

ChromoQuant® QF PCR kit 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
- 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 ABI sequencers

High specificity

ChromoQuant STaR holds 35 unique genetic markers in two tubes.

With **a total of 35 markers**, the ChromoQuant® Optima kit will analyse 99,9% of all samples with an informative result.

CE marked IVD kit

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

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.



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Intended Use

In vitro diagnostics for diagnosis of chromosome 13, 18, 21, X and Y aneuploidy

No. of markers

35 genetic markers in two tubes

Chromosome;			
13	18	21	
8	8	8	
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

514.300-68 (68 tests) Optima 1 + 2
 514.300-136 (136 tests) Optima 1 + 2

STaR Optima 1

514.100-68 (68 tests) single tube test 22 makers
 514.100-136 (136 tests)

STaR Optima 2

514.200-68 (68 tests) complement to Optima 1
 14 markers, not stand alone, single tube

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

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About CyberGene AB

CyberGene AB is 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