CYBERGENE AB

ChromoQuant® QF PCR kit

Optima Basic

Detection of aneuploidy in chromosomes 13, 18 and 21

IVD kit for fast and accurate diagnosis of

- Down syndrome Trisomy 21
- Edward syndrome, Trisomy 18
- Patau syndrome, Trisomy 13

Key advantages

- Single tube test with markers for chromosomes 13, 18 and 21
- 16 chromosome markers in total
- No sex chromosomes included, the kit can be used where information about fetal sex is not wanted or illegal
- Combine with Optima XY for sex chromosome information
- Taq polymerase included, ready to use
- Detection of maternal contamination eliminates the risk of misdiagnosis
- The diagnostic procedure is based upon amniocentesis/CVS.
- Results are achieved within 6 hours enabling a "time to reply" of less than 24 hours.
- The ChromoQuant® kits are validated for all sequencers from Life Technologies/ ThermoFisher Scientific

High specificity

The Optima Basic kit holds 16 unique genetic markers. The ChromoQuant kit will analyse 99% of all samples with an informative result.

Singel tube test

One single PCR reaction per clinical sample is required to obtain results. 6 markers for chromosome 21. 5 markers each for chromosomes 13 and 18.
Flexible- combine with ChromoQuant Optima XY for sex chromosome analysis

Interpretation of results

GeneMarker and GeneMapper templates for easy interpretation and reporting are available as downloads.

Visualizer STaR software

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

www.chromoquant.com

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Intended Use	In vitro diagnostics for diagnosis of chromosome 13, 18 and 21
No. of markers in Optima Basic	*16 genetic markers in a single tube test* ***13 18 21*** *5 5 6*
Complies with Best Practice guidelines for QF-PCR	Yes
CE-labelled for IVD use	Yes
Taq polymerase	Included
Detection format	Capillary Electrophoresis with Genetic Analyser
Validated Genetic Analysers	ABI 310, 3100, 3130, 3730, 3500
Part no. and kit size	414.001-26 (26 tests)
Rection volume	Total reaction volume 10µl Add only 4µl of DNA/reaction

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ChromoQuant® has been thoroughly validated. ChromoQuant® was clinically introduced in early 2004 and is used world wide.
ChromoQuant® is CE marked in accordance with the IVD Directive 98/79/EC and produced by CyberGene AB under quality system ISO 13485.

About CyberGene AB

CyberGene AB is a Swedish company, active in the MedTech field by developing, manufacturing and selling In Vitro diagnostic products. ChromoQuant is a registered trademark of CyberGene AB.