St George's University Hospitals NHS
NHS Foundation Trust

the SAFE test
St George's Antenatal Fetal Evaluation

Non-Invasive Prenatal Testing (NIPT)

Information for Private Patients

What is NIPT?

Non-Invasive Prenatal Testing (NIPT) can evaluate with remarkable accuracy whether a pregnancy is at risk of certain chromosomal conditions. It involves a small blood sample from the mother and cutting-edge genetic technology. The testing is non-invasive, so the pregnancy is not put at risk.

What is Down's syndrome?

Down's syndrome (or Trisomy 21) is a genetic condition caused by an extra copy of chromosome 21 (three chromosome copies rather than the usual two). Around one in every 1000 babies born in the UK will have Down's syndrome and there are over 40,000 people in the UK with the condition. Anyone can have a baby with Down's syndrome and although the chance increases for older mothers, more babies with Down's syndrome are born to younger women.

Down's syndrome is a life-long condition typically characterised by learning disabilities and an increased likelihood of developing medical problems. The condition is extremely variable and it is impossible to know to what extent a baby with Down's syndrome will be affected. Some adults do live fairly independent lives; however most will need long-term support.

What is the SAFE test?

The SAFE test is a non-invasive prenatal test (NIPT), which evaluates whether a pregnancy is at risk of certain chromosomal conditions. It can be performed as early as 10 weeks by taking a small sample of the mother's blood. The blood is then sent to the laboratory for assessment with results available within 5 days from sample receipt. The SAFE test has a detection rate of over **99%** for Down's syndrome, **99%** for Edward's Syndrome and **99%** for Patau Syndrome.

Can the SAFE test tell me the sex of my baby?

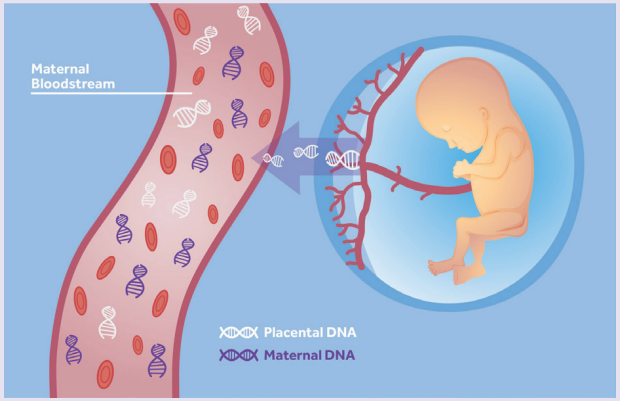
Yes. The SAFE test offers optional testing to determine the baby's sex with **97%** accuracy. Please note that the sex determining technique is not a screening test for rare sex chromosome conditions.

Can the SAFE test screen for all conditions?

No. Down's syndrome is the most common condition looked for as well as two rarer and more serious conditions known as Edwards' syndrome (trisomy 18) and Patau's syndrome (trisomy 13). Many babies affected by these two rarer conditions do not survive the pregnancy or die soon after birth.

How does the SAFE test work?

During pregnancy the placenta leaks baby's DNA into the mother's bloodstream. As a result, the mother's blood contains a mixture of baby's and mother's DNA. By looking at the baby's DNA in the mother's blood, the SAFE test is able to predict whether or not the baby is affected by chromosomal conditions like Down's syndrome.



Who can have the SAFE test?

The test is suitable from 10 weeks of pregnancy for all single and identical twins pregnancies, including IVF, egg donor or surrogate pregnancies. For non-identical twins test sensitivity is reduced to **95%**.

The test is not suitable for multiple pregnancies (greater than twins), or if the mother has cancer or a chromosomal or genetic abnormality (including Down's syndrome). It is also unsuitable for mothers who have undergone a blood transfusion in the last 12 months, or had transplant surgery, immunotherapy or stem cell therapy.

How does the SAFE test differ from the usual 'combined test'?

The 'combined test' and the SAFE test are very different; both in how they test and in the accuracy of their results. The 'combined test' evaluates hormonal blood levels with ultrasound findings to assess the risk of chromosomal or structural abnormalities. Although the range of disorders that can be detected by this method is broader than the number of disorders identified by the SAFE test, it is not as accurate as the SAFE test for detecting Down's syndrome (**85%** accuracy compared to over **99%** accuracy with the SAFE test).

Where does amniocentesis and CVS fit in?

Traditionally, if you were to receive a "high risk" result following the combined test you would be offered an invasive procedure such as amniocentesis or chorionic villus sampling (CVS). Both amniocentesis and CVS involve using a fine needle to collect either a small sample of the amniotic fluid that surrounds the baby (amniocentesis) or a small sample of cells from the placenta (CVS). Although these invasive procedures give a definitive diagnosis they do carry a small risk of miscarriage. The chance of miscarriage in addition to an **85%** detection rate is often a dilemma for 'parents to be' with many women opting to have the assurance of a non-invasive prenatal test such as the SAFE test before proceeding to an invasive procedure.

Because the SAFE test is a genetic test that analyses your baby's DNA, it is more accurate in identifying certain chromosomal abnormalities, such as Down's syndrome. This high detection rate of over **99%** means that less women will undergo the unnecessary stress and miscarriage risk associated with invasive procedures.

How is the SAFE test reported?

Your test result will fall into one of three categories:

Low Risk: means that it is very unlikely that your pregnancy is affected by trisomy 21, 18 or 13, and therefore very unlikely that your baby has Down's, Edwards' or Patau's syndrome.

High Risk: means that your pregnancy is at increased risk for trisomy 21, 18 or 13 and that the result should be confirmed by an invasive diagnostic test, such as amniocentesis or CVS to give a definitive diagnosis.

Failed Test: in a very small number of cases tests may need repeating due to insufficient placental DNA in the mother's blood. Under these rare occasions another blood sample will be required.

What happens if I get a "high risk" result?

If the SAFE test result shows a chromosomal abnormality you will be offered an invasive diagnostic test such as amniocentesis or CVS. These tests give a definite 'yes' or 'no' result as to whether your baby has Down's, Edwards' or Patau's syndrome. It is important to consider the need to be certain about the diagnosis compared to the risk of losing the pregnancy through an invasive procedure before you decide whether or not to undergo further testing. Your midwife and/or obstetrician will be on hand to answer any questions you may have and to support you through this time.

Who can I contact for further information?

If you have any questions about the SAFE test, please contact your named midwife or consultant obstetrician.

Where can I get the SAFE test?

The SAFE test is available through different healthcare providers. Please email: **theSAFEtest@nhs.net** for further information.

About St George's University Hospitals NHS FT

The maternity unit at St George's University Hospitals NHS Foundation Trust is a regional and tertiary referral unit ranking one of the safest in the country. Delivering over 5,000 babies each year, the unit has achieved exceptional clinical outcomes, the highest possible external accreditations and boasts the highest 'midwife: birth' ratios in London. The unit has consultant and midwifery led maternity care and state of the art equipment, including neonatal intensive care and a special care baby unit.

The Fetal Medicine Unit at St George's Hospital is a leading tertiary referral centre and research centre located within a purpose built unit. It houses state of the art facilities for all aspects of care from routine assessment up to invasive procedures, including fetal surgery (surgery in the womb). The unit routinely accepts referrals from the 10 district general hospitals in the south-west London region including approximately 35,000 women a year for antenatal care. Extra-regional referrals are also received for complex fetal surgical procedures and maternal care from other hospitals in the UK and Europe. The unit has recognised international expertise in the clinical and supportive management of high-risk care in pregnancy.