CyberGene AB

CyberGene AB in Sweden is active in the MedTech field by developing, manufacturing and marketing In Vitro diagnostic products. CyberGene AB is also a service provider within the Biotech field in oligonucleotide (DNA) supply.

CyberGene AB´s customers include researchers, hospital clinics, together with biotech and pharmaceutical companies.

The company started in 1995 as a biotech supply company focusing on DNA sequencing services and production of synthetic DNA

ChromoQuant® was the first **CE marked** kit for QF-PCR of aneuploidies on the market in 2004.

Cat no.	*No. of tests*		*Analysed chromosomes*
311.003-52	52	Duplex test	Chromosomes 13, 18, 21, X and Y including all extra markers
311.003-24	24	Duplex test	Chromosomes 13, 18, 21, X and Y
412.002-24	24	1 tube test	Chromosomes 13, 18, 21
313.003-10	10	1 tube test	Chromosome 13 Extra markers
318.003-10	10	1 tube test	Chromosome 18 Extra markers
321.003-10	10	1 tube test	Chromosome 21 Extra markers
330.003-10	10	1 tube test	Chromosomes X and Y Extra markers and unique marker for diagnosis of Turner

ISO9001 • ISO13485

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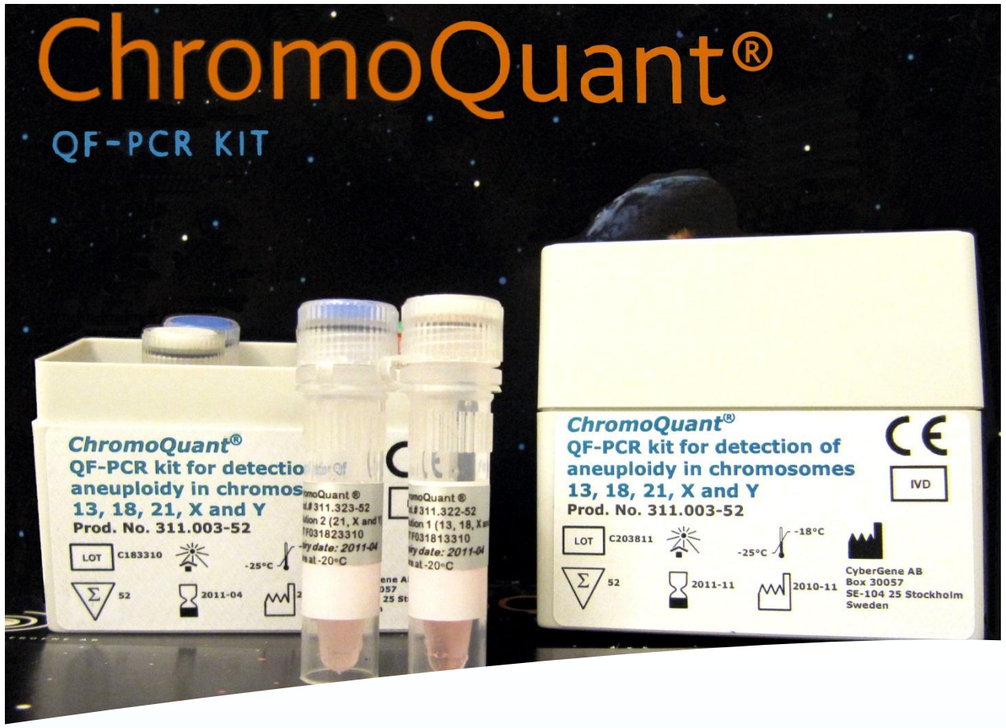
chromoquant@cybergene.se
www.chromoquant.com

Q07-159-E01

CYBERGENE AB



ChromoQuant QF-PCR

ChromoQuant® QF-PCR kits is a family of products for fast and reliable diagnosis of the most common chromosomal disorders in foetuses.

ChromoQuant® detects Trisomy 21 (Down syndrome), Trisomy 13 (Patau syndrome), Trisomy 18 (Edwards syndrome) and aneuploidies in the sex chromosomes i.e. Klinefelter syndrome and Turner syndrome.

ChromoQuant® is validated for In Vitro Diagnostics and CE marked in accordance to ISO 13485-2003 and ISO 9001-2008.

ChromoQuant® was clinically introduced in early 2004 and is used worldwide. More than 45.000 clinical tests have been performed with the ChromoQuant test since 2004.

The diagnostic procedure is based upon amniocentesis. Results are achieved within 6 hours enabling a "time to reply" of 24 hours

The QF-PCR method:

Possible genotypes – normal or trisomic sample

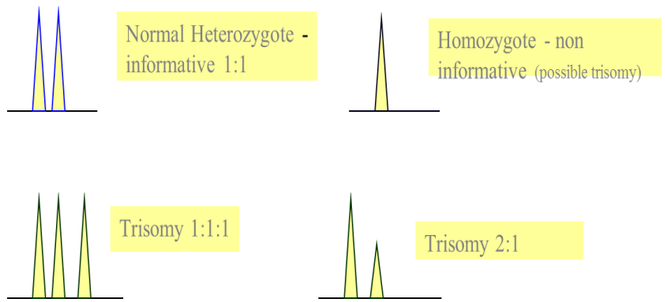
Each PCR fragment peak corresponds to a STR (short tandem repeat) e.g.: $(\text{-GATA-GATA-GATA-})_n$.

Each peak uniquely represents an allele (one of maternal and one of paternal origin).

Upon PCR;

A normal (heterozygote) sample will generate two peaks.

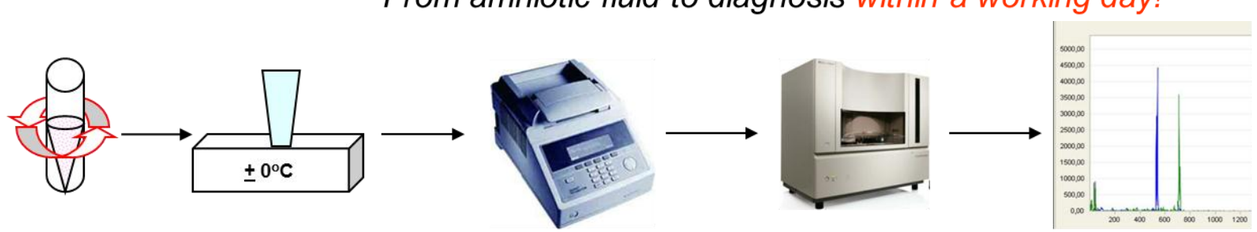
A trisomy will generate two or three peaks. The ratio of the peaks will lead to the diagnosis.



ChromoQuant® QF-PCR work flow

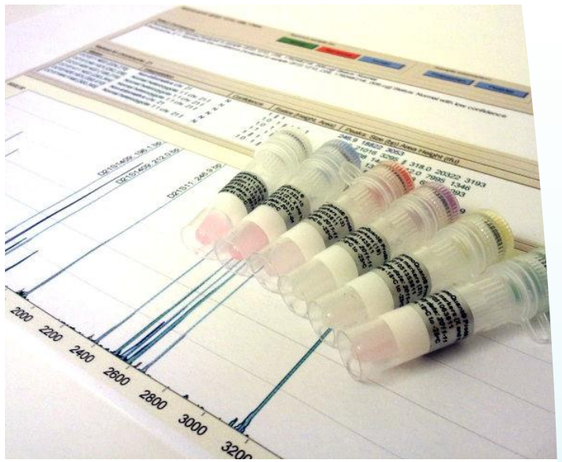
1. DNA extraction from e.g. amniotic fluid
2. PCR amplification
3. Capillary Electrophoresis (ABI or MegaBACE systems)
4. Export of data and Diagnosis

From amniotic fluid to diagnosis within a working day!



Extract DNA	*Prepare for PCR*	*PCR*	*Capillary Electrophoresis*	*Export data*
20 min	*5 min*	*2,5-3h*	*30 min*	*5 min*

➡ **Diagnosis**



Advantages using *ChromoQuant*®

- Clinically validated
- High precision – many STR markers
- Maternal contamination and mosaicism can be detected
- **CE marked** IVD product
- LIM System included in product (*Visualizer*™)
- Fast and objective diagnosis

Visualizer™ software

Decision support software for objective and fast interpretation of results, Visualizer™ is licensed to all users. Visualizer™ is also a database for safe storing and traceability of data.

- Objective analysis of data
- Fast diagnosis
- Full traceability and quality control
- Storage in database
- Results can be exported to patient handling system

.

Validated Taq polymerases to be used with ChromoQuant:

- Hot Start: HotStar Taq polymerase, *Qiagen*
- Hot Start: True Start Taq polymerase, *Fermentas*
- Go Taq polymerase, *Promega* (not Hot Start)

ChromoQuant is validated to function with ABI or MegaBACE Genetic Analyzers:

- ABI 3100
- ABI 3130
- ABI 3730
- ABI 310
- ABI 3500
- MegaBACE 500/1000