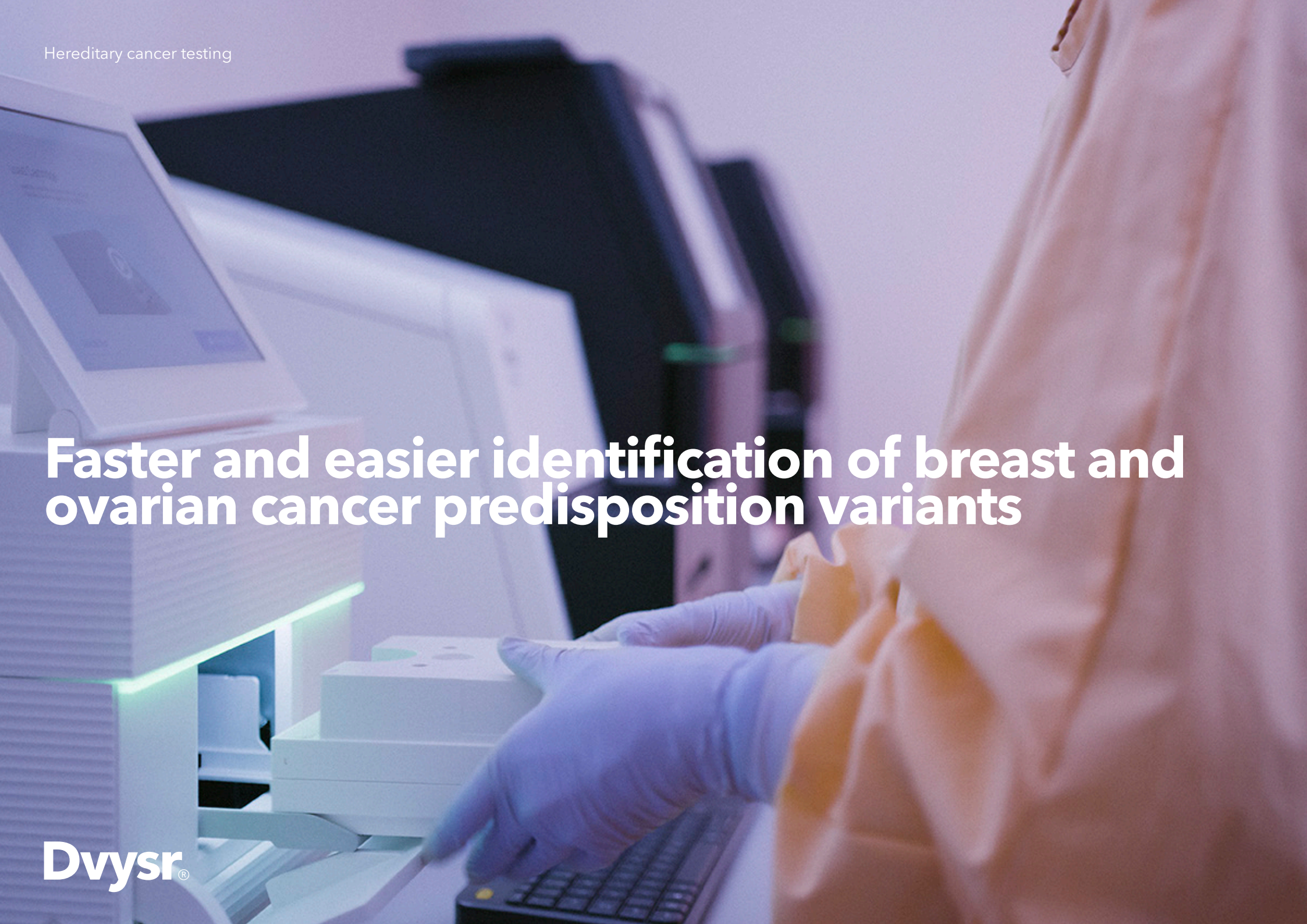


Faster and easier identification of breast and ovarian cancer predisposition variants

Dvysr®

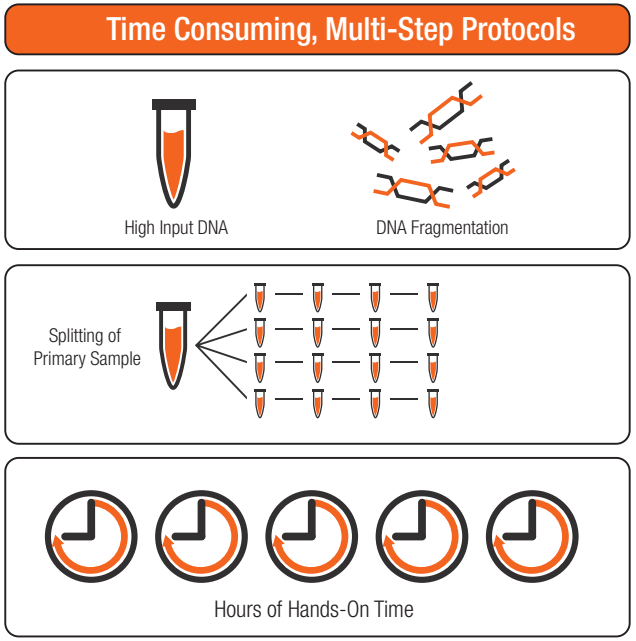
Challenges for routine diagnostic laboratories

■■■ The simultaneous sequencing of multiple genes using Next Generation Sequencing (NGS) has become more cost-effective than the analysis of individual genes by traditional Sanger sequencing.

Nonetheless, the implementation of NGS assays into clinical routine use can be limited by the complexity of the associated protocols and data analysis.

Large, comprehensive oncology gene panels may include genes that are not relevant or of unknown significance to the disease being tested by the laboratory.

This can result in higher sequencing costs and significantly increases the complexity of data analysis and clinical decision making due to the increased number of detected variants of unknown significance as well as other incidental findings.



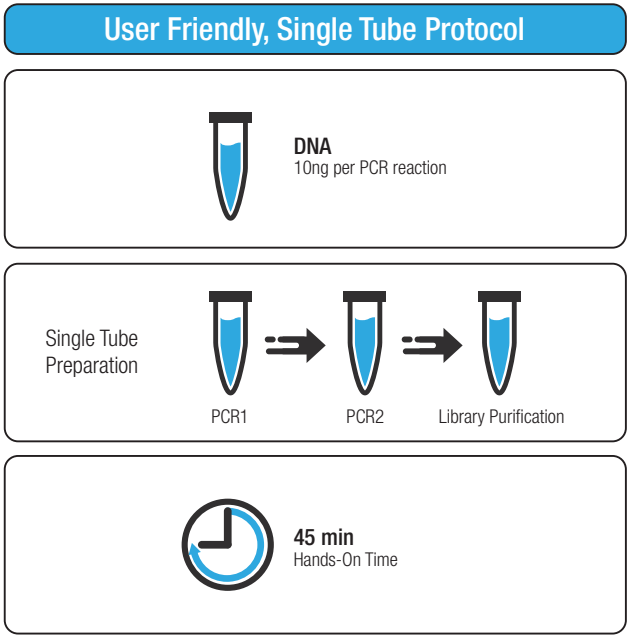
Devyser hereditary breast and ovarian cancer solutions

■■■ Devyser BRCA and Devyser HBOC kits are rapid targeted NGS library preparation assays intended for the detection of variants in BRCA1, BRCA2, and 12 additional genes where mutations are known to significantly increase the risk of developing breast and/or ovarian cancer.

- Devyser BRCA and Devyser HBOC can be used simultaneously as a first-line protocol for the analysis of 14 highly relevant HBOC-associated genes.
- Devyser HBOC kit can also be used as a follow-up after negative BRCA testing with Devyser BRCA.

Optimised for routine laboratory use, both kits employ a unique, simplified NGS library preparation based on Devyser's proprietary multiplex PCR chemistry.

Easy to implement and highly cost-effective, Devyser BRCA and Devyser HBOC are suitable for laboratories of any size.



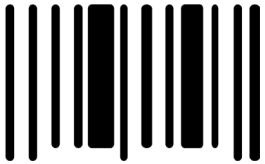
Fast and simple NGS workflow

■■■ Devyser's NGS kits offer a single tube library protocol with indexes that are delivered pre-dispensed in strip or plate format. This workflow minimises hands-on time and significantly reduces the risk for sample mix up and contamination. All patient samples are pooled to a single tube before clean-up.

Target amplification

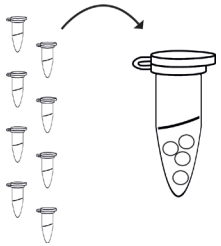
All target sequences are amplified using one single tube per patient sample.

Index addition



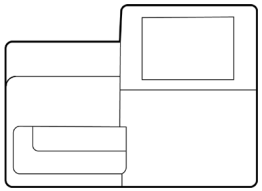
Patient specific molecular indexes are added to all samples.

Pooling and cleanup



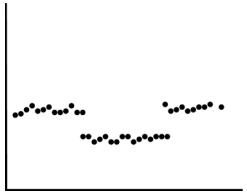
Combine and purify up to 96 samples simultaneously in a single tube.

NGS



Patient samples are sequenced using Next Generation Sequencing.

Data analysis

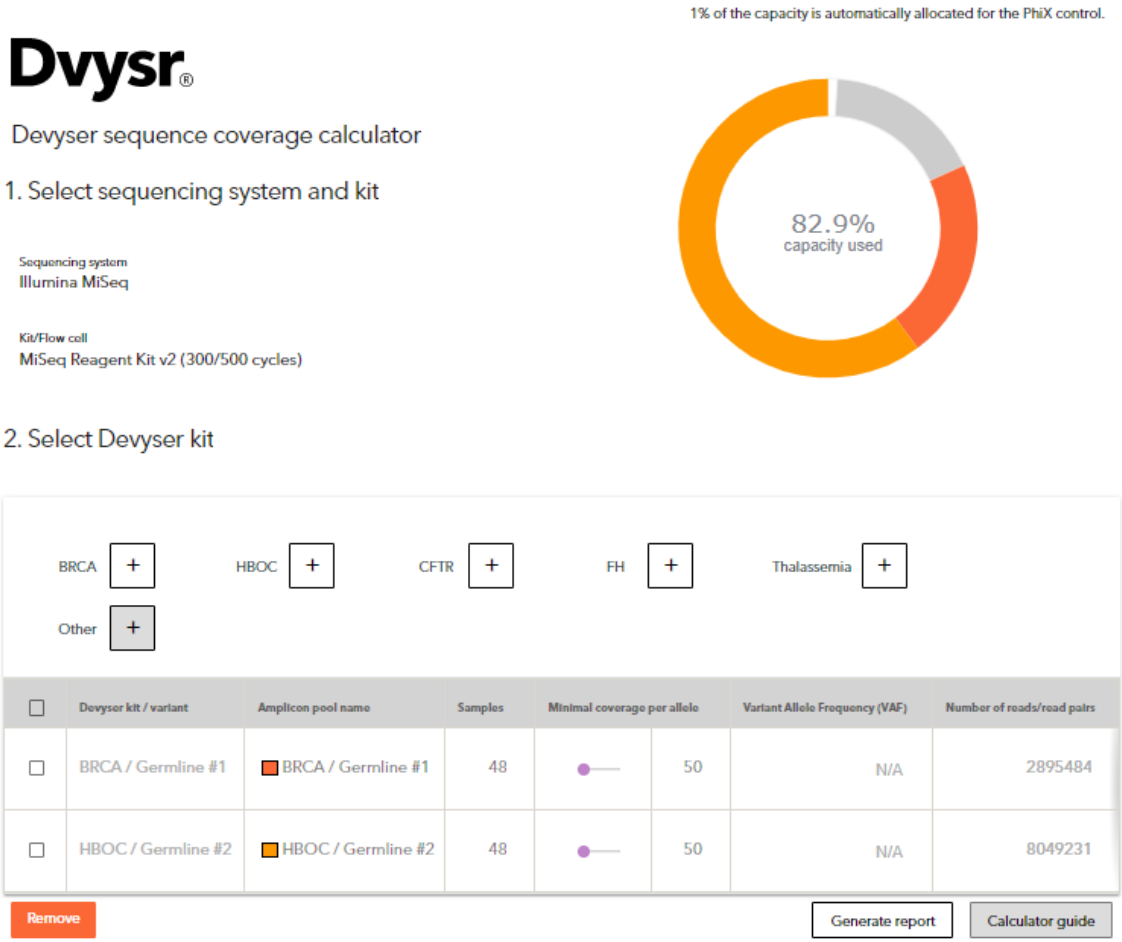


Data analysis and results reporting using a tailored Thalassemia analysis pipeline.

Software and sequence planning

■■■ Laboratories have a choice of fully supported analytical software solutions, locally deployed or cloud-based.

The planning of NGS sequencing runs is made easier by using the Devyser Sequence Coverage Calculator that provides information on the number of samples that can be pooled together in one flow cell in order to achieve the required coverage and maximise flow cell usage.
The capacity is calculated automatically in just 2 steps.



Devyser BRCA

■■■ Devyser BRCA is a CE-IVD kit intended for the detection of germline and somatic sequence variants in the coding regions of BRCA1 and BRCA2 genes.

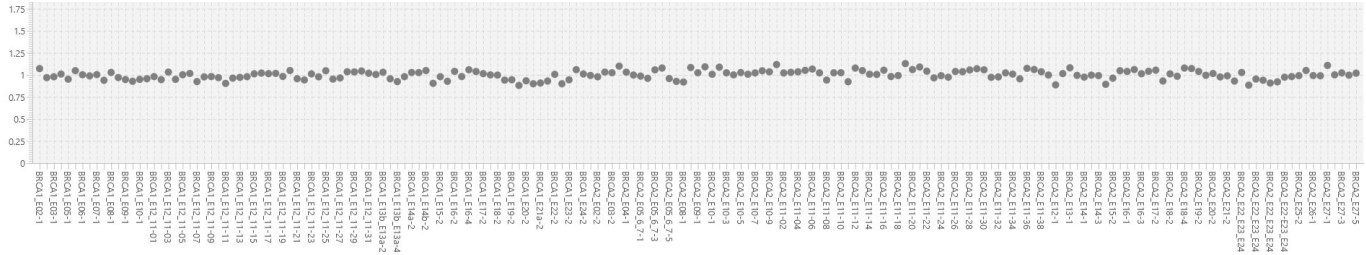
· **Number of mixes**	1
· **Optimal input DNA**	10 ng
· **Sequencer**	Illumina MiSeq
· **Coverage uniformity (>0.2x mean coverage)**	>99.9 %
· **Specificity**	>99%
· **Sensitivity**	>99%
· **Total library preparation time**	<45 min.

"Devyser BRCA for routine diagnostics is really simple, rapid, and straightforward. Library preparation is easier compared to other brands. Devyser is faster and easier to use"

Dr. Laura Papi
Careggi University Hospital
Florence, Italy

Devyser BRCA

Outstanding coverage uniformity



Key features and benefits

- Detect all mutations in BRCA1 and BRCA2
- One tube per sample means no need for sample splitting
- Reduce hands-on time from days to under 45 minutes
- One kit for both germline and somatic mutations
- Choice of several validated software options, including CNV analysis

Publication featuring Devyser BRCA

- Concolino, P. et al. A comprehensive BRCA1/2 NGS pipeline for an immediate Copy Number Variation (CNV) detection in breast and ovarian cancer molecular diagnosis. Clin. Chim. Acta 480, 173–179 (2018).
- Capone, G. L. et al. Evaluation of a Next-Generation Sequencing Assay for BRCA1 and BRCA2 Mutation Detection, J Mol Diagnostics 20, (2018).
- Costella, A. et al. High-resolution melting analysis coupled with next-generation sequencing as a simple tool for the identification of a novel somatic BRCA2 variant: a case report. Hum. Genome Var. 5, 0–3 (2018).

Devyser HBOC

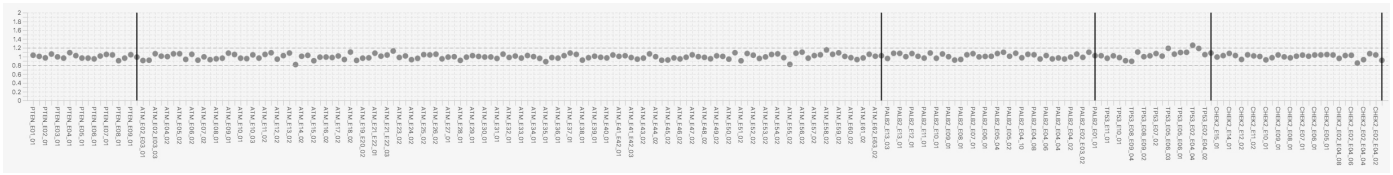
■■■ Devyser HBOC is a CE-IVD kit intended for the detection of germline sequence variants in 12 genes associated with an increased risk of developing breast and/or ovarian cancer.

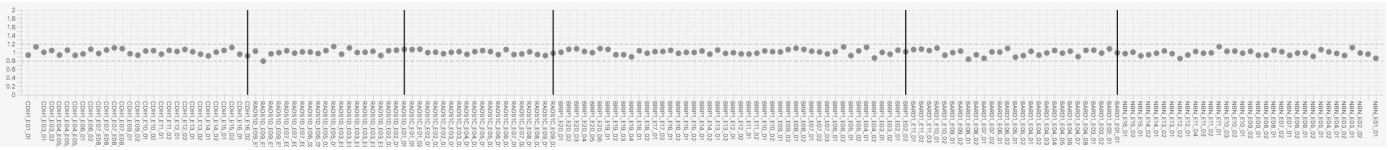
- **Number of mixes** 2 mixes pooled before PCR2
- **Optimal input DNA** 20 ng total, 10 ng per PCR reaction
- **Sequencer** Illumina MiSeq
- **Coverage uniformity (>0.2x mean coverage)** >99.9 %

Gene	Breast cancer	Ovarian cancer
PTEN	●	
CDH1	●	
TP53	●	●
STK11	●	●
RAD51C		●
RAD51D		●
BARD1	●	●
BRIP1	●	●
NBN	●	
PALB2	●	
CHEK2	●	
ATM	●	

Devyser HBOC

Outstanding coverage uniformity

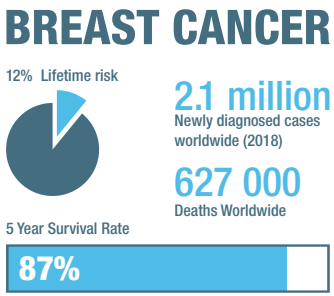


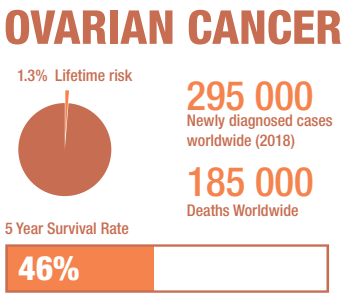


Key features and benefits

- Detect mutations in genes with a recognised connection to the development of breast and ovarian cancers
- Can be used as a follow-up after negative BRCA testing, or combined with Devyser BRCA for analysis of 14 genes in total
- End-to-end CE-IVD solution including NGS library preparation and a customised data interpretation software
- Targeted sequencing with high uniformity reduces sequencing costs by maximising sample capacity on every NGS flowcell
- User friendly workflow with 45 mins hands-on time and a total laboratory process time of five hours from DNA to sequencing

About breast and ovarian cancer





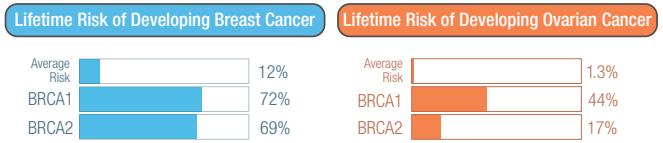
■■■ The breast and ovarian cancer threat

As the most common form of cancer for women, an estimated one in eight women will develop breast cancer over the course of her lifetime. Although the mortality rate has declined over the past two decades, breast cancer is still the leading cause of cancer-related death in women. While less common, ovarian cancer has a higher associated mortality rate, mainly due to the advanced stage at diagnosis or the lack of effective screening strategies.

Hereditary breast and ovarian cancer (HBOC)

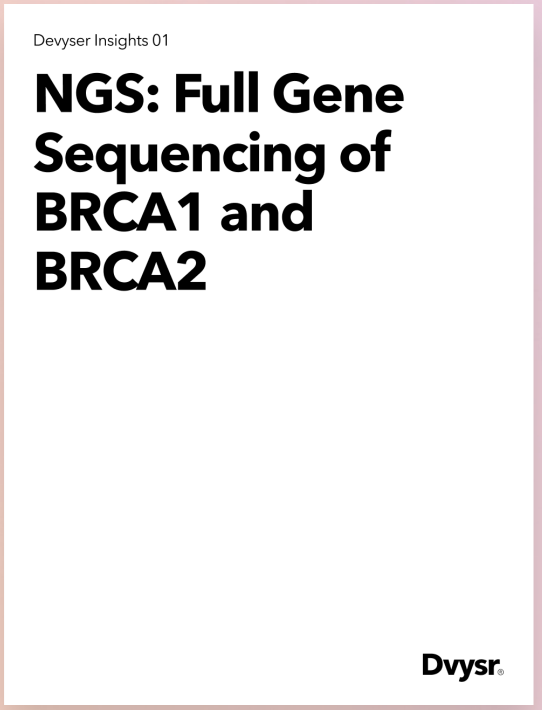
Hereditary Breast and Ovarian Cancer (HBOC) syndrome is an inherited disorder accounting for 5 to 10% of all breast and ovarian cancers. Mutations in either BRCA1 or BRCA2 genes are responsible for the majority of HBOC cases. Mutations in other genes displaying varying degrees of penetrance in HBOC syndrome have also been identified, leading to an increased lifetime risk of developing breast, ovarian, and other cancers compared to the general population. People with HBOC syndrome may also have an increased risk of other types of cancer, including pancreatic cancer, prostate cnacer, and melanoma.

Genetic testing of risk-associated genes may confirm a diagnosis and can help guide screening, prevention and therapeutic strategies for patients and their family, with the ultimate goal of reducing mortality.



Discover our Devyser Insight article: NGS: Full gene sequencing of BRCA1 and BRCA2

With the increasing use of new sequencing technologies such as NGS, the number of detected variants in BRCA1 and BRCA2 are increasing fast. As a consequence, the absolute numbers of Variants of Uncertain Significance (VUS) are also increasing. It will eventually be possible to classify these variants as more studies are completed, but for now the uncertainty concerning their clinical importance remains. When one or more VUS are detected in patients undergoing genetic testing of BRCA1 and BRCA2, counseling is difficult.



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bit.ly/devyser-brca
bit.ly/devyser-hboc
bit.ly/oncology-knowledge-hub

Article numbers
Devyser BRCA
8-A100-8 (8 tests)
8-A100-24 (24 tests)
8-A100-96 (96 tests)

Devyser HBOC
8-A111-24 (24 tests)
8-A111-48 (48 tests)

Accessories
Devyser Library Clean
8-A204

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