NEXT BIOSCIENCES

minimi

Early Fetal Sex Test

Informed Consent and Terms and Conditions

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INTRODUCTION

These terms and conditions apply to the MiniMi Early Fetal Sex Test. We set out below the benefits, risks, and limitations of the MiniMi Early Fetal Sex Test, which you agree to.

This screening test is performed at the Next Biosciences Laboratory, in Johannesburg, South Africa. Please read the terms and conditions carefully before making your decision to test.

PURPOSE AND TEST OPTIONS

The purpose of MiniMi is to determine the suspected sex of the fetus by testing for the presence or absence of a Y chromosome; where presence of a Y chromosome would indicate a male fetus and the absence of a Y chromosome would indicate a female fetus. MiniMi can be performed as early as 10 weeks 0 days gestational age. Gestational age is calculated from the first day of your last menstrual period. Contact Next Biosciences on minimi@nextbio.co.za should you like more information about this screening test, including risks, limitations, performance data, and error rates. The test will only provide information about the suspected sex of your fetus and will not report on any potential sex chromosome disorders or anomalies as the test is not designed to meet this purpose.

HOW THE TEST WORKS

During pregnancy, DNA (genetic material) from the placenta circulates in the mother's bloodstream. The blood sample includes a combination of maternal DNA and the DNA from the placenta. This test screens for the presence or absence of Y chromosome DNA by looking at the cell-free placental DNA in your blood. This test is platform agnostic and can either be NGS-based or done by using real-time PCR.

LIMITATIONS OF THE TEST

This is a screening test and not a diagnostic or clinical test. These tests, like many tests, have limitations, including false negative and false positive results. This means that the Y chromosomes being tested for may be present even if you receive a negative result (this is called a 'false negative'), or that you may receive a positive result for the Y chromosomes being tested for, even though they are not actually present (this is called a 'false positive').

In addition, in approximately 1% of cases, the results will be inconclusive, and we will not be able to provide a result.

You understand these limitations and agree that Next Biosciences cannot be held responsible for any false negative, false positive, or inconclusive results.

What may cause a false positive, false negative, or inconclusive result:

- There is a possibility that the test results might not reflect the chromosomes of the fetus but may reflect chromosomal changes occurring in the placenta only (confined placental mosaicism-CPM).
- In the case of a vanishing twin, the test result may reflect the DNA of the vanishing twin, leading to a higher probability of false positive or false negative results.
- In some cases, we may not be able to obtain a result, the causes of which may include, among others, technical limitations or insufficient fetal cell-free DNA.
- Certain maternal factors such as a high body mass index (BMI), medication, inflammatory and autoimmune conditions, and certain aneuploidies are known to decrease fetal fraction of cell free DNA with Y chromosome material then being below the detection limit of the test.
- An incorrect result may be produced for clients who received blood transfusions or tissue transplants from a non-sex match (i.e. male) donor.
- Doing the test prior to a gestation of 10 weeks or more, as the test has only been validated from 10 weeks.
- Doing the test for a twin pregnancy, as we cannot differentiate between the twins' different cell-free DNA.
- Sex chromosome anomalies or disorders may decrease the accuracy of the test and the assay cannot detect these disorders.

No clinical decisions should be made based on results from this test, these results are not to be used as a tool for sex selection in pregnancy.

TEST PROCEDURE

A tube of your blood (single 10ml tube) will be drawn by a nurse or healthcare provider and sent to Next Biosciences in Johannesburg, South Africa, where the sample will be analysed. Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and, rarely, infection at the blood draw site. The test is performed on, or after, 10 weeks, 0 days of pregnancy. After analysis, the test results will be returned to you. In the unlikely event of additional samples being required, Next Biosciences shall arrange for this to be done. Additional samples may be required in the event of a laboratory quality control failure or when sample acceptance criteria are not met upon sample receipt. Sample acceptance criteria include: At least 10 weeks gestational age, sample volume of ≥7ml, sample in correct non-expired tube, sample is not visibly compromised, sample clearly labelled with two patient identifiers, and transit time does not exceed five days.

REFUND POLICY

In the event that the test yields inconclusive results, then it is Next Biosciences' policy to offer one re-draw free of charge, however, certain circumstances will render this offer void including:

- Conducting the test before reaching a gestation period of 10 weeks, as the validation of the test is applicable solely from the 10th week of gestation.
- Administering the test in a twin pregnancy, as the differentiation of cell-free DNA between the twins is not possible.

Should an incorrect result occur, Next Biosciences will initiate a refund process under the condition that substantiating evidence is provided. Such evidence may encompass outcomes from screening examinations (ultrasounds) OR diagnostic tests (amniocentesis or chorionic villus sampling). These results must bear a date and the signature of a medical provider or specialist. If an ultrasound is conducted, the refund request will be processed after the birth of the baby, given the potential inaccuracies associated with prenatal ultrasound.

IMPORTANT POINTS ABOUT THE TESTING AND REPORTING PROCESS

1. Your test results are confidential and will only be disclosed to you or someone you authorise.
2. Only authorised and requested tests as per your test requisition form will be performed on your identifiable blood sample.
3. Your sample will be kept for a minimum of 24 months. This is in line with international best practice.
4. Next Biosciences may from time to time collect information on your pregnancy after testing. As such, we may contact you to obtain this information, which you consent to.
5. Pursuant to best practices and clinical laboratory standards, leftover de-identified (anonymous) specimens, as well as de-identified (anonymous) genetic and other information learned from your testing, may be used by Next Biosciences for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement, which you consent to. All such uses will be conducted in compliance with applicable laws.
6. Next Biosciences may also use your leftover specimen and health information, including genetic information, in an anonymised or de-identified form, for research purposes, which will be carried out in compliance with applicable law. Such uses may result in the development of commercial products and services. You consent to these uses and agree that you will not receive notice of any specific uses and you will not receive any compensation for these uses nor derive any benefit from any commercial products or services which may be developed arising from these uses.
7. You agree and accept that the maximum aggregate of all and any amounts which Next Biosciences may be liable for in respect of any claims arising from the testing services requested (whether to you or any third party), will be limited to the amount paid by you to Next Biosciences for such testing services.

COMPLIANCE WITH THE PROTECTION OF PERSONAL INFORMATION ACT (POPIA)

- You understand that Next Biosciences takes the privacy of its patients very seriously and has implemented reasonable security measures to guard against the unauthorised disclosure of your private patient information (personal information) in line with the Protection of Personal Information Act (POPIA), and as more fully provided for in the Privacy Policy available at: https://nextbio.co.za/Legal/Privacy-Policy.
- You acknowledge that your personal information may be disclosed to Next Biosciences personnel, or to Next Biosciences', its affiliates, sub-contractors and vendors, solely for the purposes of providing the testing services.
- You acknowledge that your personal information may be disclosed by Next Biosciences in response to a specific request by a law enforcement agency, subpoena, court order, or as required by law.
- You confirm that the personal information supplied by you is true and correct and that you are responsible for updating your information to ensure that it remains correct.
- You acknowledge that your personal information will be retained by Next Biosciences for the required retention periods applicable to the medical and healthcare industry.
- Next Biosciences may from time to time provide you with marketing information relating to testing services which may be relevant to you personally. You agree and consent to Next Biosciences using your personal information for these purposes and to inform you about any changes to the testing services offered by any of the companies forming part of the Next Biosciences group of companies.
- By sharing personal information with Next Biosciences, you agree and consent to the use of your personal information as set out above and more fully set out in the Privacy Policy available at: https://nextbio.co.za/Legal/Privacy-Policy.
- You warrant that you are entitled to provide Next Biosciences with the information and data that you provide and you indemnify Next Biosciences against any claims of a data breach by a third party.