CYBERGENE

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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 ±Reaction 1 STaR Optima 2 ±Reaction 2	3[illegible] genetic markers in two tubes **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, 35006HT6XGLR
Part no. and kit size SuperSTaR Optima	[illegible]2SWPD 514.301-68 (68 tests) Optima 1 + 2 514.301-136 (136 tests) Optima 1 + 2
STaR Optima 1	514.100- (tests) [illegible] [illegible] single tube test 22 markers
STaR Optima 2	514.201-26 (26 tests) complement to Optima 1 13 markers, not stand alone, single tube

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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.

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