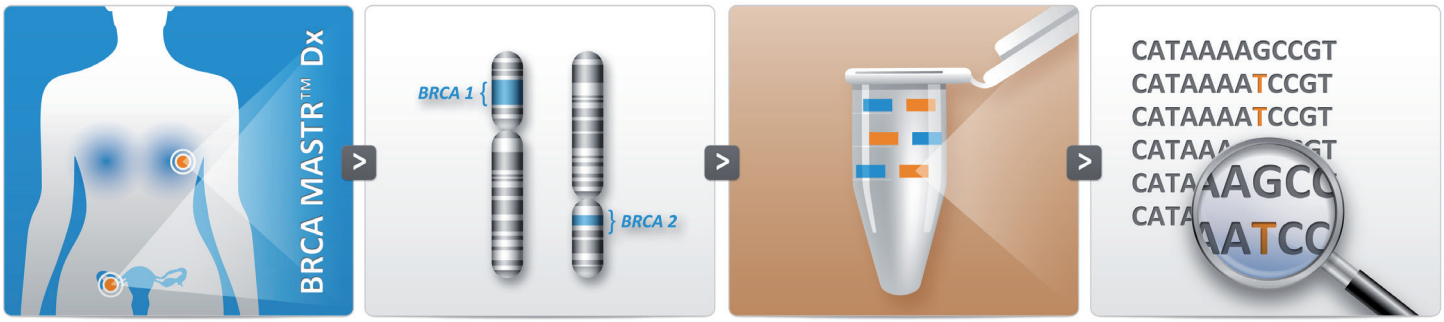
BRCA MASTR™ Dx

A simple, robust and complete CE-IVD validated diagnostic test of breast and ovarian related cancer for detection in MPS

CE-IVD

The BRCA MASTR Dx is a molecular diagnostic assay for the identification of all mutations in the *BRCA1* and *BRCA2* genes underlying breast, ovarian and/or related cancer.
Multiplicom's BRCA MASTR Dx assay is provided as a ready-to-use kit that offers robust performance with minimum hands-on time. All reagents necessary to enable multiplex amplification of 93 amplicons (289-430 bp) in five PCR reactions are included, for complete coverage of all coding sequences.
The assay is compatible with all current Massively Parallel Sequencing (MPS) systems, providing the flexibility to choose your preferred method.



Helping clinicians diagnose, treat and manage breast and ovarian cancer

Mutations in *BRCA1* and *BRCA2* have been linked to the development of hereditary breast and ovarian cancer. Female mutation carriers, for either gene, have 60% to 80% lifetime risk of developing breast cancer and 20% to 50% of developing ovarian cancer. Male *BRCA2* carriers have 6% to 8% lifetime risk of developing pancreatic, hepatic, prostate and breast cancer.

Family history and age are the most important criteria for a genetic testing request. When a mutation is detected there are various follow-up treatments such as hormone replacement therapy, chemoprevention strategies and prophylactic measures that clinicians can offer to lower the breast/ovarian cancer and overall mortality rate.

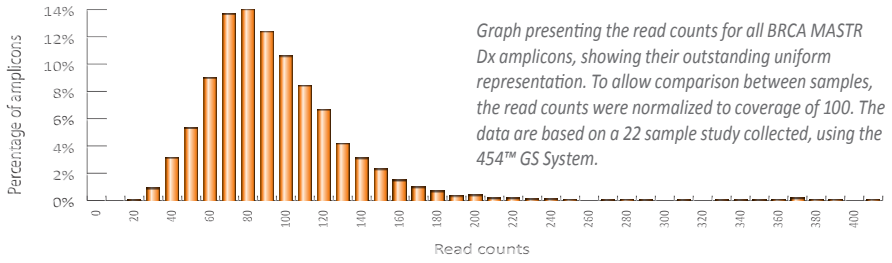
Due to an increased relevance of different treatments available for the various *BRCA* gene mutations, the use of Multiplicom's BRCA MASTR™ Dx makes it the ideal testing method used by geneticists to expedite the information needed for clinicians to make an early diagnostic and select the best treatment options available to increase the survival rate of their patients.

Added Value

Advantages	Specifications
Highly efficient workflow	*Ready-to-use kit with simple-to-follow protocols for various MPS systems*
Uniform coverage	*100% amplicons detected ≥ 0.2X mean coverage*
High target specificity	*> 96% on target read counts*
Low amount of DNA required	*As low as 20 ng per multiplex PCR reaction from fresh-frozen tissue and/ or blood samples*

Simple, fast, accurate and flexible

Optimized primer concentrations and the robustness of the assay guarantee a uniform representation of all amplicons, resulting in maximizing the sample throughput of your sequencing run.



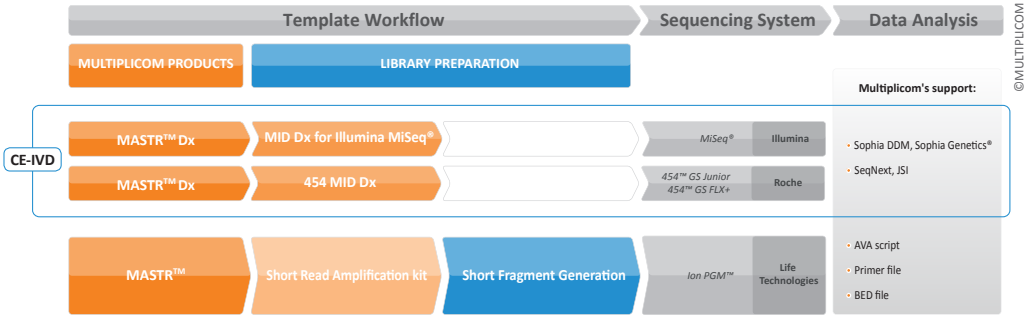
Graph presenting the read counts for all BRCA MASTR Dx amplicons, showing their outstanding uniform representation. To allow comparison between samples, the read counts were normalized to coverage of 100. The data are based on a 22 sample study collected, using the 454™ GS System.

Sequencing System	CE- IVD validated with BRCA MASTR™ Dx					Research Use Only	
	MiSeq®			454™ GS		Ion PGM™	
Flowcell/Chip	MiSeq Reagent Nano kit v2	MiSeq Reagent kit v2	MiSeq Reagent kit v3	Junior	FLX+	Ion 316™ Chip	Ion 318™ Chip
Sequencer Capacity	*500 Mb@ 2 x 250 bp*	*7.5 Gb@ 2 x 250 bp*	*15 Gb@ 2 x 300 bp*	*35 Mb@ 400 bp*	*350 Mb@ 400 bp*	*300 - 600 Mb@ 200 bp*	*600 - 1000 Mb @ 200 bp*
Total Reads	*800,000*	*12,000,000*	*22,000,000*	*70,000*	*700,000*	*1,000,000*	*5,000,000*
BRCA MASTR™ Dx (SNV only) samples per run	*27*	*407*	*746*	*6*	*60*	*18*	*93*

Maximum number of samples performed per run with various sequencers.

Works with all current MPS systems

A key advantage of the BRCA MASTR Dx is its high degree versatility. The reagents are applied with standard PCR protocols and equipment, and the assay is compatible with all MPS systems such as Illumina MiSeq®, Life Technologies Ion PGM™ and Roche 454™ GS.



BRCA MASTR™ Dx provides a simple and practical CE-IVD workflow from start to finish.

Product specifications

CE-IVD

MASTR™ Products for in-vitro diagnostic use

Cat. No.	Product Name	Genomic target	Contents	Reactions
MR-2012.008	BRCA MASTR™ Dx	BRCA 1&2 (SNV) (93 amplicons)	5 PCR mixes, Taq, AR1	8
MR-2012.040	BRCA MASTR™ Dx	BRCA 1&2 (SNV) (93 amplicons)	5 PCR mixes, Taq, AR1	40

MASTR™ Complementary Products for in-vitro diagnostic use

Cat. No.	Product Name	Target Sequencing Tech.	Contents	Reactions
ML-2204.240	MID Dx 1-48 for Illumina MiSeq®	MiSeq® System, Illumina	MID mix, PCR mix, Taq, FAM labeling, Primer mix	5 x 48 MIDs comb for a total of 240
ML-2205.240	MID Dx 49-96 for Illumina MiSeq®			
ML-2008.192	454 MID Dx kit 1-8	GS Junior/FLX+ System, Roche 454™	MID mix, PCR mix, Taq, FAM labeling	24 x 8 MIDs for a total of 192
ML-2116.192	454 MID Dx kit 9-16			
ML-2124.192	454 MID Dx kit 17-24			
ML-2032.192	454 MID Dx kit 25-32			
ML-2040.192	454 MID Dx kit 33-40			

Additional MASTR™ Complementary Product for research use only

Cat. No.	Product Name	Target Sequencing Tech.	Contents	Reactions
SR-0010.096	Short Read Amplification kit	sequencers with short reads: up to 200 bp	PCR mix, Taq, FAM labeling	96

Additional Products for research use only

Cat. No.	Product Name	Genomic target	Contents	Reactions
MP-0401.050	BRCA HP	BRCA 1&2 Homopolymer stretches (> 6bp or longer, n=31)	2 PCR mixes, Taq	50
MQ-0110.050	BRCA MAQ	BRCA 1&2 (CNV) (72 amplicons)	2 PCR mixes, Taq	50

- *MASTR™ Dx in combination with corresponding MID Dx (Molecular Identifiers), CE-IVD, validated for in vitro diagnostic use according to EU regulations by independent medical genetic laboratories with the Illumina MiSeq® and/or 454™ Roche GS Junior/FLX+ Systems. Note: All MASTR CE-IVD products are designed, developed, manufactured and distributed according to ISO 13485:2012 standard.*
- *HP (Homopolymer) assay for detection of changes in length of homopolymer stretches using capillary electrophoresis.*
- *MAQ (Multiplex Amplicon Quantification) assays for detection and analysis of copy number variations using capillary electrophoresis.*

Further information

- The BRCA MASTR™ Dx has been developed and tested in close collaboration with diagnostic centers and experts around Europe.
- Shelf life: Two years from manufacturing date.
- Storage conditions: -20°C.

About Multiplicom

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. It was the first company in Europe achieving a BRCA CE-IVD certification and it continues to develop and market quality-controlled, MPS-based assays. Therefore, it enables clinical laboratories to diagnose patients with a genetic disease or predisposition, steer cancer therapy, and identify congenital defects early in pregnancy. The Multiplicom N.V. site, located at Galileilaan 18 in Niel, Belgium, operates a Quality Management System to design, develop, manufacture and distribute CE-IVD products according to ISO 13485:2012.

Multiplicom

Molecular Diagnostics

Enabling personalized medicine

v.1503

Multiplicom NV [a] Galileïlaan 18, B-2845 Niel, Belgium [w] www.multiplicom.com [e] customerservice@multiplicom.com [p] +32 3 289 14 00 [f] +32 3 400 23 16