

NAME AND INTENDED USE

The Seraseq® T18 Female - Matched Reference Material (Lyophilized) 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 chromosomal aneuploidies such as Trisomy 18 (Edwards 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 T18 Female - Matched Reference Material (Lyophilized) 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 T18 Female - Matched Reference Material (Lyophilized) is derived from cfDNA extracted from a pregnant donor blood sample whose female fetus has been diagnosed with Trisomy 18 (Edwards Syndrome). The material is further processed to maintain the natural cfDNA size profile of fetal and maternal DNA of approximately 170 base pairs on average (Figure 1). The aneuploidy status of the final product is confirmed by an external NIPT assay (refer to the batch-specific Technical Product Report).

Table 1. Seraseq T18 Female - Matched Reference Material (Lyophilized)

Material No.	Product	Format
0720-1138	Seraseq® T18 Female - Matched Reference Material (Lyophilized)	1x 10 ng Lyophilized

One (1) vial, >10 ng per vial, based on extracted ccfDNA recovered from a QIAamp® ccfDNA extraction kit, is provided. Refer to the batch-specific Technical Product Report for exact yield. Manufactured in the USA.

WARNINGS AND PRECAUTIONS

Safety and Handling Precautions

Handle Seraseq T18 Female - Matched Reference Material (Lyophilized) 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 specimens¹. 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 at ambient temperature (15°C to 25°C).

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq T18 Female - Matched Reference Material (Lyophilized) is derived from naturally occurring human cfDNA supplied lyophilized previously diluted in 1 mL of ~1X SeraCon™ Matribase Negative Diluent with 5 mM EDTA. It should appear as a powder. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

PROCEDURE

Materials Required but not Provided

Molecular grade water

Instructions for Use

This material is intended for use as a single-use aliquot. Detach blue cap from the vial. Break and remove the metal seal covering the opening of the vial. Remove the gray stopper and rehydrate the lyophilized cake with 1 mL of molecular grade water. Reinsert the gray stopper and continuously swirl the vial in a gentle circular motion for approximately 30 seconds or until the lyophilized cake has dissolved completely into solution. Avoid inverting or shaking the vial vigorously. The rehydrated solution can be kept at room temperature for up to one hour, though it is recommended to perform extraction immediately.

Seraseq T18 Female - Matched Reference Material (Lyophilized) should be integrated into library preparation before the DNA extraction 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.

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.

Quality Control

Seraseq T18 Female - Matched Reference Material (Lyophilized) does not have assigned values for 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 T18 Female - Matched Reference Material (Lyophilized) 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 parameters². Each laboratory should establish its own range of acceptable values for each lot of Seraseq T18 Female - Matched Reference Material (Lyophilized). 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.

LIMITATIONS OF THE PROCEDURE

SERASEQ T18 FEMALE - MATCHED REFERENCE MATERIAL (LYOPHILIZED) 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 T18 Female - Matched Reference Material (Lyophilized) 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 T18 Female - Matched Reference Material (Lyophilized) 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.

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

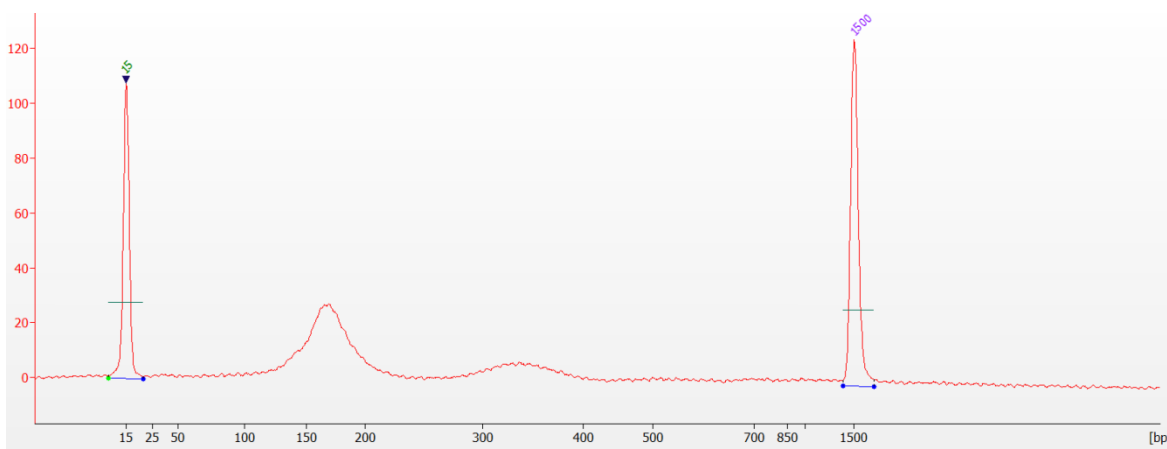


Figure 1: Representative cfDNA size distribution for Seraseq T18 Female - Matched Reference Material (Lyophilized). The cfDNA fragments separated by electrophoresis show a prominent peak around 167 bp.