

# Non-Invasive Prenatal Testing Reference Material (NIPT/NIPT+)



## NIPT entire workflow QC



GW Non-Invasive Prenatal Testing (NIPT) Reference Material consists of fragmented human cell line genomic DNA spiked into a commutable matrix (human plasma). These reference materials are formulated to mimic patient samples and serve as excellent quality controls by acting as performance indicators for the entire NIPT diagnostic workflow including sample extraction, library preparation and sequencing. This product is designed to be compatible with shotgun massively parallel sequencing, targeted massively parallel sequencing and single nucleotide polymorphism methods which are used to screen the chromosomal abnormality in cell-free fetal DNA (cfDNA).

## Key Features



### Entire Workflow Quality Control

Reference materials formulated in human plasma can mimic patient samples and monitor the entire workflow from extraction.



### Applicable for Multiple NIPT Assay Methods

Matched or unrelated maternal-fetal reference materials suit a broad range of NIPT assays such as massively parallel sequencing and single nucleotide polymorphism methods.



### Evaluate the Workflow Performance

The Reference panel covers common chromosomal abnormalities as well as pathogenic copy number variations ranging from 2Mb to 30 Mb.



### Flexible Portfolio of Fetal Fraction Levels

Fetal DNA ratio can be customized to match your assay and to determine the limit of detection.

## Applications

 Internal quality control: Evaluate the stability of the experiment and analysis pipeline.

 Negative and positive reference material/quality control in IVD kits.

 Platform comparison.

## Product Information

<b>Product Name</b>	NIPT plus Reference Standards
<b>Product Format</b>	Fragmented DNA in plasma
<b>Fetal Gender</b>	Male
<b>Fetal Fraction</b>	3.5%/5%/10%/15% pCNV less than 2Mb 10%/15%
<b>Chromosome Abnormality Type</b>	Chromosomal aneuploidies and pCNVs
<b>Solvent</b>	Native plasma
<b>Size</b>	1.2mL/vial
<b>QC</b>	Chromosome Abnormality: CMA & NGS
	Fetal Fraction: NGS
<b>Storage and validity</b>	-20°C, 18 months
<b>Attached Data</b>	CMA verification results

## Fast-track Product List

Product Code	Product Name	Fetal Fraction
CA2420	T21 10% NIPT Reference Standard	10.00%
CA2363	T21 5% NIPT Reference Standard	5.00%
CA2421	T21 3.5% NIPT Reference Standard	3.50%
CA2422	T13 10% NIPT Reference Standard	10.00%
CA2423	T13 5% NIPT Reference Standard	5.00%
CA2424	T13 3.5% NIPT Reference Standard	3.50%
CA2425	T18 10% NIPT Reference Standard	10.00%
CA2426	T18 5% NIPT Reference Standard	5.00%
CA2427	T18 3.5% NIPT Reference Standard	3.50%
CA2428	1p36 del 10% NIPT Reference Standard	10.00%
CA2429	1p36 del 5% NIPT Reference Standard	5.00%

Product Code	Product Name	Fetal Fraction
CA2430	4p del 10% NIPT Reference Standard	10.00%
CA2431	4p del 5% NIPT Reference Standard	5.00%
CA2364	5p del 10% NIPT Reference Standard	10.00%
CA2432	5p del 5% NIPT Reference Standard	5.00%
CA2433	15q del 10% NIPT Reference Standard	10.00%
CA2434	15q del 5% NIPT Reference Standard	5.00%
CA2435	17p del 10% NIPT Reference Standard	10.00%
CA2436	17p del 5% NIPT Reference Standard	5.00%
CA2437	22q11.2 del 10% NIPT Reference Standard	10.00%
CA2438	22q11.2 del 5% NIPT Reference Standard	5.00%
CA2257	46XY 10% NIPT Reference Standard	10.00%



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