PRODUCT SHEET

Seraseq® Newborn DNA Mixes

Comprehensive reference materials for NGS-based Newborn assay development, validation, and routine QC use

Traditionally, newborn screening relied on biochemical markers (e.g., enzyme activity or metabolite levels) via dried blood spots. However, the field is rapidly shifting toward Genomic Newborn Screening. By using NGS, labs can screen for a much broader array of conditions with higher specificity, often identifying disorders before clinical symptoms appear.

Despite rapid adoption of genomic newborn screening, laboratories often face limited access to well-characterized reference materials that accurately reflect real clinical samples. They also face several hurdles:

- Rarity of Samples: Sourcing high-quality positive samples for rare diseases like Hemophilia B is difficult and often unsustainable.
- Complex Inheritance: Accurate screening often requires understanding the maternal-fetal genetic relationship to rule out false positives or confirm carrier status.
- Lot-to-Lot Variability: Patient-derived remnants are inconsistent, making longitudinal quality control (QC) nearly impossible.

Sustainable, renewable standards are essential to support assay validation, regulatory compliance, and ongoing performance monitoring.

Highlights

Reference materials for rare disease and newborn screening workflows.

Matched maternal and offspring samples for evaluation of inheritance & variant transmission.

Sustainable, consistent, and readily available.

Seraseq® Newborn Reference Materials address this gap by providing clinically relevant, inheritance-ready genomic controls specifically designed for newborn screening applications. They consist of genomic DNA isolated from immortalized maternal and fetal cell lines collected from either a Hemophilia B carrier pregnant patient with a non-affected fetus or from a healthy pregnant patient carrying a fetus with Spinal Muscular Atrophy (SMA).

FEATURES AND BENEFITS

- **Inheritance-ready sample design (duo option):** material available as **matched maternal + offspring (duo)** to support evaluation of inheritance analysis in rare disease workflows.
- **Designed for newborn screening workflows:** helps labs establish assay accuracy, precision, sensitivity/LoD, and reproducibility using standardized, ready-to-use reference materials.
- **Clinically relevant content:** includes confirmed clinically significant variants relevant to Hemophilia B and Spinal Muscular Atrophy (SMA) screening.
- **Sustainable, scalable supply:** cell line–based approach supports lot consistency and ongoing availability for repeated validation and longitudinal QC.
- **Manufactured under quality systems:** produced in cGMP-compliant, ISO 13485-certified facilities with stringent release testing.

ORDERING INFORMATION

Product	Material	Concentration	Fill in Size	Total Mass
Seraseq® Newborn DNA Mix SMA - Child	0720-1173	>15 ng/µL	1 x 25 µL	>375 ng
Seraseq® Newborn DNA Mix SMA - Mother	0720-1174	>15 ng/µL	1 x 25 µL	>375 ng
Seraseq® Newborn DNA Mix Hemo - Child	0720-1175	>15 ng/µL	1 x 25 µL	>375 ng
Seraseq® Newborn DNA Mix Hemo - Mother	0720-1176	>15 ng/µL	1 x 25 µL	>375 ng