

CHOOSE COMFORT

QF Chromosome kit: multiplex QF-PCR assay for diagnosis of autosomal trisomies and analysis of sex chromosomes status

Prenatal diagnosis to identifying fetal genetic disorders started in the early 1970s. Women with pregnancies at increased risk of chromosome abnormality (usually because of maternal age, altered serum metabolites, or ultrasound abnormalities of the fetus) undergo invasive sampling of either amniotic fluid (AF), chorionic villi (CVS) or, rarely, fetal blood. Material from these samples is cultured to obtain dividing cells and then harvested and prepared for full karyotype analysis of metaphase chromosomes. Quantitative fluorescence polymerase chain reaction (QF-PCR), applied to foetal nondividing cells and DNA, are now used routinely for rapid and simple diagnosis of the most frequent aneuploidy (numerical chromosome abnormalities), including in particular trisomy 21, 13 and 18 (giving rise to the Down, Patau and Edward syndromes, respectively) and sex chromosome abnormalities (associated with the XXY-Klinefelter, XYY, XXX and X-Turner syndromes).

QF-PCR involves the amplification of chromosome-specific, repeated DNA sequences known as small (short) tandem repeats (STRs). STRs are stable and polymorphic, that is, they vary in length between subjects, depending on the number of times the tri-, tetra- or penta-nucleotides are repeated.

This technique is mainly applied to amniotic fluid but doesn't require additional sampling: 1 or 2 ml of AF prepared by amniocentesis for the traditional culture, can be used for QF-PCR analysis getting a first result within 24-48h.

After PCR amplification, the analysis is expected to take about 5 min per sample. QF-PCR is amenable to automation and a large number of samples can be handled simultaneously, allowing substantial economy of scale.



Features of the product

- DNA extraction kit included.
- DNA quantification not required.
- Every component of the kit is stable at +2/+8°C for 12 months.
- The product is ready to use: it is required only add the DNA to the Master mix.
- Five-Dye DNA fragment analysis.
- Suitable for prenatal and postnatal analysis.
- IVD CE marked: QF Chromosome Kit has been manufactured according to the community directives for In vitro Diagnostic (n° 98/79/CEE).
- Conformity: QF Chromosome Kit is developed and manufactured by EuroClone S.p.A. within quality systems accredited to EN ISO 9001:2000 and ISO 13485:2003.

Multiplex QF-PCR assay for diagnosis of autosomal trisomies and analysis of sex chromosomes status

Principle of the analysis

DNA derived from 2 ml of AF is amplified following the flow chart reported below without any quantification. The sample DNA is amplified by PCR using fluorescent primers so that products can be visualized and quantified as peak areas of the respective repeat lengths using an automated DNA sequencer with the GeneScan® or GeneMapper® software.

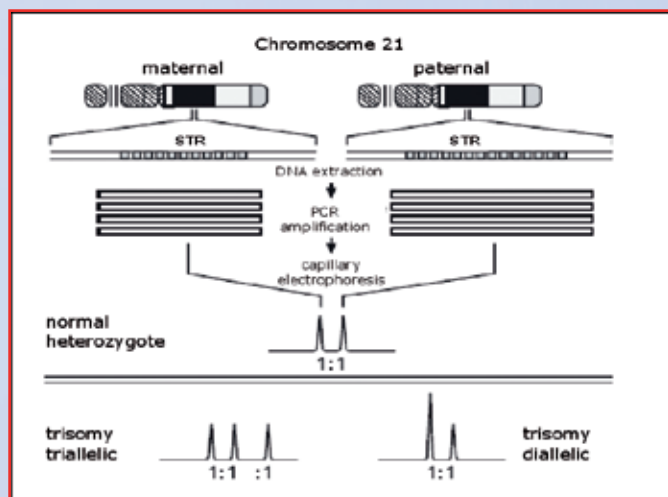


Fig. 1 – Principle of the assay

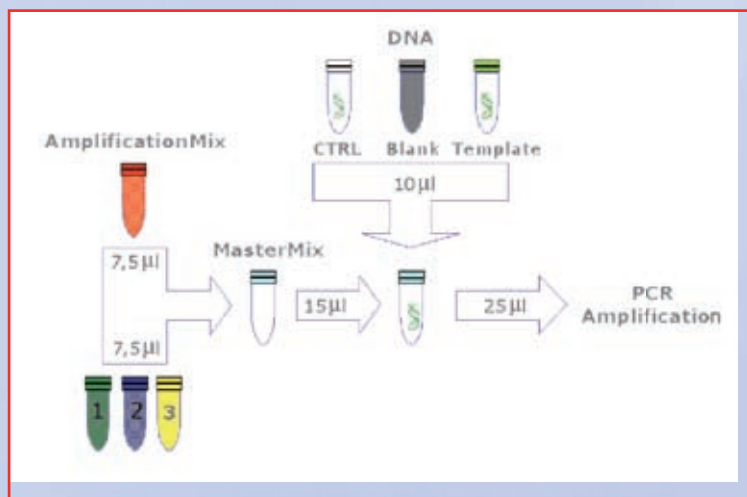


Fig.2- Amplification flow chart

A normal diploid sample has the normal complement of two of each of the somatic chromosomes, thus two alleles of a chromosome specific STR are determined as two peaks in ratio 1:1. Only heterozygote patterns are informative and can be used for correct interpretation. A normal peak ratio is between 0,8 – 1,4. Omozygote patterns are uninformative and cannot be used for analysis.

Cat.No.	Description	Intended Use	Format
EKAMQ001050	QF 13.18.21 Chromosome Kit	For routine detection of the three most common autosomal trisomies Patau, Edwards and Down syndrome	50 tests
EKAMQ002050	QF XY Chromosome Kit	For routine analysis of sex chromosomes status including the common aneuploidies Klinefelter and Turner syndrome	50 tests
EKAMQ003050	QF Complete Chromosome Kit	For routine detection of Patau, Edwards, Down syndrome and analysis of sex chromosomes status	50 tests

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