



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.





CYBERGENE AB

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| Intended Use | In vitro diagnostics for diagnosis of chromosome 13, 18 and 21 |
| No. of markers in Optima Basic | <i>16 genetic markers in a single tube test</i> 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 |

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.

www.chromoquant.com