



CYBERGENE AB

ChromoQuant® QF PCR kit

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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
- 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 higher resolution.

Interpretation of results

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





CYBERGENE AB

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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

34 genetic markers in two tubes

STaR Optima 1 – Reaction 1
STaR Optima 2 – Reaction 2

Chr.	13	18	21	X	Y	XY	X0
	5	5	6	2	1	2	1
	3	3	1	3	1	1	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

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.