

Technical Product Report

For Research Use Only; Not for Use in Diagnostic Procedures

Product Description:	Seraseq® Trisomy 13 Female - Matched Reference Material			
Material Number:	0720-0780	Batch Number:	1067	1807
Material Description:	A ccfDNA-like mixture of human genomic DNA (matched maternal and fetal) in a commutable matrix (simulated plasma)			
Date of Manufacture:	20 JUN 2023	Expiration Da	ate:	15 MAR 2027
Fill Volume:	1.0 mL			
Storage:	2-8 °C			
Concentration (Invitrogen [™] Qubit [™] dsDNA BR Assay):	23.2 ng/mL			
Method Used for NIPT:	Veriseq NIPT solution v2 (Illumina, Inc). This assay uses whole- genome sequencing (WGS) approach to NIPT. NIPTIFY Focus Plus test. This cell-free DNA test uses Focus Plus (Fragmented DNA Compact Sequencing Assay for enriched fetal material) technology. The Focus Plus technology analyzes fetal aneuploidies using whole-genome low-coverage Illumina sequencing.			
Fetal Fraction:	VeriSeq: 6%; NIPTIFY Focus Plus:18.2**%			
	**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 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 Chromosome 13:	Pass			
Call for Fetal Gender:	ХХ			

Approval:

Prepared By

26 JUN 2023

Date

LGC Clinical Diagnostics, Inc • 37 Birch Street, Milford, MA 01757 • 508.244.6400 • 800.676.1881 Toll Free

www.seracare.com