Seraseq®

Newborn Screening DNA Mixes

Package Insert

PLEASE NOTE:
THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE

The Seraseq® Newborn DNA Mixes are intended for use with Next Generation Sequencing (NGS) assays that identify variants present in the genome. The Seraseq Newborn DNA Mixes are intended as quality reference materials for translational and disease research testing, and monitor library preparation, sequencing, and variant allele detection under a given set of bioinformatics pipeline parameters.
For Research Use Only. Not for use in diagnostic procedures.

SUMMARY

A well-designed quality control program can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent reference products may provide valuable information concerning assay accuracy and bioinformatics pipeline analysis.

PRINCIPLES OF THE PROCEDURE

The Seraseq Newborn DNA Mix SMA - Child and Seraseq Newborn DNA Mix Hemo - Child products consist of purified fetal genomic DNA isolated from an immortalized cell line derived from cord blood. The pregnancies were characterized as either a healthy individual carrying a fetus with Spinal Muscular Atrophy (SMA) or as a Hemophilia B carrier carrying a healthy fetus.

Seraseq Newborn DNA Mix SMA - Mother consists of purified genomic DNA isolated from an immortalized cell line derived from a postpartum (or postnatal) healthy pregnant patient's blood sample whose fetus has been identified with and treated for Spinal Muscular Atrophy (SMA).

Seraseq Newborn DNA Mix Hemo - Mother consists of purified genomic DNA isolated from an immortalized cell line derived from a postpartum (or postnatal) pregnant patient's blood sample. The pregnancy has been characterized as a Hemophilia B carrier carrying a non-affected fetus. See Table 2 for variant detail.

The Seraseq Newborn DNA Mixes are ready-to-use in Next Generation Sequencing (NGS) assays in steps that follow DNA isolation; no further purification or DNA isolation is needed. The reference materials should follow the same workflow as unknown samples. The products contain DNA at a nominal concentration of 15 ng/µL.

The reference materials are formulated in 1 mM Tris, 0.1 mM EDTA pH 8.0 which is a buffer that is compatible with both PCR-based target amplification and hybridization-based target selection methods.

REAGENTS

Table 1. Seraseq Newborn DNA Mixes

Material No.	Product
0720-1173	Seraseq Newborn DNA Mix SMA - Child
0720-1174	Seraseq Newborn DNA Mix SMA - Mother
0720-1175	Seraseq Newborn DNA Mix Hemo - Child
0720-1176	Seraseq Newborn DNA Mix Hemo - Mother

Each Material No. is available as an individual product. Information in this Package Insert applies to all products. 1 vial, 25 µL per vial, >15 ng/µL concentration.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle the Seraseq Newborn DNA Mixes and all materials derived from human blood products as though they are capable of transmitting infectious agents. The Seraseq Newborn DNA Mixes are manufactured using genomic DNA extracted from pregnant patients' cell lines, derived either from blood drawn postpartum or from umbilical cord blood. Purified genomic DNA is formulated in 1 mM Tris, 0.1 mM EDTA pH 8.0 (0.1X TE pH 8.0).

Safety Precautions
Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens[1]. Do not pipette by mouth; do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions
Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store the Seraseq Newborn DNA Mixes frozen at -20 °C or colder. Once opened, a vial can be thawed and re-frozen up to five (5) times. Sub-aliquoting of the product into low DNA binding tubes may be advisable to limit the number of freeze/thaw cycles to five (5) or less.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

The Seraseq Newborn DNA Mixes are mixtures of human genomic DNA derived from immortalized patient white blood cells. It should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

PROCEDURE

Materials Provided
The Seraseq Newborn DNA Mixes are a mixture of human genomic DNA derived from immortalized patient white blood cells. The Seraseq Newborn DNA Mixes are formulated in a 1 mM Tris / 0.1 mM EDTA pH 8.0 aqueous buffer. Twenty-five (25) µL is provided per tube and the concentration is 15 ng/µL.

Materials Required but not Provided
Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use
Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous solution and spin briefly. The Seraseq Newborn DNA Mixes should be integrated into library preparation after the DNA isolation step. If a DNA shearing step is part of the workflow, the Seraseq Newborn DNA Mixes should be integrated into library preparation after the DNA isolation step. Refer to standard assay procedures in order to determine the amount of material to use.

Quality Control
Although the Seraseq Newborn DNA Mixes are designed to simulate a gDNA sample from a person with SMA or Hemophilia B, the products do not have assigned values for mutation frequencies. There are many reasons why assays may observe deviation from the representative data which may or may not be of significance. It is therefore recommended that each laboratory qualify the use of the Seraseq Newborn DNA Mixes with each assay system prior to its routine use.

INTERPRETATION OF RESULTS

Detection of the variants within the Seraseq Newborn DNA Mixes may vary with different types of tests and different test kit lots. Since the reference material does not have an assigned value, the laboratory must establish a range for each lot of the Seraseq Newborn DNA Mixes. When results for the product are outside of the established acceptance range, it may indicate unsatisfactory test performance. Possible sources of error include deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents or change in bioinformatics pipeline parameters.

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LIMITATIONS OF THE PROCEDURE
THE SERASEQ NEWBORN DNA MIXES MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES and *INTERPRETATION OF RESULTS* provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. The Seraseq Newborn DNA Mixes are not calibrators and should not be used for assay calibration. Adverse shipping and storage conditions or use of outdated products may produce erroneous results.

EXPECTED RESULTS
Specific detection of variants and variant allele frequencies will vary among different assays, different procedures, different lot numbers, and different laboratories. Each laboratory should establish its own acceptance criteria. For example, the acceptable range for each variant might include all values within two standard deviations of the mean of 20 data points obtained in 20 runs[2].

SPECIFIC PERFORMANCE CHARACTERISTICS
The Seraseq Newborn DNA Mixes have been designed for use with NGS sequencing procedures for the purpose of evaluating assay performance. The Seraseq Newborn DNA Mixes do not have assigned values. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

REFERENCES
1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
2. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Fourth Edition. CLSI document C24, 2016.

Table 2: Key pathogenic mutation in the factor IX gene (F9) observed in the hemophilia B carrier or "Seraseq Newborn DNA Mix Hemo – Mother" (Material No. 0720-1176):

Gene ID	Nucleotide change	Protein change	Hg38 Nucleotide No.	hg19 Nucleotide No.	Mutation Type	Mechanism	Chromosome
F9	c.797C>T	p.(Ala266Val)	g.139560814C>T	g.138642973C>T	Missense	Substitution	Chromosome X Exon 7