Paternitysafe®

SIMPLE RAPID SAFE

PATIENT INFORMATION LEAFLET

Paternitysafe® is the safest way to determine paternity during pregnancy.

CLIN-GEN-QI-12 V.1 Authorised by Roy Naja

WHAT IS THE **PATERNITY**SAFE® TEST?

Paternitysafe is an advanced non-invasive prenatal test that can provide information on who a child's biological farther is before birth.

By "non-invasive" we mean procedures such as amniocentesis or CVS are not needed. Only a simple blood draw is required. Until recently, the only way to verify paternity before birth was to collect the amniotic fluid or chorionic villi, thus an "invasive" test that carries risks of procedure induced miscarriage.

HOW IS THE **PATERNITY**SAFE® TEST PERFORMED?

The test is performed by collecting and analysing DNA obtained via two buccal swabs from the suspected father. The DNA collected is compared with fetal DNA obtained via a blood sample from the expectant mother **after 10 weeks' gestation.**

The kit contains two swabs for one alleged father. Additional swabs can be provided to test multiple alleged fathers.

HOW DOES THE **PATERNITY**SAFE® TEST WORK?

Paternity is determined by analysing the baby's DNA present in the mother's blood. During pregnancy, some fragments of fetal DNA circulate in the maternal blood. It is possible to extract this DNA, analyse it and compare it with DNA collected from the alleged father.

WHO CAN HAVE THE **PATERNITY**SAFE® TEST?

The Paternitysafe test should be discussed during a detailed consultation. The Eurofins group offers both a pre-test and post-test genetic consultation service.

The test can be performed on **singleton and monozygotic (identical) twin pregnancies**, with at least **10 weeks of gestation** who have had an **ultrasound scan**. For technical reasons, the test cannot be performed if the alleged fathers are monozygotic twins, if the pregnancy is dichorionic (non-identical) twins or if the pregnancy is obtained from assisted reproductive techniques (IVF) with female heterologous fertilization (donor egg) and a sample from the donor is not available.

In pregnancies that began as dizygotic or multiple twins, followed by the spontaneous abortion of one or more fetuses with resorption of the gestational sac (vanishing twin), DNA from the aborted fetus may also be present in the maternal blood. This could affect the quality of the results.

WHAT RESULTS CAN BE EXPECTED FROM THE **PATERNITY**SAFE® TEST?

The genetic profile of the child is inherited half from the mother and half from the father. Therefore, the genetic characteristics of the child which are not present in the mother are mostly inherited from the father.

If the alleged father has these characteristics in his DNA, he is the biological father (**COMPATABILITY**), otherwise he is excluded as the biological father (**NON-COMPATABILITY**).

At the end of the process, a report is issued, which indicates whether or not the man who carried out the test is the biological father.

In some cases (approximately 1%) the test can produce a suboptimal or inconclusive result.

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HOW ACCURATE IS THE **PATERNITY**SAFE® TEST?

PaternitySafe® has a margin of error of less than 1%. However, the final probability of paternity will never reach the value of 100%, for both statistical and genetic reasons.
Although the risk of error of the test is low (<1%), it cannot be excluded. The result can be confirmed either in the prenatal phase with invasive procedures (CVS/amniocentesis) or in the postnatal phase using traditional techniques.

WHAT ARE THE LIMITATIONS OF THE **PATERNITY**SAFE® TEST?

PaternitySafe®, while extremely reliable, is limited by several factors.

The fetal fraction is the percentage of cell-free fetal DNA detected from the total DNA extracted from the maternal blood. Sometimes, the fetal Fraction may not be sufficient to highlight the SNPs of the paternal cffDNA. A fetal fraction that is too low to ensure the accuracy of the test can be obtained for several reasons such as high maternal BMI.

PaternitySafe® is also limited by the possibility that there is strong genetic homology between the alleged father and the real biological father (for example, if they are closely related. The test is also not able to distinguish between two potential fathers who are monozygotic twins, since they are genetically indistinguishable. Additionally, if it is the biological mother is genetically similar to the biological father (related), there will be an increased risk that the test will give an "inconclusive" result, regardless of the genotype of the alleged father being tested.

PaternitySafe® cannot be performed in dizygotic (non-identical) twin pregnancies or greater, or if the expectant mother has received any allogenic transfusions or transplants. In pregnancies that have started as non-identical or multiple twins, followed by the spontaneous abortion of one or more foetuses with resorption of the gestational chamber (vanishing twin), the cffDNA of the aborted foetus may also be present in the maternal blood and this could interfere with the quality of the result.

PaternitySafe® cannot be performed in IVF pregnancies where a donor egg was used.

PaternitySafe® is also limited by the reliability of the technology used. For example, certain genetic variants that are incompatible with the real father may result from de-novo mutational events, which is considered at the interpretation stage. In addition, DNA analysis technologies that use next generation sequencing can generate technical artefacts, which are also considered at the interpretation stage.

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