

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseg® Antepartum T21 Male cfDNA

Material Number: 0720-1100 Batch Number: 10695017

Material Description:

A purified ccfDNA-like mixture of human genomic DNA (matched maternal

and fetal) derived from an antepartum (or prenatal) blood sample

Date of Manufacture: 15 MAR 2024 Expiration Date: 20 FEB 2028

Diluent: 1 mM Tris 0.1 mM EDTA 10 mM KCL

Fill Volume: 25 µL

Storage: -20°C

Concentration

(Invitrogen[™] Qubit[™] dsDNA BR Assay):

Nominal value: 10 ng/µL

Average measured value for this batch: 13.5 ng/µL

**NIPTIFY Focus Plus test. This cell-free DNA test uses Focus Plus (Fragmented

DNA Compact Sequencing Assay for enriched fetal material) technology. The Focus

Method used for NIPT: Plus technology analyzes fetal aneuploidies using whole-genome low-coverage

Illumina sequencing.

47%

*The fetal fraction has been enriched by the NIPTIFY® Focus Plus assay workflow.

The average enrichment factor is 3.6, but efficiency may vary. For a male fetus, the

NIPTIFY®Focus Plus fetal fraction estimation is based on FFY (fetal fraction based on Y-chromosome) and for a female fetus, it is based on the PREFACE (PREdict FetAl Component) algorithm. This fetal fraction is provided for information only and

may depend on assays and methodologies used.

Trisomy Call for

Fetal Fraction:

Chromosome 21:

High risk for Trisomy 21

Call for Fetal Gender: XY

Approval:

Sanchite Jamisha 26 MAR 2024

Prepared By Date