

## About Next Biosciences

Next Biosciences is a leading biotech company that has operated in South Africa since 2005. It combines medicine, science, and technology to invest in innovative health technologies, enabling people to take personal ownership of their future health. Next Biosciences' group of companies are involved in the manufacture of biological products, stem cell banking, genetic testing, and other pathology lab testing. Next Biosciences is ISO accredited and licenced by the Department of Health in South Africa. The company believes in a collaborative business approach to ensure that it accesses the best scientific minds and other key players in the industry to deliver its core purpose.

## Next Biosciences validation study results

MimiMi is a non-invasive molecular test for determining fetal sex in singleton pregnancies, which can be done from as early as 10 weeks of gestation.

## Background

The aim of this validation study was to determine the accuracy of an in-house developed molecular test in determining the fetal sex from maternal blood. A validation study was performed, which included 200 stored maternal plasma samples of early gestation pregnancies.

## Samples and methods

Blood drawn from the mother via venipuncture into a cell-free DNA Streck blood collection tube was processed and the sex determined using a next-generation sequencing (NGS) based protocol for non-invasive prenatal testing (NIPT). This test is >99.9% accurate in correctly identifying the sex chromosomes of the fetus as XX or XY. Stored plasma for these samples were used to determine the fetal sex with a quantitative real-time polymerase chain reaction (qPCR) based test which targets Y chromosome sequences. The paired analysis included 200 samples of singleton pregnancies between 10 and 12 weeks gestation (average of 10 weeks, four days), for which no chromosomal anomalies were detected with NIPT.

## Results

Of the 200 samples with an NGS fetal sex chromosome result (100 male and 100 female), the fetal sex could be determined by qPCR for 198 cases, resulting in inconclusive results for 1% of cases. This was a retrospective study and redraws were therefore not requested for inconclusive cases. From the 198 cases with a result, 194 were concordant with NGS data for an overall accuracy of 98%. The average fetal fraction (as determined with NIPT) was 9% (1%-20% range).

Number of samples	n = 200
Sensitivity (Y chromosome detection)	98/100 (98%)
Specificity (absence of Y chromosome)	96/98 (98%)
Accuracy	194/198 (98%)
Redraws required due to inconclusive results	2/200 (1%)

## Conclusion

MiniMi is a non-invasive test which is highly accurate in determining the fetal sex in singleton pregnancies from as early as 10 weeks gestation (calculated based on last menstrual period), before an ultrasound is able to identify the fetal sex. Inconclusive (indeterminate) results are rare. Although this test is aimed at early gestations, it can also be performed for later gestation pregnancies.