



CYBERGENE AB

ChromoQuant® QF PCR kit

STaR and SuperSTaR

Optima

Detection of aneuploidy in chromosomes 13, 18, 21, X and Y

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)
- Sex determination

Key advantages

- Superior number of markers
- Optimised performance
- High flexibility for users
- Many X markers in combination with Turner X0 verifying marker
- Turner X0 verifying TAF9B marker present in both reaction mixes
- Taq polymerase included, ready to use
- Detection of maternal contamination eliminates the risk of misdiagnosis
- Objective data evaluation by the proprietary ChromoQuant® Visualizer™ software, licensed to all users
- 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 SuperSTaR Optima kit holds 34 unique genetic markers in two tubes. This large number of markers means the ChromoQuant® Optima kit will analyse 99,9% of all samples with an informative result.

High Flexibility

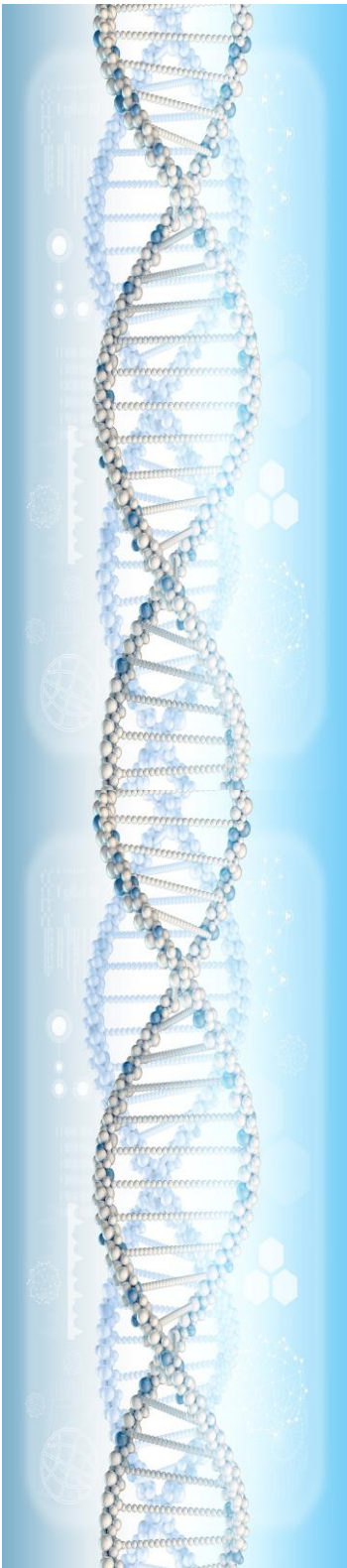
The Optima kits can be used as single tube tests (STaR Optima1) with the availability of extra markers (STaR Optima2) or as a duplex test (SuperSTaR Optima) for guaranteed result immediately.

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.

Interpretation of results

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





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Intended Use	In vitro diagnostics for diagnosis of chromosome 13, 18, 21, X and Y aneuploidy
No. of markers in SuperSTaR Optima (=STaR Optima 1 + STaR Optima 2)	34 genetic markers in two tubes Chromosome; 13 18 21 8 8 7 X Y XY X0 verifying 5 2 3 1
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	
SuperSTaR Optima	514.301-68 (68 tests) Optima 1 + 2 514.301-136 (136 tests) Optima 1 + 2
STaR Optima 1	514.100-68 (68 tests) single tube test 22 makers
STaR Optima 2	514.201-26 (26 tests) complement to Optima 1 13 markers, not stand alone, single tube

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