



Parameter Biotinidase (BIOT)

Intended Use Biotinidase Screening Assay is an enzymatic assay for the quantitative determination of biotinidase activity 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 as an aid in identifying biotinidase deficiency in new-borns. The kit should not be used for confirmatory testing or to monitor therapy.

Principle The biotinidase from cellulose paper (dried blood spot samples) is extracted with a buffer containing the artificial substrate biotin 4-amidobenzoic acid (B-PAB). The biotinidase enzyme catalyses the release of free 4-amidobenzoic acid (PABA) from B-PAB. The reaction is stopped by trichloroacetic acid which denatures the biotinidase. Then the colour reaction begins: the PABA produced reacts with sodium nitrite to form a diazotized compound (the nitrite in excess is neutralized with the ammonium sulfamate); after that the diazotized compound reacts with the NED to form an azo-dye. The purple colour produced can be measured colorimetrically with a photometer at 550 nm and is directly proportional to the activity of biotinidase present in the sample.

Kit Components **Reagents**

- Calibrators and Controls blood spots: 1+1 set of blood spot cards of porcine whole blood spotted onto Whatman S&S 903 paper containing 6 calibrators (with known concentrations of PABA) and 2 controls. Refer to the quality control sheet for the exact concentrations of the Calibrators and acceptable value ranges of the Controls.
- Substrate buffer: 4 X 2.5 ml of lyophilized buffer containing substrate (B-PAB), a preservative and a stabilizer. Reconstitute each vial with 2.5 ml of distilled water. The reconstituted substrate is stable for 3 months at 2-8 °C.
- Stop solution: 1 x 10 ml of trichloroacetic acid 30% (w/v). Ready to use.
- Colour Reagent 1: 1 X 3 ml of sodium nitrite with a preservative. Ready to use.
- Colour Reagent 2: 1 X 3 ml of ammonium sulfamate with a preservative. Ready to use.
- Colour Reagent 3: 1 X 3 ml of N-(1-Naphthyl) ethylenediamine dihydrochloride (NED). Ready to use.

Accessories	● Microtubes	Linearity	2.4-93.3 µmol/dL
	● Flat-bottom microtiter plates with superior optical quality (Assay Plates)	Pack size	96 Tests

Key Distinctions

 Born Safe Biotinidase 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).
  Born Safe Biotinidase Calibrators & assay kits are validated by CDC samples.
  Excellent correlation to other 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. Reaction wells, Microtubes are supplied along with other assay reagent components without any extra charge.