Seraseq®

PGT-A Trisomy 21 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 21 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 21 (Down Syndrome) chromosomal abnormality in embryo biopsy or non-invasive embryo testing. The Seraseq PGT-A Trisomy 21 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.

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 21 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. 0720-0775 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 21 Reference Material and all materials derived from human blood products as though it is capable of transmitting infectious agents. Seraseq PGT-A Trisomy 21 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 21 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 21 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 21 Reference Material is produced from gDNA extracted from a male fetal source sample with confirmed Trisomy 21, 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 21 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 21 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 21 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 21 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 21 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 21 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 21 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 21 result, Seraseq PGT-A Trisomy 21 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.

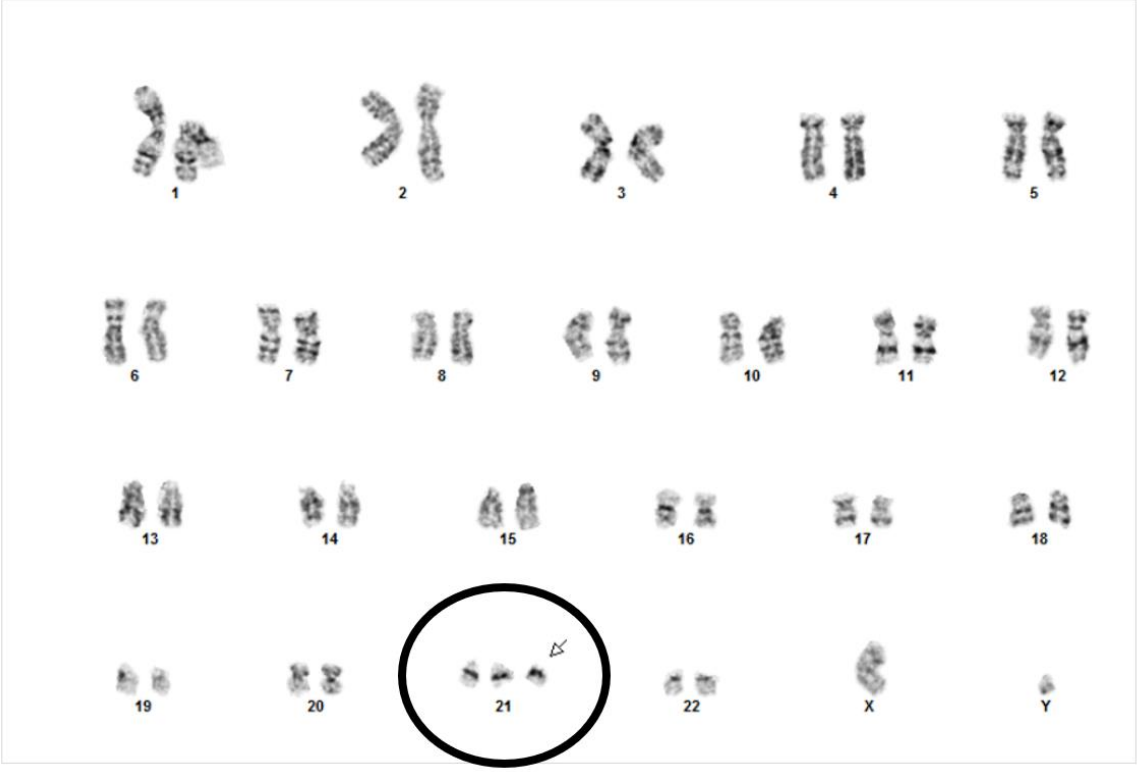

Figure-1: Karyotyping results of the source cell line showing that the sample is a confirmed male Trisomy 21. Testing was done using GTG banding technique and counting 20 metaphases.

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