CYBERGENE AB

ChromoQuant®

412

For detection of aneuploidy in chromosomes 13, 18 and 21

- **Proven technology** QF-PCR
- **Fast analysis** Turnaround reporting time is less than 24 hours
- **High Throughput** PCR based system. Automatable for cost efficient analysis
- **High specificity** with 12 markers in total
- **Single tube test**
- **Decision support software** *Visualizer™*

IVD kit for fast and accurate diagnosis of

- Down syndrome Trisomy 21
- Edward syndrome, Trisomy 18
- Patau syndrome, Trisomy 13
- Klinefelter syndrome (XXY)

Key advantages

- One single PCR reaction gives all results. ChromoQuant® 412 is a single tube test
- The diagnostic procedure is based upon amniocentesis. Results are achieved within 6 hours enabling a "time to reply" of less than 24 hours
- The tests have been clinically validated for In Vitro Diagnostics and are CE marked
- The ChromoQuant® kit is validated for ABI and MegaBACE sequencers.
- Fast data evaluation is facilitated by the proprietary ChromoQuant® Visualizer™ software licensed to all users

High specificity

12 genetic markers in total. The ChromoQuant kit will analyse 99% of all samples with an informative result.

Single tube test

One single PCR reaction per clinical sample is required to obtain results.

Visualizer software

Visualizer™ software is a powerful decision support system and a database for safe storage of data. Visualizer™ is free to all ChromoQuant® users. Gives objective interpretation of results based upon Guidelines from CMGS; the Clinical Molecular Genetic Society.

CE marked IVD kit

ChromoQuant® is CE marked in accordance with the Directive 98/79/EC. ChromoQuant® is produced under quality system ISO 13485:2003 / ISO 9001:2008.

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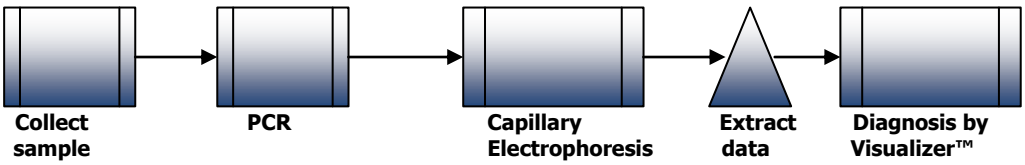
ChromoQuant Work flow



About CyberGene AB
CyberGene AB is active in the MedTech field by developing, manufacturing and selling In Vitro diagnostic products. CyberGene AB is also a service provider within the Biotech field in oligodeoxynucleotide (DNA) synthesis.

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ISO9001 • ISO13485 001

Intended Use	In vitro diagnostic for diagnosis of chromosome 13, 18 and 21
Total number of markers	12
No. of 13 markers	4
No. of 18 markers	4
No. of 21 markers	4
Kit size	24 test kits
CE-labelled for IVD use	Yes
Detection format	Capillary Electrophoresis with Genetic Analysers
Validated Genetic Analysers	ABI 310, 3100, 3130, 3500, 3730, MegaBACE systems
Reaction volume	25 µl
Control DNA included	Optional
Part no.	412.002-24

ChromoQuant® has been thoroughly validated. ChromoQuant® was clinically introduced in early 2004 and is used world wide. More than 45.000 clinical tests have been performed with the ChromoQuant® test since 2004 (February 2011).