CYBERGENE AB

ChromoQuant® QF PCR kit

Optima Single Chromosome

Detection of aneuploidy in chromosomes 13, 18, 21

IVD kits for fast and accurate diagnosis of

- Down syndrome Trisomy 21 – single tube test – 10 markers
- Edward syndrome, Trisomy 18 – single tube test – 9 markers
- Patau syndrome, Trisomy 13 – single tube test – 9 markers

Key advantages

- Used in prenatal testing
- Can be used as stand alone tests
- Can be used for verification of results obtained with other tests, e.g. NIPT
- Superior number of markers for each separate chromosome
- Single tube test with markers for one chromosome
- Optimised performance
- High flexibility for users
- Taq polymerase included, ready to use
- Detection of maternal contamination eliminates the risk of misdiagnosis
- Results are achieved within 6 hours enabling a "time to reply" of less than 24 hours.
- The ChromoQuant® kits are validated for all ABI Capillary Electrophoresis sequencers

High specificity

Optima Single Chromosome kits holds many unique genetic markers in separate tubes. This large number of markers means the ChromoQuant® Optima kit will analyse 99,9% of all samples with an informative result.

High Flexibility

The Optima kits can be used in combination or as stand alone tests for fast diagnosis of aneuploidy.

The kits can be used in combination with other ChromoQuant tests or for verification of results obtained with other tests e.g. NIPT screening.

Optima XY

ChromoQuant Single chromosome tests for Chr. 13, 18 and 21 can be combined with ChromoQuant Optima XY for diagnosis of aneuploidy in the sex chromosomes.

Interpretation of results

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

www.chromoquant.com

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Intended Use	In vitro diagnostics for diagnosis of chromosome 13, 18 and 21 aneuploidy
No. of markers in **Optima 13** **Optima 18** **Optima 21**	***Chromosome; 13 18 21*** *9 9 10*
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	514.601-26 (26 tests) Optima 13 514.602-26 (26 tests) Optima 18 514.603-26 (26 tests) Optima 21
Optima 13	514.601-26 single tube test 9 makers
Optima 18	514.602-26 single tube test 9 makers
Optima 21	514.603-26 single tube test 10 makers

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ChromoQuant® QF-PCR was clinically introduced in 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.