



Parameter MSUD









Intended Use The Born Safe™ Neonatal MSUD Screening Assay is an enzymatic colorimetric method for the quantitative detection of Maple Syrup Urine Disease in new born using blood spot samples dried on Whatman S&S 903 filter paper. This test is intended as a screening method for measuring the L-branched-chain amino acid (BCAA) concentrations in newborn blood spot specimens. Elevated results are not diagnostic *per se* of maple syrup urine disease, but indicate the urgent need for further study of the newborn from which the presumptive positive specimen was received. The kit should not be used for confirmatory testing or to monitor therapy.

Principle The Leucine and BCAAs from cellulose paper (dried blood spot samples) are extracted with trichloroacetic acid (Elution buffer). After extraction, the eluted sample is combined with the enzyme reagent Leucine dehydrogenase. This enzyme reagent catalyses the NAD-dependent oxidative deamination of Leucine and L-BCAAs to α -ketoisocaproate acid. 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 Leucine and BCAA present in the sample.

- Kit Components** **Reagents**
- Calibrators and Controls blood spots: 1+1 set of blood spots cards of human whole blood spotted onto Whatman S&S 903 paper containing 5 calibrators and 2 controls with low and high concentrations of Leucine. 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. Ready to use.
 - Enzyme: 4 X 1 ml of Leucine dehydrogenase lyophilized with buffer and a stabilizer. Reconstitute each vial with 1ml of distilled water. After reconstitution, the reagent can be stored at 2-8° C for one month.
 - Coenzyme: 4 X 1 ml of Lyophilized NAD. Reconstitute each vial with 1 ml of distilled water. After reconstitution, the reagent can be stored at 2-8° C for one month.
 - Colour Reagent: 1 X 8 ml. of tetrazolium salt. Ready to use. Preservative: NaN_3 (<0.1%).
 - Colour Booster: 1 X 1.0 ml of a solution of an intermediate electron receptor in buffer. Ready to use. Preservative NaN_3 (<0.1%).
 - Dilution Buffer: 1 X 2 ml of buffer. Ready to use. Preservative NaN_3 (<0.1%).

Accessories	● Round bottom microtiter plates (Elution Plates)	Linearity	0-17.4 mg/dl
	● Flat-bottom microtiter plates with superior optical quality (Assay Plates)	Pack size	96 Tests

Key Distinctions

 Born Safe MSUD 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 MSUD Calibrators & assay kits are validated by CDC samples.
  Excellent correlation to other commercial Colorimetric assay 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.