Seraseq®

22q11 Male Twins - Matched cfDNA

Package Insert

NAME AND INTENDED USE

The Seraseq® 22q11 Male Twins - Matched cfDNA is a reference material intended for use in the development, validation, and evaluation of routine performance monitoring of Non-Invasive Prenatal Testing/Screening (NIPT /NIPS) using circulating cell-free DNA (cfDNA) in maternal blood to screen for fetal microdeletion (DiGeorge syndrome). 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.

The Seraseq 22q11 Male Twins - Matched cfDNA is 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 22q11 Male Twins - Matched cfDNA is derived from cfDNA extracted from a pregnant patient source sample carrying two monochorionic diamniotic (MCDA) twins - two identical male fetuses with a confirmed 22q11 microdeletion. The material is further processed to maintain natural cfDNA size profile of both fetus and maternal DNA of approximately 170 base pairs in average (Figure 1). The microdeletion status of the final product is confirmed by an external NIPT assay (eefer to the batch-specific Technical Product Report).

Table 1. Seraseq 22q11 Male Twins - Matched cfDNA

Material No.	Product	Format
0720-1116	Seraseq® 22q11 Male Twins - Matched cfDNA	1x 25 µL

One (1) vial, 25 µL per vial, at a nominal concentration of >10 ng/µL (>250 ng total mass) is provided. Refer to the batch-specific Technical Product Report for exact concentration. Manufactured in the USA.

WARNINGS AND PRECAUTIONS

Safety and Handling Precautions

Handle Seraseq 22q11 Male Twins - 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 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 the reagent 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 22q11 Male Twins - Matched cfDNA is derived from naturally occurring human cfDNA supplied in 25 µL 1 mM Tris, 0.1 mM EDTA, 10 mM KCl buffer. 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 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 22q11 Male Twins - 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 22q11 Male Twins - 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.

Optional Reagents Not Supplied

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

Quality Control

Seraseq 22q11 Male Twins - Matched cfDNA does not have assigned values for the microdeletion 22q11 or fetal fraction. 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 22q11 Male Twins - Matched cfDNA with each assay system prior to its routine use.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Detection of chromosomal abnormality and estimation of fetal fraction will vary among different assays, bioinformatic parameters, procedures, lot numbers, and other parameters[2]. Each laboratory should establish its own range of acceptable values for each lot of Seraseq 22q11 Male Twins - 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.

LGC Clinical Diagnostics, Inc. | 37 Birch Street, Milford, MA 01757 USA
Phone: +1 508.244.6400 | Toll Free (US Only) 800.676.1818
CDx-info@LGCGroup.com | www.seracare.com

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LIMITATIONS OF THE PROCEDURE

SERASEQ 22Q11 MALE TWINS - 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 22q11 Male Twins - Matched cfDNA is not a calibrator and should not be used for assay calibration. Adverse shipping and storage conditions or use of outdated products may produce erroneous results.

Note that Seraseq 22q11 Male Twins - Matched cfDNA may not be compatible with certain NIPT methods based on the specific assay design and methodology.

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.
3. Human Genetic and Genomic Testing Using Traditional and High-Throughput Nucleic Acid Sequencing Methods. Third Edition. CLSI guideline MM09, 2023.

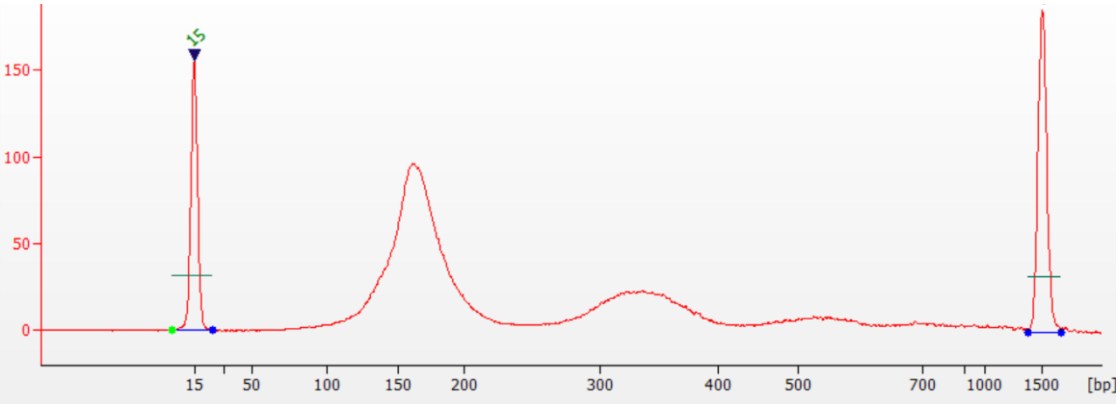

Figure 1: Representative cfDNA size distribution for Seraseq 22q11 Male Twins - Matched cfDNA. CfDNA fragments separated by electrophoresis show a prominent peak around 162 bp.

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