



Parameter	РКИ		
Intended Use	The Born Safe <sup>™</sup> Neonatal PKU Screening Assay is an enzymatic assay for the quantitative determination of phenylalanine 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 Phenylalanine concentrations as an aid in identifying Phenylketonuria in new-borns. Elevated results are not diagnostic per se of phenylketonuria, but indicate the urgent need for further study o the new born from which a presumptive positive sample was received. The kit is not intended for use in monitoring the circulating phenylalanine concentrations of phenylketonuria patients for the purpose of assessing dietary control, nor for confirmatory testing.		
Principle	The Phenylalanine from cellulose paper (dried blood spot samples) is extracted with trichloroacetic acid (Elution buffer) After extraction, the eluted sample is combined with the enzyme reagent Phenylalanine dehydrogenase. This enzyme reagent catalyses the NAD-dependent oxidative deamination of Phenylalanine to phenylpyruvate and ammonia. 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 Phenylalanine present in the sample.		
Kit Components	Reagents		
	<ul> <li>Calibrators and Controls blood spots: 1 +1 sets of blood spots cards of human whole blood spotted onto Whatman S&amp; 903 paper containing 5 calibrators calibrated with 5<sup>th</sup> ISNS-Reference Preparation for Neonatal Screening (5<sup>th</sup> ISNS RPNS) and 2 controls. Refer to the quality control sheet for the exact concentrations of the Calibrators and acceptabl value ranges of the Controls.</li> </ul>		
	• Elution Buffer: 1 X 10 ml of TCA 3% w/v. Ready to use.		
	<ul> <li>Enzyme: 4 X 1 ml of Phenylalanine dehydrogenase lyophilized with buffer and a stabilizer. Reconstitute each vial wit 1ml of distilled water. After reconstitution, the reagent can be stored at 2-8° C for one month.</li> </ul>		
	<ul> <li>Coenzyme: 4 X 1 ml of Lyophilized NAD. Reconstitute each vial with 1 ml of distilled water. After reconstitution, th reagent can be stored at 2-8° C for one month.</li> </ul>		
	<ul> <li>Colour Reagent: 1 X 8 ml. of tetrazolium salt. Ready to use. Preservative: NaN<sub>3</sub> (&lt; 0.1%).</li> </ul>		
	<ul> <li>Colour Booster: 1 X 1 ml of a solution of an intermediate electron receptor (&lt; 0.1%).</li> </ul>	in buffer. Ready to use	e. Preservative NaN
	• Dilution Buffer: $1 X 2 ml$ of buffer. Ready to use. Preservative NaN <sub>3</sub> (< 0.1%).		
Accessories	<ul> <li>Round bottom microtiter plates (Elution Plates)</li> </ul>	Linearity	0- 18.9 mg/dl
	• Flat-bottom microtiter plates with superior optical quality (Assay Plates)	Pack size	96 Tests
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born Sale PKO is Indian PDA 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 PKU Calibrators are traceable to international CRMs e.g. 5th ISNS-RPNS/ 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.