Seraseq®

Trisomy 13 Female - Matched Reference Material

Package Insert

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

NAME AND INTENDED USE

The Seraseq® Trisomy 13 Female - Matched Reference Material is formulated for use with whole genome or targeted Next Generation Sequencing (NGS) assays, dPCR or microarray assays that screen for Trisomy 13 (Patau Syndrome) chromosomal abnormality in cell-free fetal DNA (cfDNA). The Seraseq Trisomy 13 Female - Matched Reference Material, created with matched (or related) maternal-fetal source material, is intended as a reference material for researchers and Non-Invasive Prenatal Testing (NIPT) labs to monitor library preparation, sequencing, and detection performance.
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

Seraseq Trisomy 13 Female - Matched Reference Material is ready-to-use in an assay starting with DNA extraction similar to an actual test sample. The Reference Material contains processed human cfDNA derived from matched maternal-fetal source material and is formulated in a commutable matrix (simulated plasma) that is compatible with varying assays including shotgun sequencing and microarray-based methods following extraction.

REAGENTS

Table 1. Seraseq Trisomy 13 Female - Matched Reference Material

Material No.	Product
0720-0780	Seraseq® Trisomy 13 Female - Matched Reference Material

1 vial, 1mL per vial, >20 ng/mL concentration (see batch-specific Technical Product Report for exact concentration).

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Trisomy 13 Female - Matched Reference Material and all materials derived from human blood products as though it is capable of transmitting infectious agents. Seraseq Trisomy 13 Female - Matched Reference Material is manufactured using processed human cfDNA. Purified cfDNA mixture is formulated in a commutable matrix (simulated plasma) containing human protein isolates (SeraCare's SeraCon™ Matribase).

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 Seraseq Trisomy 13 Female - Matched Reference Material refrigerated at 2 - 8°C. Do not freeze. Samples are designed to be single use.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq Trisomy 13 Female - Matched Reference Material is a mixture of human DNA (maternal and fetal). It should appear as a clear to pale yellow liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

PROCEDURE

Materials Provided

Seraseq Trisomy 13 Female - Matched Reference Material is produced from DNA extracted from a pregnant patient source sample carrying a female fetus with confirmed Trisomy 13. 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 DNA is stabilized and introduced into a dilution of SeraCare's SeraCon™ Matribase (simulated plasma). One (1) mL is provided per tube at >20 ng/mL concentration.

Materials Required but not Provided

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

Instructions for Use

Seraseq Trisomy 13 Female - Matched Reference Material may be inserted into workflows in a manner consistent with plasma fractions prior to DNA extraction. Mix by vortexing to ensure a homogeneous solution. Do not centrifuge. Following extraction, Seraseq Trisomy 13 Female - Matched Reference Material must go through the entire library preparation and sequencing steps in parallel with the test specimens. Refer to your usual assay procedures in order to determine the amount of material to use. Each vial is intended for a single use.

Quality Control

Although Seraseq Trisomy 13 Female - Matched Reference Material does not have assigned values for trisomy 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 Trisomy 13 Female - Matched Reference Material with each assay system prior to its routine use.

INTERPRETATION OF RESULTS

Detection of aneuploidy may vary with different NGS and microarray assays and different test reagent lots. Since the reference material does not have an assigned value, the laboratory must establish an acceptable range for each lot of Seraseq Trisomy 13 Female - Matched Reference Material. 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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14239-01 June 2023

LIMITATIONS OF THE PROCEDURE

Seraseq Trisomy 13 Female - Matched Reference Material 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. Seraseq Trisomy 13 Female - Matched Reference Material is not a calibrator and should not be used for assay calibration. Note that the Seraseq Trisomy 13 Female - Matched Reference Material may not be compatible with certain NIPT methods based on the specific assay design and methodology.
Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

Specific detection of chromosomal abnormality and fetal fraction estimation will vary among different assays, different procedures, different lot numbers, and different laboratories. Each laboratory should establish its own range of acceptable values.

SPECIFIC PERFORMANCE CHARACTERISTICS

Seraseq Trisomy 13 Female - Matched Reference Material has been designed for use with NGS sequencing procedures and other type of assays for the purposes of evaluating assay performance. Although designed to produce a positive Trisomy 13 result, Seraseq Trisomy 13 Female - Matched Reference Material does 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.

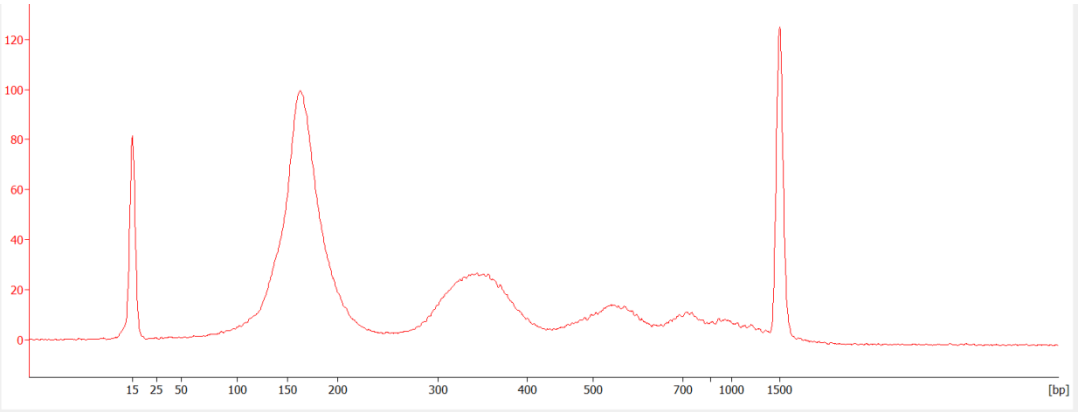

Figure-1: Representative cfDNA size distribution for Seraseq® Trisomy 13 female - Matched Reference Material.

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