BornSafe™

G-6PD

Parameter	G-6PD
Intended Use	The Born Safe™ Neonatal G-6-PD Screening Assay is an enzymatic colorimetric assay for the quantitative determination of glucose-6-phosphate dehydrogenase (G6PD) activity in blood specimens dried on Whatman 903 filter paper. This test is intended for use as a screening method for red cell glucose-6-phosphate dehydrogenase deficiency in new-borns.
Principle	The Neonatal G-6-PD Screening Assay uses dried blood spots specimens (cellulose paper) eluted in a buffer. After the elution step, the eluate containing G-6-PD is incubated with a reagent containing glucose-6-phosphate, which in the presence of NADP, catalyses the oxidation of glucose-6-phosphate to 6-phosphogluconate. The NADPH produced reacts with a colour reagent in which a tetrazolium salt gets reduced producing a distinct colour. This colour is measured at 550 nm and is directly proportional to the concentration of Glucose-6-phosphate dehydrogenase present in the sample. The results are calculated by evaluating the increase in OD per minute for unknowns against the calibrator with known G-6-PD activity. The reduced tetrazolium salt can be measured by a two-point measurement mode using two measurements one at time = 0 min, and the second one at time = 15 min.
Kit Components	**Reagents** ● Calibrator and Controls blood spots: 1 +1 set of dried blood spots cards of human whole blood spotted onto Whatman S&S 903 paper containing 1 calibrator and 2 controls. ● Elution Buffer: 1 X 8 ml of buffered solution. Ready to use. Preservative NaN_3 (< 0.1%). ● Reagent: For 96T: 4 X 2 ml of Glucose-6-phosphate solution. Lyophilized. Reconstitute with 2 ml of distilled water. After reconstitution, the reagent can be stored at 2-8° C for one month. Preservative: NaN_3 (< 0.1%). ● Colour Reagent: 1 X 8 ml. of tetrazolium salt. Ready to use. Preservative NaN_3 (< 0.1%). ● Colour Booster: 1 X 1 ml of intermediate electron acceptor. Ready to use. Preservative NaN_3 (< 0.1%).
Accessories	● Round bottom microtiter plates (Elution Plates) ● Flat-bottom microtiter plates with superior optical quality (Assay Plates)
Pack size	96 Tests

Key Distinctions

Born Safe G6PD 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, G6PD-PMF, Taiwan). Born Safe G6PD 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.