CYBERGENE AB

ChromoQuant® QF PCR kit

311

For detection of aneuploidy in chromosomes 13, 18, 21, X and Y

- **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 38 markers in total including extra markers
- **GeneMapper and Genemarker panels**
- **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)
- Turner syndrome (X0)

Key advantages

- 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® kits are validated for ABI and MegaBACE sequencers.
- GeneMapper and GeneMarker plug ins are available
- Fast data evaluation is facilitated by the proprietary ChromoQuant® Visualizer™ software licensed to all users. The interpretation follows the recommendations given in the Best Practice Guidelines 2012.
- Detection of maternal contamination eliminate risk of misdiagnosis

High specificity

24 genetic markers in total plus 14 unique extra markers, 38 markers in total. The ChromoQuant® kit will analyse 99% of all samples with an informative result.

Extra markers included

Supplementary; Extra markers for all chromosomes are included in version 311.003-52. Cross identifying markers are included in all Extra Marker sets.

Visualizer software

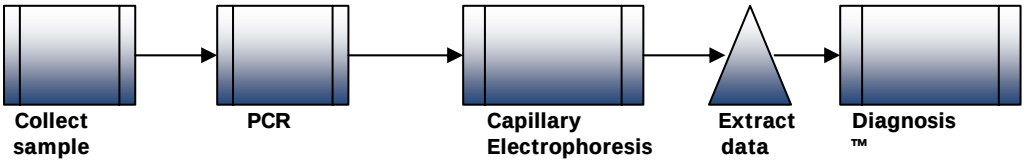
Visualizer™ software is a powerful decision support system and a database for storage of data. Visualizer™ is free to all ChromoQuant® users. Gives objective interpretation of results based upon Guidelines from CMGS; the Clinical Molecular Genetic Society.

CE marked IVD kit

ChromoQuant® is CE marked in accordance with the Directive 98/79/EC. ChromoQuant® is produced under quality system ISO 13485:2012 / ISO 9001:2008.

CYBERGENE AB

ChromoQuant Work flow



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

www.cybergene.com

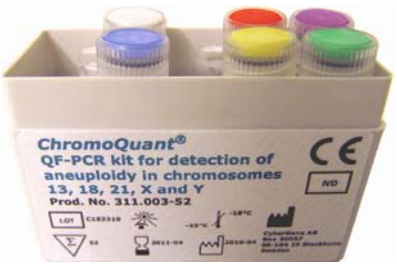
CyberGene AB
Box 30057
SE-104 25 Stockholm
Sweden

Telephone:
+46 8 608 23 90

Technical support:
chromoquant@cybergene.se

ISO9001 • ISO13485 001

Intended Use	In vitro diagnostics for diagnosis of chromosome 13, 18, 21, X and Y aneuploidy
No. of 13 markers	5 + 5 Extra markers (8 unique 13 markers)
No. of 18 markers	6 + 4 Extra markers (8 unique 18 markers)
No. of 21 markers	6 + 6 Extra markers (10 unique 21 markers)
No of X/Y markers	7 + 6 Extra markers (Including unique marker for identification of Turner syndrome (12 uniqe X/Y markers)
Cross identification	Each Extra marker set contains cross identifying markers
Kit size	24/52 tests
CE-marked for IVD use	Yes
Detection format	Capillary Electrophoresis with Genetic Analyser
Validated Genetic Analysers	ABI 310, 3100, 3130, 3500, 3730, MegaBACE systems
Data Interpretation	GeneMapper and GeneMarker plugins are available Visualizer decision support software free of charge
Complies with Best Practice Guidelines 2012	Yes
Part no.	52 tests 311.003-52 (includes extra markers) 24 tests 311.003-24 (does not include extra markers)



ChromoQuant® has been thoroughly validated in hospital clinics. ChromoQuant® was clinically introduced in early 2004 and is used world wide.