Seraseq®

Antepartum & Postpartum SMA Male – Matched cfDNA Package Insert

NAME AND INTENDED USE

The Seraseq® Antepartum SMA Male - Matched cfDNA and Postpartum SMA Male - Matched cfDNA are intended as reference materials for non-invasive prenatal testing (NIPT) of fetal Spinal Muscular Atrophy (SMA) in pregnant patients via cell-free DNA (cfDNA) analysis. This reference material is suitable for use by clinical laboratories, research institutions, and diagnostic assay developers to ensure consistent and reliable results across different sequencing runs and laboratory conditions.

Those Seraseq reference materials are not intended for use in patient diagnosis, treatment, or in any therapeutic procedures. It is intended for use by trained laboratory personnel proficient in NGS technologies and familiar with proper laboratory practices and quality control procedures. *For Research Use Only (RUO). Not for use in diagnostic procedures.*

REAGENT PROVIDED

Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA materials are a mixture of matched (or related) maternal and fetal circulating cell-free DNA in pregnant donor blood samples whose male fetus has been diagnosed with SMA. The antepartum cfDNA is derived from a blood sample drawn prenatally, whilst the postpartum cfDNA is derived from a blood sample drawn after birth from the same patient.

Those products are intended to be used as supplied. To establish assay limit of detection (LoD), the antepartum material can be diluted using the Seraseq Postpartum SMA Male - Matched cfDNA to decrease the observed fetal fraction of the Seraseq Antepartum SMA Male cfDNA.

Table 1. Seraseq Antepartum and Postpartum SMA Male cfDNA

Material No.	Product	Format
0720-1115	Seraseq® Antepartum SMA Male - Matched cfDNA	Purified cfDNA 1 vial of 25 µL (1 mM Tris, 0.1 mM EDTA, 10 mM KCl. pH 8.0)
0720-1129	Seraseq® Postpartum SMA Male - Matched cfDNA	

Supplied as one (1) vial, 25 µL per vial, 250 ng total mass, at a nominal concentration of 10 ng/µL is provided. The product is formulated in a 1 mM Tris / 0.1 mM EDTA pH 8.0 aqueous buffer. Refer to the batch-specific Technical Product Report for exact concentration and estimated Fetal Fraction measured. Manufactured in the USA.

WARNINGS AND PRECAUTIONS

Safety and Handling Precautions

Handle Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA and all materials derived from human blood products as though it is capable of transmitting infectious agents. 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 it up with 0.5% sodium hypochlorite solution. Avoid contamination of the product when opening and closing the vials. Dispose of all specimens and materials appropriately.

STORAGE INSTRUCTIONS

Store Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA 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

Seraseq Antepartum and postpartum SMA Male - Matched cfDNA 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 Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use

Thaw the product vial on ice before use. Mix by vortexing to ensure a homogeneous solution and spin briefly. Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA – should be integrated into library preparation after the DNA isolation step and go through the entire library preparation and sequencing or microarray hybridization steps in parallel with test specimens. Refer to standard assay procedures in order to determine the amount of material to use.

If the NIPT assay workflow does not allow inputting the sample after the cfDNA isolation step, the Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA may be inserted into the workflow in a manner consistent with plasma fractions prior to extraction. This can be achieved by further dilution in a buffer compatible with the cfDNA extraction procedure, such as SeraCare SeraCon™ Matribase, PBS, or other suitable diluent. Refer to standard assay procedures in order to determine the total volume and minimum amount of DNA to use. Perform the additional dilution immediately before proceeding with cfDNA extraction; do not store, freeze, or thaw diluted product.

The Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA products may be diluted by the user to decrease the estimated fetal fraction of the sample.

Optional Reagents Not Supplied

- SeraCon™ Matribase Negative Diluent (cat #1800-0022). Available at www.seracare.com
- Phosphate buffered saline (PBS)

INTERPRETATION OF RESULTS

Detection of monogenic disease and determination of fetal fraction may vary with method used, bioinformatic parameters, test reagent lots and other parameters[2]. Since the reference material does not have assigned values, the laboratory must establish an acceptable range for each lot of Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA. 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.

EXPECTED RESULTS

Specific detection of chromosomal abnormality and estimation of fetal fraction will vary among different assays, procedures, lot numbers, and laboratories[2]. Each laboratory should establish its own range of acceptable values. It is recommended that any blending of the Antepartum and Postpartum cfDNA is performed based on the fetal fraction determination established in each laboratory with the assay with which the product is intended to be used.

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LIMITATIONS OF THE PROCEDURE

Seraseq Antepartum and postpartum SMA Male - Matched cfDNA MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE 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. Data are provided for informational purposes. LGC Clinical Diagnostics does not claim that others can duplicate test results exactly. Note that based on your particular assay and analysis parameters, a different fetal fraction value may be calculated. Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA 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.

Note that the Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA may not be compatible with certain NIPT methods based on the specific assay design and methodology.

SPECIFIC PERFORMANCE CHARACTERISTICS

The Seraseq Antepartum and postpartum SMA Male - Matched cfDNA does not have assigned values for SMA or fetal fraction. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory. There are many reasons why assays may observe variations in performance, which may or may not be of significance. It is therefore recommended that each laboratory qualify the use of each lot of Seraseq Antepartum and Postpartum SMA Male - Matched cfDNA with each assay system prior to its routine use.

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. Becking, EC, Linthorst J, Patton S. et al., 2023. Variability in Fetal Fraction Estimation: Comparing Fetal Fractions Reported by Noninvasive Prenatal Testing Providers Globally. Clinical chemistry, 69(2), 160–167. https://doi.org/10.1093/clinchem/hvac207

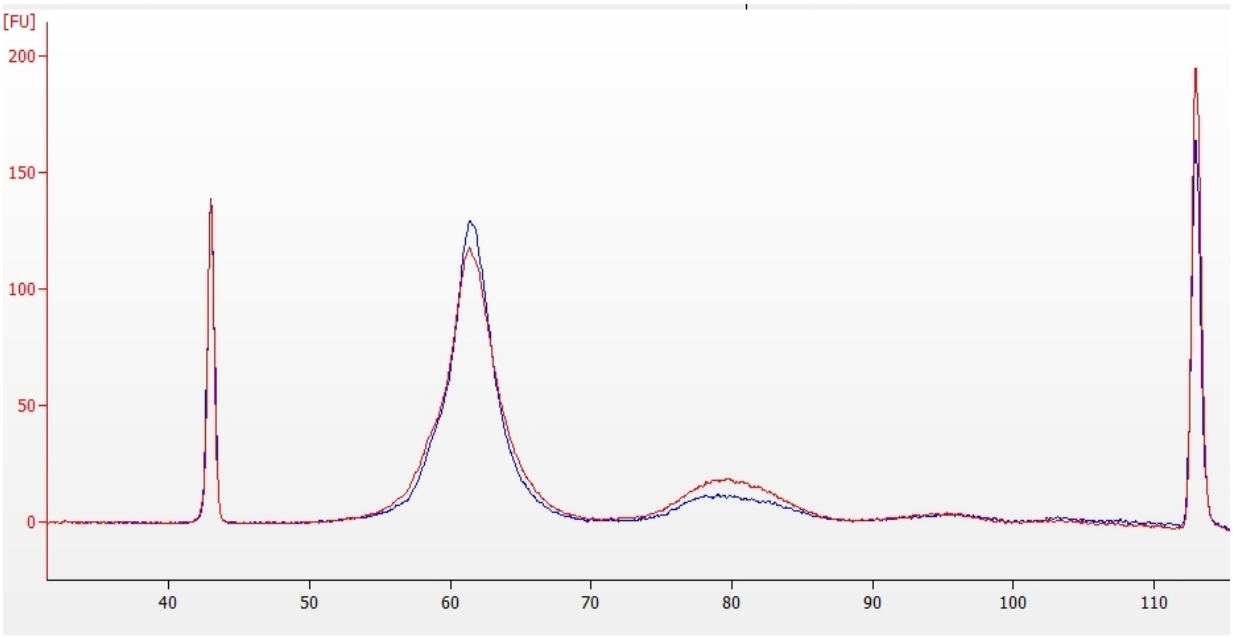

Figure 1: Representative DNA fragment size distribution for Seraseq Antepartum (red) and Postpartum (blue) SMA Male – Matched cfDNA. Main cfDNA peak is present at 162 bp, additional peak at approximately 330 bp.