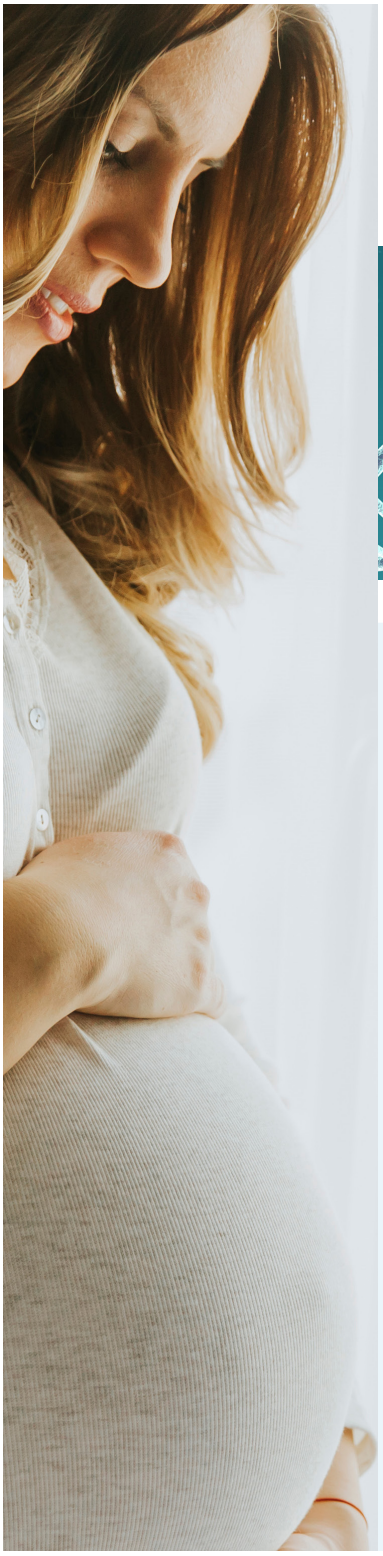
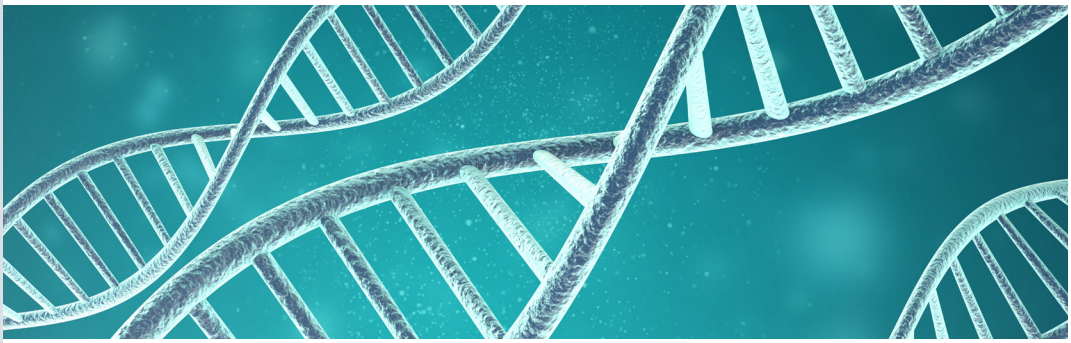


Non-Invasive Prenatal Testing (NIPT)



With NIPT,"Molecular genetics allow for changes in structure and sequence of human genes to be related to functional changes in protein functions, and ultimately health and disease"1

Fragments of cell-free DNA (cf-DNA) within maternal plasma can be purified and labelled with "universal sequence adapters" to create a library that may be amplified through NGS or other types of technologies.[2]

Sample type: maternal blood

Analyte: cf-DNA

The genes can then be assessed to determine the probability, with high accuracy, of genetic abnormalities or aneuploidies occurring within the genome of the fetus.

Genetic sequencing and identification of errors allow physicians and parents to better understand potential health risks or diseases their future child may possess.

Alongside genetic counseling, parents can be better informed and prepared.

1. (www.ncbi.nlm.nih.gov/books/NBK560712/)

2.(www.illumina.com/clinical/reproductive-genetic-health/nipt/labs/nipt-technology-types.html)

NORGEN BIOTEK

ISO 13485:2016 CERTIFIED QUALITY

ISO 9001:2015 CERTIFIED QUALITY

GMP

Common Challenges Experienced Leading to Test Failure

Test failures refer to no-call results or inconclusive results of the NIPT because of laboratory or technical issues, common challenges include:

1. Inadequate sample collection or preservation during transport

HIGH REDRAW RATE

High redraw rate for laboratories with long turn-around-times (TATs) Especially for those in Middle Eastern countries.

VERY COSTLY AND STRESSFUL ENDEAVOR

as test failures require retesting for a dditional costs and result in increased wait times for expectant mothers and families

THE STORAGE AND TRANSPORT OF BLOOD SAMPLES IS CRUCIAL FOR PRESERVING cf-DNA

Hemolysis (rupture of red blood cells) and white blood cell lysis, among other concerns, can prevent proper analysis of cell-free nucleic acids (source)
The lysis of white blood cells releases cellular DNA and RNA into the plasma, which can mask the cf-DNA/cf-RNA concentrations, making sequencing more difficult and expensive

The lysis of red blood cells releases contents into the plasma that can co-elute with nucleic acids or harm them, resulting in inhibited sequencing performance

2. Poor test sensitivity

LOW FETAL FRACTION

The fraction of fetal DNA over all the DNA present in the mother's blood is known as the fetal fraction (source)

Typically a fetal fraction < 4% is considered "low" (source)

Generally caused by testing too early in the gestation period but can also be caused by poor extraction of cf-DNA from the maternal blood, resulting in a very low yield

INADEQUATE EXTRACTION TECHNIQUES

cf-DNA relates to small fragments of DNA and is typically present in low concentrations within blood plasma which makes it an inherently difficult analyte to extract

Thus, purification of cf-DNA must be highly sensitive and well-developed

The challenge

Inadequate sample collection or preservation during transport:

THE SOLUTION

cf-DNA/cf-RNA Preservative Tubes

DIAGNOSTIC USE: CAT. DX63950

RESEARCH USE: CAT. 63950

- ☑ Preserve cf-DNA for 30 days at room temperature and ~8 days at 37°C
- ☑ No plasma volume loss after transportation
- ☑ Prevent hemolysis
- ☑ Prevent apoptosis of blood cells and fragmentation of genomic DNA
- ☑ High quality and quantity of cf-DNA

The challenge

Poor test sensitivity due to low fetal fraction or improper extraction techniques

THE SOLUTION

Plasma/Serum Cell-Free Circulating DNA Purification Kits (Midi)

DIAGNOSTIC USE: CAT. DX55600

RESEARCH USE: CAT. 55600

- ☑ Isolate inhibitor-free cf-DNA (circulating)
- ☑ Compatible with Norgen's cf-DNA and Streck cf-DNA BCT® Tubes
- ☑ Purification is based on spin column chromatography that uses Norgen's proprietary resin separation matrix

THE SOLUTION

Plasma/Serum cfc-DNA Advanced Purification Kit

RESEARCH USE: CAT. 68000

- ☑ Spin column format
- ☑ Versatile plasma and serum input volumes
- ☑ Minimal high molecular weight gDNA contamination in the purified cfc-DNA
- ☑ Isolate inhibitor-free circulating cf-DNA
- ☑ Purify superior quantity and quality DNA in 45 minutes
- ☑ Compatible with fresh, preserved or frozen serum/plasma prepared from blood collected on either Norgen's cf-DNA/cf-RNA Preservative Tubes, Cell-Free DNA BCT ® (Streck), Heparin, EDTA or Citrate
- ☑ Automation capabilities

The Norgen Workflow

1. Collect and preserve your sample
cf-DNA/cf-RNA Preservative Tubes

2. Extract cf-DNA from maternal blood
Plasma/Serum cell free circulating DNA Midi Kit or Plasma/Serum cfc Advanced Purification Kit

3. Prepare DNA Libraries for Sequencing
Compatible with all commercially available kits

4. Next Generation Sequencing

5. Advanced Bioinformatics Analysis

Equip Your Lab With High Quality Tools Optimized for NIPT

Contact a us today to learn more.

Visit **norgenbiotek.com**
Call at **1-866-NORGENB** or **905-227-8848**
Email at **orders@norgenbiotek.com**

SOURCES

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3 Best Tips for Processing Plasma Cell-Free DNA & RNA
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Response to BRAF/MEK Inhibition in A598_T599insV BRAF Mutated Melanoma
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Purification Kits
Recover Highest Amount of Small DNA Fragments when Compared to Other Commercially Available Purification Kits
NORBLOG

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Norgen Application Note #87

How to Preserve Cell-Free DNA and Prevent Cellular Genomic DNA Contamination in Plasma
Application Note #86

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