PRODUCT SHEET

Seraseq® PGT-A Reference Materials

ASSAY VALIDATION AND DAILY-RUN QC MATERIAL FOR PRE-IMPLANTATION GENETIC TESTING (PGT-A)

HIGHLIGHTS

SINGLE-VIAL FORMAT OF GENOMIC DNA IN BUFFER AT CONCETRATION SUITABLE FOR PGT-A ASSAYS

UNIQUE ANEUPLOIDY REFERENCE MATERIALS FOR COMMON TRISOMIES, PGT-A-TESTED MATERIALS ASSURING PLOIDY.

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL SAVES TIME AND COST PROCURING SAMPLES OR PRODUCING HOMEBREW REAGENTS WITH SPECIFIC VARIANTS

INTRODUCTION

Pre-implantation Genetic Testing (PGT) is a genetic test performed on embryos produced by in vitro fertilization (IVF). The aim of the testing, also referred to as preimplantation genetic screening (PGS), is to screen embryos for genetic anomalies and improve the odds of a successful pregnancy[1]. PGT for chromosomal aneuploidies (PGT-A) is the most commonly used screening method.

LGC SeraCare offers PGT-A reference materials for the most common trisomies - 21, 18, 13 along with euploid material which can be used as a negative control.

Product Benefits

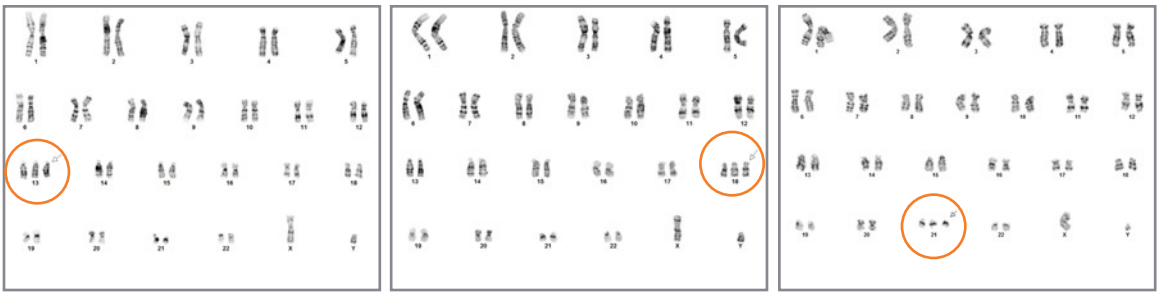
- Ideal for introduction to the PGT-A workflow at the WGA (amplification) step
- Can be used for PGT-A assay development, validation or routine QC
- Compatible with NGS as well as array-based PGT-A assays
- Save time, cost and increase QC consistency with these conveniently formatted reference materials
- Eliminate the need to find, source and maintain remnant samples

Product Features

- Collection of common chromosomal aneuploidies – trisomy 21, 18 and 13 as well as Euploid
- Formulated as genomic DNA from confirmed trisomic cells in buffer
- Ability to create mosaicism samples by blending aneuploidy and euploid samples
- Offered at a concentration suitable for PGT-A
- Ensure lot-to-lot consistency with materials manufactured in GMP-compliant and ISO 13485-certified facilities

Product Design:

Seraseq PGT-A Reference Materials are produced from gDNA extracted from a fetal source sample (Figure 1) with confirmed Trisomy (or Euploid status) and provided in a 1 mM Tris / 0.1 mM EDTA pH 8.0 buffer.



A. B. C.

Figure 1.: Karyotypes of the source cells. A. Trisomy 13, B. Trisomy 18 and C. Trisomy 21.

ABOUT SERACARE

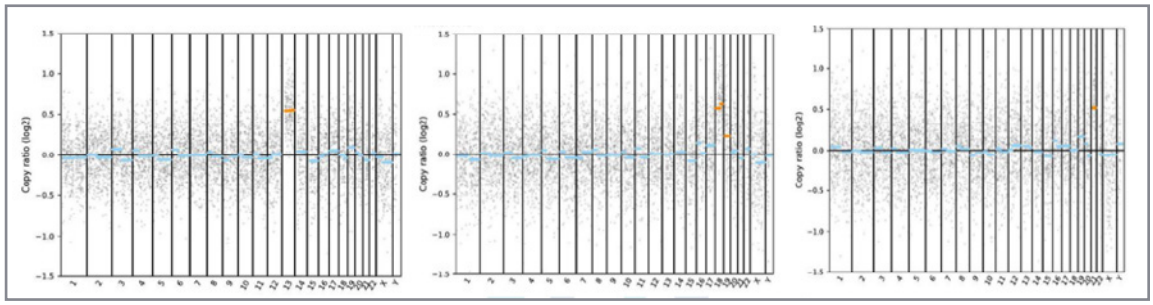
TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS

HIGH-QUALITY CONTROL PRODUCTS, RAW BIOLOGICAL MATERIALS, AND IMMUNOASSAY REAGENTS.

INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM.

The materials were tested for performance in NGS-based PGT-A assays (Figure 2).



A. B. C.

Figure 2. Performance in an NGS PGT-A assay. A. Trisomy 13, B. Trisomy 18 and C. Trisomy 21.

RELIABLE, CONSISTENT REFERENCE MATERIAL

As a manufactured control reference material, developed under cGMP compliance in ISO 13485 certified facilities, Seraseq PGT-A Reference Materials provide a consistent source of reference material for your PGT assay. This not only ensures a reliable supply which is consistent from lot-to-lot; it also eliminates the need to obtain, characterize, blend, and document your own mixes of cell lines, saving you time and resources in your assay development and validation efforts. Not for In Vitro Diagnostic Use. Research Use Only.

ORDERING INFORMATION

PGT-A REFERENCE MATERIALS		
Material #	**Product**	**Fill Size**
0720-0775	Seraseq® PGT-A Trisomy 21 Reference Material	1 vial x 10 uL
0720-0776	Seraseq® PGT-A Trisomy 18 Reference Material	1 vial x 10 uL
0720-0777	Seraseq® PGT-A Trisomy 13 Reference Material	1 vial x 10 uL
0720-0778	Seraseq® PGT-A Euploid Reference Material	1 vial x 10 uL

CUSTOM PGT-A MATERIALS	
The above products can be customized with regard to concentration, volume or blending to create mosaicism samples. Please contact SeraCare for customization options.	1 vial x 10 uL

LEARN MORE

To learn more about Seraseq PGT-A Reference Materials and SeraCare's product offering for reproductive health, visit https://www.seracare.com/Controls---Reference-Materials-NGS-Reproductive-Health/.

Contact us at 508.244.6400 and 800.676.1881 or email info@seracare.com.

REFERENCES

1. Fesahat F, Montazeri F, and Hoseini S. Preimplantation genetic testing in assisted reproduction technology. J Gynecol Obstet Hum Reprod, (2020), 49(5), 101723

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

MKT-00532-01

Seraseq®

PGT-A Trisomy 13 Reference Material

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® PGT-A Trisomy 13 Reference Material is formulated for use with Preimplantation Genetic Testing (PGT) methods assessing chromosomal aneuploidy status by using Next Generation Sequencing (NGS) assays that screen for Trisomy 13 (Patau Syndrome) chromosomal abnormality in embryo biopsy or non-invasive embryo testing. The Seraseq PGT-A Trisomy 13 Reference Material, is intended as a reference material for researchers and PGT-A testing labs to monitor whole genome amplification, library preparation, sequencing and detection performance.
For Research Use Only. Not for use in diagnostic procedures.
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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 PGT-A Trisomy 13 Reference Material is 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 product contains DNA at a concentration of 30 pg/µL. The Reference Material is formulated in 1 mM Tris /0.1 mM EDTA pH 8.0. It may be adjusted to volume and concentration required by the specific PGT-A protocol before use with the same buffer as the actual patient samples.

REAGENTS

Material No. 0720-0777; 1 vial, 10 µL per vial, 30 pg/µL concentration.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq PGT-A Trisomy 13 Reference Material and all materials derived from human blood products as though it is capable of transmitting infectious agents. Seraseq PGT-A Trisomy 13 Reference Material is manufactured using genomic DNA extracted from cultured human trophoblast progenitor cell lines. Purified genomic DNA is formulated in a 1 mM Tris / 0.1 mM EDTA pH 8.0 aqueous buffer.

Safety Precautions

Use Center 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 PGT-A Trisomy 13 Reference Material frozen at -20 °C or colder. Once opened, a vial can be thawed and re-frozen once.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq PGT-A Trisomy 13 Reference Material is a solution of human genomic DNA. 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

Seraseq PGT-A Trisomy 13 Reference Material is produced from gDNA extracted from a male fetal source sample with confirmed Trisomy 13, and provided in a 1 mM Tris / 0.1 mM EDTA pH 8.0 buffer. Ten (10) µL is provided per tube and the concentration is 30 pg/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 thaw on ice before use. Mix by vortexing to ensure a homogeneous solution and spin briefly. Seraseq PGT-A Trisomy 13 Reference Material should be integrated into whole genome amplification (WGA) step after the DNA isolation step. Refer to standard assay procedures in order to determine the amount of material to use.

Quality Control

Seraseq PGT-A Trisomy 13 Reference Material does not have assigned value for trisomy. It is therefore recommended that each laboratory qualify the use of each lot of Seraseq PGT-A Trisomy 13 Reference Material with each assay system prior to its routine use.

INTERPRETATION OF RESULTS

Detection of aneuploidy may vary with different NGS 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 PGT-A Trisomy 13 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.

LIMITATIONS OF THE PROCEDURE

Seraseq PGT-A Trisomy 13 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 PGT-A Trisomy 13 Reference Material is not a calibrator and should not be used for assay calibration. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

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EXPECTED RESULTS

Specific detection of chromosomal abnormality 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 PGT-A Trisomy 13 Reference Material been designed for use with whole genome or targeted NGS assays for the purposes of assessing assay characteristics. The product is manufactured from purified human genomic DNA. Although designed to produce a positive Trisomy 13 result, Seraseq PGT-A Trisomy 13 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.

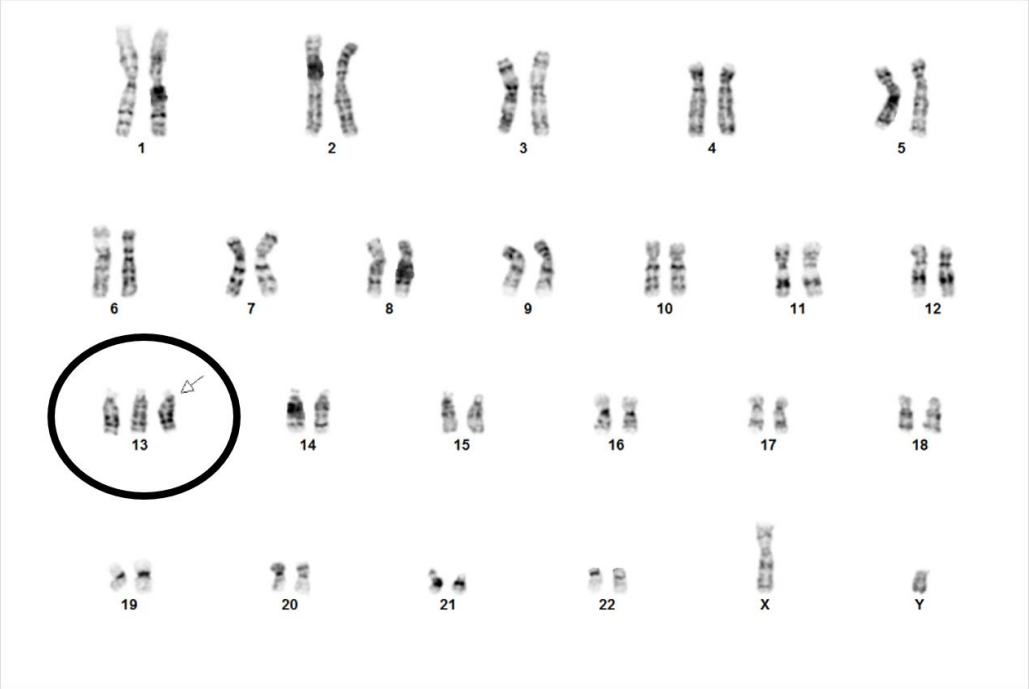

Figure-1: Karyotyping results of the source cell line showing that the sample is a confirmed male Trisomy 13. Testing was done using GTG banding technique and counting 20 metaphases.

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