A decentralized lab solution for NIPT

Multiplicom

ORHUN®
Healthcare Services

Clarigo™

The non-invasive prenatal test

Clarigo is a reliable and flexible solution for NIPT in local clinical laboratories

Reliable

Highly accurate trisomy risk assessment

Simple

Established MASTR technology with streamlined data analysis

Rapid

Optimized for straightforward implementation in standard lab environment

Affordable

Efficient use of lab resources enables cost-effective integration in prenatal care programs

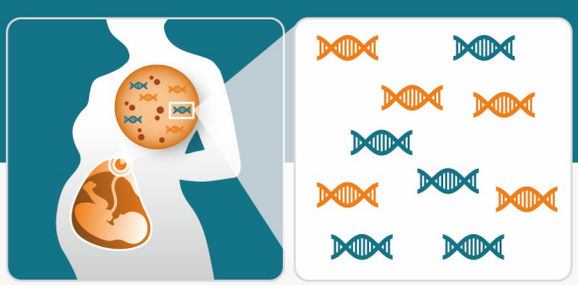
	Observed sensitivity	Observed specificity
Chr21	100.00% (54/54)	99.94% (1573/1574)
Chr18	95.00% (19/20)	100.00% (1626/1626)
Chr13	100.00% (4/4)	99.88% (1604/1606)

Data of this extended study of > 1900 samples meet specifications for CE-IVD label

Clarigo™

Clarigo™ is an innovative non-invasive prenatal test (NIPT) that analysis fetal cell-free DNA obtained from blood of the mother. Clarigo provides a highly reliable risk assessment for trisomy of chromosome 13 (Patau syndrome), 18 (Edwards Syndrome) and 21 (Down syndrome) of the fetus early in the pregnancy.

Clarigo has a superior accuracy and significantly lower false positive rate compared to the conventional prenatal screening methods, empowering improved confidence in the outcome for both pregnant women and their doctors and as a result a decreased need for invasive testing.



Fetal cfDNA
Maternal cfDNA

The Clarigo test is specially designed for implementation in local clinical laboratories using standard lab equipment and any of the current massively parallel sequencing systems.

The test is based on Multiplicom's proprietary Multiplex PCR technology, which facilitates straightforward, targeted and cost effective analysis of these common aneuploidies.

The interpretation of the data from the test is streamlined by the usage of the dedicated data analysis tool: the Clarigo Reporter.

The optimized and simple procedure enables rapid implementation of the test using local resources and infrastructure.

Clarigo workflow MPS options are Illumina's MiSeq, HiSeq and NextSeq.

Availability

Launch of the Clarigo test under CE-IVD label is announced in Fall 2015 and since then the Clarigo test is available to clinical laboratories who wish to offer NIPT results generated in their own facility.

Key features of the Clarigo™ test

Clarigo test kit(s)

- Ready-to-use reagents to start Clarigo
- Specific reagents for sequencer
- MPS as read out: MiSeq, HiSeq and NextSeq

Clarigo Reporter

- Private cloud-based data analysis platform
- Trisomy calling for chromosomes 21, 18, 13
- Fetal fraction determination included
- Optional gender calling

Visit us at:
clarigo.com
For More Information:
Sales and Marketing
irem.serger@orhunsaglik.com
Technical Issues
ozgecan.ayhan@orhunsaglik.com

About Multiplicom, Belgium

Multiplicom develops, manufactures and commercializes molecular diagnostic assays, provided as kits, which enable personalized medicine. Founded in 2011 as a spin-off from the University of Antwerp and VIB, Multiplicom achieved end of 2012 its first CE-IVD certification for the BRCA MASTR Dx assay for breast and ovarian cancer predisposition as the first company in Europe achieving a BRCA CE-IVD certification and it continues to develop and market quality-controlled, MPS- based assays, operating a Quality Management System to design, develop, manufacture and distribute CE-IVD products according to ISO 13485:2012.

About Orhun Healthcare Services, Turkey

Orhun Healthcare has been in Turkish Healthcare sector since 2002 as a service provider in radiology, radiotherapy and molecular diagnostics. Well known with its high technology investments and growing professional staff since its foundation, Orhun serves both in private and public sectors. Orhun Healthcare Services, who perceives molecular diagnostics and genetics as an inseparable part of medical screening, is the distributor of Clarigo, the test that brings a laboratory solution to the non-invasive prenatal testing.

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ORHUN® Healthcare Services

Orhun Healthcare Services Cemal Sahir Sok. Polat Mecidiyeköy İş Merkezi No:29 D:34 Şişli/İstanbul [w] www.orhunsaglik.com [p] 0212 272 9400 [f] 0212 272 9407