the SAFE test
St George's Antenatal Fetal Evaluation

St George's University Hospitals NHS
NHS Foundation Trust

PATIENT DETAILS

NHS Number:
Patient ID:

Forename(s):
Surname:

Date of Birth (DD/MM/YY):
Address:

Postcode:
Telephone Contact:

E-mail:

Age: Weight:

CLINIC DETAILS

Hospital/ Clinic Name: The Birth Company

Consultant Name: Dr Gibb

Contact Number: 02077250528

CURRENT MEDICAL HISTORY

	Yes	No
Cancer	☐	☐
Transplant/immunotherapy	☐	☐
Blood transfusion (< 3 months)	☐	☐
Genetic disorders	☐	☐

If yes, please give further details:

N.B. If Yes, in some cases this test may not be suitable. Please refer to the reverse of the form or contact a clinician for more information.

DETAILS OF PREGNANCY

EDD by USS:
Current Gestation by USS: (weeks) (days)
If IVF:
Age of mother/donor at egg harvest:

Twin Pregnancy:
Dichorionic ☐ Monochorionic ☐ Vanishing Twin ☐

N.B. If dichorionic or vanishing twin, please inform the patient of the reduced sensitivity (>95%)

PRIOR SCREENING TEST RESULTS

		Twin 2 (if applicable)
T21 risk ratio:	1 in	1 in
T18 risk ratio:	1 in	1 in
T13 risk ratio :	1 in	1 in
Nuchal (NT) measurement:	(mm)	(mm)

N.B. If NT>3.5mm, invasive prenatal diagnosis is typically recommended to exclude array CGH abnormalities.

ADDITIONAL TEST REQUESTS

Sex Determination Request Yes ☐ No ☐

NB: Inform the patient that sex determination is inconclusive in 3% of cases and is unsuitable for sex aneuploidy screening. It is also unsuitable for dichorionic or vanishing twin pregnancies.

BLOOD DRAW DETAILS

Date:

Time:

PATIENT CONSENT

My signature below indicates that I have:

- Read and understood the information provided.
- Been given the opportunity to ask questions.
- Received appropriate counselling about this type of screening from a healthcare provider.

I give my consent for my sample to be analysed using the SAFE test, or, through a carefully chosen contractor. I agree that the information provided may be used for auditing and quality control and that my data will be anonymised for such purposes. I understand that if I do not tick the relevant box below I give my permission for surplus sample and associated data to be stored and used as detailed on the reverse of this form.

☐ **Tick box to opt out of laboratory studies using surplus sample (plasma) and associated anonymised data**

Patient name (please print):

Patient signature:

Date:

Clinician name (please print):

Clinician signature:

Designation:

FOR LAB USE ONLY	SAMPLE	Received by:	Entered on PWM by:	REPORT	Generated by:	Authoriser:
	Receipt Date and Time:	Tube Type/ Vol:	Data Entry Check:	PORTAL	Upload Result:	Checker:
		Sample Condition:	Receipt Update:	SD	Generated by:	Checker:
		Run Number:	Sample Number:		Concordant:	Checker:

What is the SAFE test?

The SAFE test is a non-invasive prenatal test (NIPT) which evaluates whether a pregnancy is more likely to have 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 usually available within 5 working days from sample receipt. The SAFE test has an accuracy of over 99% for Down's syndrome, Edwards' syndrome and Patau's syndrome and a no-call rate of less than 0.5%.

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 may have a chromosomal condition like Down's syndrome. For example, if a baby has Down's syndrome, the SAFE test will identify three copies of chromosome 21 rather than the expected two. Similarly, there will be an extra copy of chromosome 18 if the baby has Edwards' syndrome, and an extra copy of chromosome 13 if the baby has Patau's syndrome.

Who can have the SAFE test?

The SAFE test is suitable from 10 weeks of pregnancy for all single and identical twin pregnancies, including IVF, egg donor or surrogate pregnancies. For non-identical twins or a vanishing twin pregnancy, test sensitivity is reduced to 95%. The SAFE test is not suitable for higher order multiple pregnancies (greater than twins), or if the mother has cancer or a chromosomal/ genetic abnormality herself. The test is also unsuitable for mothers who have undergone a blood transfusion in the last 3 months, or had transplant surgery, immunotherapy or stem cell therapy. In some instances, a diagnostic test such as chorionic villus sampling (CVS) or amniocentesis should be considered. It is recommended that you discuss all your screening options, risk factors and results with your healthcare provider. In the event of a high-chance result (indicating that there is an increased chance that your baby will be born with Down's, Edwards' or Patau's syndrome) it is important to consider verification of the result by CVS or amniocentesis.

Patient consent for screening and future laboratory studies:

By signing this consent form you are giving your permission for the SAFE test to be performed on your blood sample. This may be through our carefully selected contractor. After the test has been performed there is usually a small amount of plasma (liquid portion of blood) remaining. You can indicate on this consent form that you are giving your permission for this sample and the associated data to be kept to develop enhance further development of non-invasive testing.

You are under no obligation to consent to your sample being used for this purpose and declining will not affect your standard of care. If you do not wish for your excess sample to be used in this way, please tick the box overleaf to opt out of further studies. If you are happy for your excess sample to be used for test development, please be assured that your information and pregnancy will be anonymised, meaning that your identity will be protected.

Please be aware the SAFE test laboratory will contact patients for pregnancy outcome information following the expected date of delivery if the referring clinic does not provide this information.