

Myriad partner laboratorium– MyChoice CDx Genome Instability Score Version 3

Skal udfyldes med blokbokstaver eller elektronisk

Analyse beskrivelse

MyChoice Genome Instability Score (GIS) giver en præcis evaluering af genomisk ustabilitet. Kombineret med *BRCA1/BRCA2* mutationsanalyse* udført på tumorvæv, giver den essentiel information om patientens Homologous Recombination Deficiency (HRD) status og mulighed for behandling med Poly-ADP Ribose Polymerase (PARP) inhibitorer, så behandlingen skræddersys til patientens unikke genomiske profil.

Platformen er kun valideret til bryst- og æggestokkræft, og det er rekvirentens ansvar at sikre, at tilsendte væv lever op til kriterierne beskrevet nedenfor.

*The safety and efficacy of *BRCA1/2* analysis, as performed by the local laboratory, has not been assessed by Myriad Genetic Laboratories, Inc.

Valg af analyse

☐ Myriad myChoice CDx GIS + analyse af *BRCA1/BRCA2*

Patientinformation

CPR-nummer (ddmmåå - XXXX): _____

Fornavn: _____

Efternavn: _____

Rekvirentinformation

Rekvirerende læge

Navn: _____

Stilling: _____

Afdeling: _____

Adresse: _____

Land: _____

Telefonnummer: _____

E-mail: _____

Underskrift

Hermed bekræfter rekvirerende læge, at patienten har samtykket til analysen:

Dato: _____

Underskrift: _____

Betalingsinformation (Skal udfyldes for at analysen kan udføres)

Navn: _____

Adresse: _____

CVR-, Vat-, SE-nr.: _____

EAN-nummer: _____

Omkostningssted: _____

Kontaktperson: _____

Reference: _____

Svar ønskes til: (sikker e-mail adresse/eller post adresse)

E-mail: _____

Udfyldes af Patologi Afdeling

- Analysen udføres på FFPE væv; enten hele blokke (returneres efter endt analyse) eller snit på glasplader.
- For at analysen kan udføres, **skal der være vedlagt en HE-farvning med en tydelig tuschmarkering af relevant tumorområde**. Alternativt vedlægges foto af tuschmarkeret HE-snit eller som Whole Slide Image (WSI). Er hele området tumor, skal **hele området** indtegnes.
 - Ved manglende indtegnning, sendes HE-glasset retur til indtegnning af relevant tumorområde.
- HUSK at vedlægge en kopi af patologibeskrivelsen
- Hvis en blok er ommærket, skal begge beskrivelser vedlægges, og det gamle nummer skal fremgå af den nye patologibeskrivelse. Der skal være en tydelig sammenhæng mellem det medsendte materiale og beskrivelsen.
- Det medsendte materiale, må ikke være ældre end 11 år og 9 måneder.

☐ **Patologibeskrivelse vedlagt**

☐ **HE vedlagt og tumorområde indtegnet**

Klinisk Information (for krav til prøvematerialet, se bilag 1)

☐ Ovariekræft (æggestokke, æggeledere, bughinde)

☐ Brystkræft

Block ID: _____

Vævstype: fx æggestokke, æggeledere, bughinde (Det modtagne væv må IKKE være fra hjerne, knogle eller endometrium)

Estimeret tumor indhold i procent*: _____ *minimum 30% tumorcelleindhold (se bilag 1 for yderligere information)

Alder ved operation: _____

Dato for biopsi/operation: _____

Kontaktoplysninger i tilfælde af spørgsmål til prøvematerialet

E-mail eller telefonnummer: _____

Returadresse til FFPE-blok:

Patologi Afdeling:

Adresse:

For yderligere spørgsmål

MGA-gruppen

Afdeling for Genomisk Medicin, Rigshospitalet

+45 5160 7324

Genomiskmedicin.rigshospitalet@regionh.dk
Rekviritionssedler
<https://www.rigshospitalet.dk/afdelinger-og-klinikker/diagnostisk/genomisk-medicin/rekvirering/Sider/Rekviritionssedler.aspx>
Prøven sendes til

 Afdeling for Genomisk Medicin, GM 4113
 Att.: Prøvemodtagelsen
 Rigshospitalet
 Blegdamsvej 9
 2100 København Ø.
 Tlf. +45 5162 8535

Bilag 1:

Selecting an optimal sample

How should samples be prioritized?

1. Chemotherapy-naïve tumors from primary debulking surgery or biopsy
2. Chemotherapy-treated tumors from primary debulking surgery or biopsy
3. Cytology cell blocks (e.g., ascites fluid) are acceptable BUT tumor content must exceed 30%

What type of samples should be taken?

MyChoice GIS can use any subtype of invasive ovarian, fallopian tube, and primary peritoneal cancer.**

**Omentum and lymph node are accepted but are not ideal for successful testing.

How to select an optimal block:

A tissue block is preferred over slides when available:

- At least one tumor block with a cross-sectional area $\geq 25\text{mm}^2$ that contains at least 40 μm of tumor

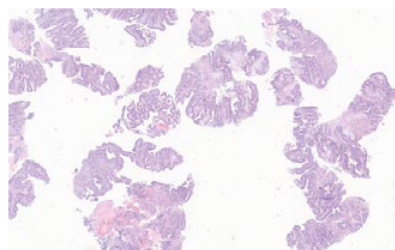
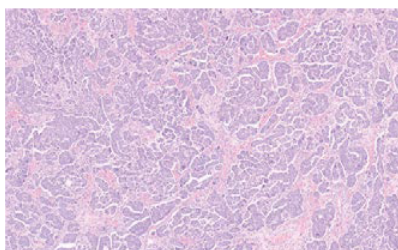
If only slides are available, follow these preparation instructions:

- Cut and label one 5 μm section for H&E staining on a charged slide
- Cut and label 5 μm sections on uncharged slides according to the table below

Area of tissue (mm ²) with tumor $\geq 30\%$	Number of slides
20-25	8
15-19	12
10-14	16
5-9	20

- Slides should be numbered in order of cutting and display a specimen identification number
- If submitting a block, include at least an equivalent amount of tissue remaining as listed in the table

All sample specimens must contain > 30% tumor content by pathologic review



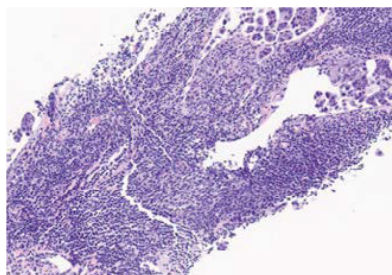
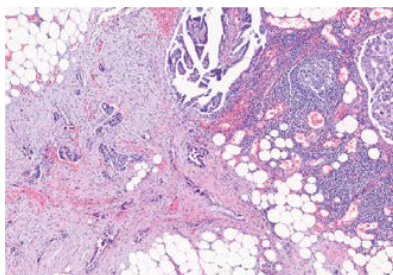
These examples illustrate high tumor percentage in comparison to normal tissue

Low-quality sample selection affects patient outcomes

Myriad Genetics understands sample selection cannot always be optimal, but MyChoice GIS can still give the results each woman needs with enough tumor content.

Ensuring specimens have at least 30% tumor cells in tissue or fluid samples is the best way to ensure MyChoice GIS success.

Which sample features are low quality?



These examples illustrate omentum with stromal response and marked inflammation (left) and lymph nodes with lymphocytes that greatly outnumber tumor cells (right)

Which samples are unacceptable?

- Brain metastases
- Bone metastases treated with acid decalcification
- Endometrial primary tissue
- Extracted DNA

Best practices for tissue handling

	Parameter	Process
Collection	Cold ischemic time	Tissue should be put into fixative as quickly as possible
	Fixative ratio	Minimum 10:1 fixative to tissue
	Fixation time	< 72 hours
	Temperature	Avoid high temperatures that will degrade DNA
Processing	Processor chemicals	Use high-quality reagents and replace regularly
	Dehydration	Full dehydration is important for long-term DNA preservation
Embedding	Wax	Use high-quality, low-melting point paraffin wax that does not contain additives or beeswax
Shipping	Temperature	Ice packs are recommended to avoid warping of the block and DNA degradation

High-quality sample selection means high-quality patient care