

How is the SAFE test reported?

Low Chance: 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 Chance: means that your pregnancy is at increased chance 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.

No call result: in a very small number of cases (1 in 200) tests may not yield a result for a variety of reasons. In this instance the clinical team will discuss your available options.

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

If the SAFE test result shows a high chance of a chromosomal condition 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.

To contact the team at St George's Hospital directly, please email:

theSAFEtest@nhs.net or visit:

www.theSAFEtest.co.uk

Where can I get the SAFE test?

The SAFE test is available through different healthcare providers. For further information email:

theSAFEtest@nhs.net or visit:

www.theSAFEtest.co.uk

Patient Advice and Liaison Service (PALS)

Your local PALS office can offer you on-the-spot advice and information when you have comments or concerns about our services or the care you have received.

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.

Other Useful organisations

NHS Choices

<http://www.nhs.uk/pages/home>.

Down's syndrome Association

www.downs-syndrome.org.uk • Tel: 020 8682 4001

Supporting organisation for Trisomy 13 and Trisomy 18 (SOFT) UK

www.soft.org.uk • Tel: 0330 088 1384

Antenatal Results and Choices (ARC):

www.arc-uk.org • Tel: 020 7631 0285

The SAFE test is a CE-marked in vitro diagnostic test from Yourgene. Yourgene is a UK based molecular diagnostics company working in partnership with St George's University NHS Hospitals Foundation Trust to create a UK Centre of Excellence in bringing the first regulated NIPT test to more pregnant women.

Powered by the IONA® test - a registered trademark of Yourgene

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theSAFEtest

St George's Antenatal Fetal Evaluation



Non-Invasive
Prenatal Testing (NIPT)

Information for NHS Patients

What is NIPT?

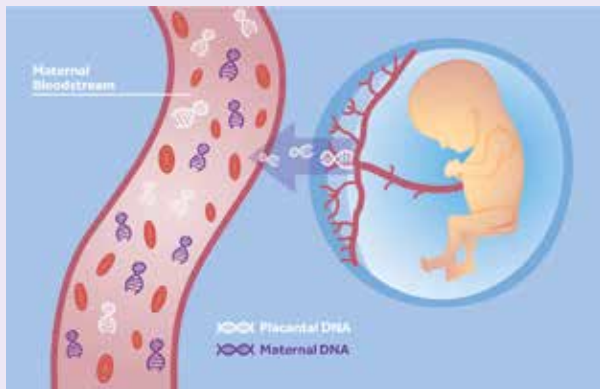
Non-Invasive Prenatal Testing (NIPT) is a blood test from the mother which uses cutting edge DNA technology to evaluate with remarkable accuracy whether a pregnancy has a high chance of certain chromosomal conditions.

What is the SAFE test?

The SAFE test is a non-invasive prenatal test (NIPT), which evaluates the chance of chromosomal condition in a pregnancy. 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 typically available within 5 working days from sample receipt. The SAFE test has an overall accuracy of >99%.

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 more likely to have a chromosomal condition such as Down's syndrome.



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, most 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 severity is extremely variable and it is impossible to know to what extent a baby with Down's syndrome will be affected. Some adults live independent lives; however, some will also need long-term support.

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 who have these two rarer conditions do not survive the pregnancy or die soon after birth.

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 and "vanishing twin" test sensitivity is reduced from 99% to 95%.

The test is not suitable for higher order multiple pregnancies (greater than twins), or if the mother has cancer or a chromosomal or genetic condition (including Down's syndrome). It is also unsuitable for mothers who have undergone a blood transfusion in the last 3 months, had transplant surgery, immunotherapy or stem cell therapy.

Clinical performance of the SAFE/IONA® test in over 20,000 patient samples			
Sample Status	Result	The Iona® test	
		Detection Rate (sensitivity)	PPV
Trisomy 21	389	99%	99%
Trisomy 18	85	92%	93%
Trisomy 13	47	99%	94%
Unaffected	20675	N/A	N/A

Based on post-market surveillance. Only singleton pregnancies included.
PPV is specific to the study population.

Overall accuracy: >99%

No call rate: <0.5%

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 are performed and in the accuracy of their results. The 'combined test' evaluates hormonal blood levels with ultrasound findings to assess the chance of chromosomal or structural anomalies. 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 chance" 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 is often a dilemma for parents, with many women opting to have NIPT, 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 conditions, 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.