. This kit is particularly suitable for use in a neonatal screening program to measure concentrations as an aid in identifying galactosemia in newborns. Elevated results are not diagnostic *per se* of galactosaemia, but indicate the urgent need for further study of the newborn from which the 'presumptive positive' specimen was received. This kit is not intended for use in monitoring the circulating concentrations of total galactose in galactosaemic patients nor for confirmatory testing.

Principle

The Total Galactose (galactose and galactose-1-phosphate) from cellulose paper (dried blood spot samples) is extracted with trichloroacetic acid (Elution buffer). After extraction, the eluted sample is combined with the enzymes-coenzyme reagent containing alkaline phosphatase (AP), galactose dehydrogenase (GaldeH) and NAD. Galactose-1-phosphate is converted to galactose by AP. GaldeH oxidizes the galactose to galactonolactone reducing NAD to NADH. The NADH produced, reacts with a colour reagent in which tetrazolium salt gets reduced producing a distinct colour. This colour can be measured colorimetrically with a photometer at 550 nm and is directly proportional to the concentration of total galactose present in the sample.

Kit Components

Reagents

- Calibrators and Controls blood spots: 1+1 set of blood spot cards of human whole blood spotted on Whatman S&S 903 paper containing 5 calibrators and 2 controls (L1-L2). Refer to the quality control sheet for the exact concentrations of the Calibrators and acceptable value ranges of the Controls.
- Elution Buffer: 1 X 10 ml of TCA 3% w/v.
- Enzyme I: 1 X 0.1 ml of Alkaline phosphatase with buffer and a stabilizer.
- Enzyme II: 1 X 0.5 ml of galactose dehydrogenase.
- Coenzyme: 4 X 1.5 ml of Lyophilized NAD. Reconstitute with 1.5 ml of distilled water each. After reconstitution, the reagent can be stored at 2-8° C for one month.
- Dilution Buffer: 1 X 5 ml of buffer. Preservative NaN_3 (< 0.1%). If a precipitate is observed, put the solution few minutes at 37°C.
- Colour Reagent: 1 X 8 ml. of tetrazolium salt. Preservative: NaN_3 (< 0.1%).
- Colour Booster: 1 X 1 ml of a solution of an intermediate electron receptor in buffer. Preservative NaN_3 (< 0.1%).

Accessories

- Round bottom microtiter plates (Elution Plates)
- Flat-bottom microtiter plates with superior optical quality (Assay Plates)

Linearity	0-59 mg/dl
Pack size	96 Tests

Key Distinctions

Born Safe TGAL 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 TGAL Calibrators & assay kits 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. **First of its kind:** Integral kit components e.g. Round bottom breakapart wells, Reaction wells are supplied along with other assay reagent components without any extra charge.