Rigshospitalet

Department of Genomic Medicine
Rigshospitalet, Copenhagen University Hospital

Myriad Partner Laboratory – MyChoice CDx Genome Instability Score

Clinical Trial Sample

Must be filled out in capital letters

Analysis description

The MyChoice Genomic Instability Score (GIS) offers a precise and expedited evaluation of genomic instability in ovarian cancer patients. Combined with *BRCA* testing* on tumor tissue, it provides essential information on the Homologous Recombination Deficiency (HRD) status of the patient, and therefore her suitability for Poly-ADP Ribose Polymerase (PARP) inhibitor therapy allowing to tailor treatments to the patient's unique genomic profile.

The analysis is validated for ovarian and breast cancer, and it is the requester's responsibility that the tissue meets the requirements as described below.

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

Choice of analysis

☐ Myriad myChoice CDx GIS + *BRCA1/BRCA2* analysis

Patient information

Date of birth (0101yyyy):

Study ID:

Requester information

Requesting doctor

Name:

Title:

Department:

Address:

Country:

Phone number:

E-mail address:

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Signature

The requesting doctor hereby confirms that the patient has consented to the analysis:

Date:

Signature:

Billing information (Must be completed in order for the analysis to be performed)

Institution name:

Address:

VAT or SE-no:

Contact person:

E-mail address:

Reference:

Results should be sent to:

E-mail address:

To be completed by The Pathology Department

- The analysis is performed on FFPE tissue; either whole blocks (returned after completed analysis) or tissue slides.
- To be able to carry out the analysis, **an HE-staining with a clear marking of the relevant tumor area is required.** Alternatively, attach a photo of the highligted HE-section with a marker or as a Whole Slide Image (WSI). If the entire tissue block is tumor, please encircle the **whole** area.
    - If there is no marking, the HE-slide will be returned to the requisitioner for marking of the relevant tumor area.
- REMEMBER to attach a copy of the pathology description.
- If a block is re-labelled, both descriptions must be attached, and the original ID-number must be included in the new pathology description.
  There must be a clear connection between the accompanying material and the description.
- The accompanying material must not be older than 11 years and 9 months.

☐ **Pathology description attached**

☐ **HE attached with a clear marking of the tumor area**

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Clinical information (For more information about the specimen please **see appendix 1**)

☐ Ovarian cancer (ovaries, fallopian tube, peritoneum)
☐ Breast cancer

Block ID:

Tissue type: e.g. ovaries, fallopian tubes, peritoneum (the received tissue must NOT be from brain, bone or endometrium)

Estimated TCP (tumor cell percentage): , **minimum 30%** tumor cell content (see appendix 1 for further information)

Age at the operation: Biopsy/operation date:

Contact information in case of any questions about the sample material

E-mail or phone number:

Return address for the FFPE:

Pathology Department:

Address:

For further inquiries

MGA group
Department of Genomic Medicine, Rigshospitalet
+45 5160 7324
E-mail: Genomiskmedicin.rigshospitalet@regionh.dk

Requisition notes	Samples should be sent to:
https://www.rigshospitalet.dk/afdelinger-og-klinikker/diagnostisk/genomisk-medicin/rekvirering/Sider/Rekvisitionssedler.aspx	Department of Genomic Medicine, GM 4113 Att.: Sample reception Rigshospitalet Blegdamsvej 9 2100 København Ø. Phone number: +45 5162 8535

Appendix 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 ≥ 25mm^2 that contains at least 40µm of tumor

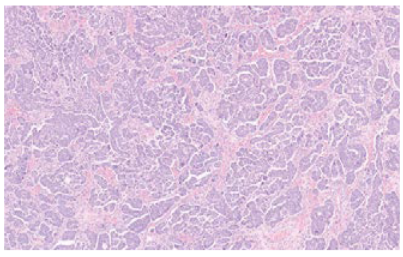
If only slides are available, follow these preparation instructions:

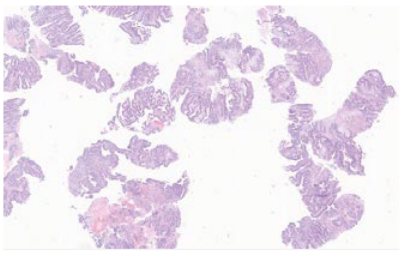
- Cut and label one 5µm section for H&E staining on a charged slide
- Cut and label 5µm sections on uncharged slides according to the table below

Area of tissue (mm^2) with tumor ≥ 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

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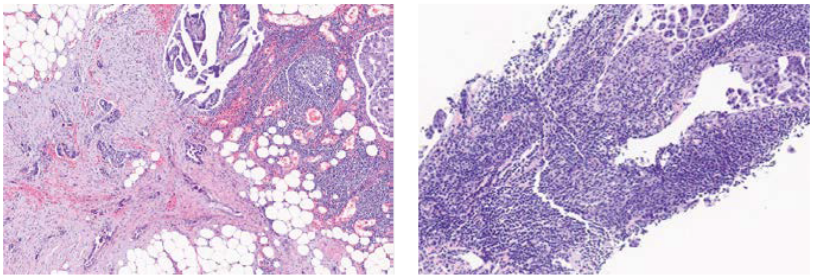
Low-quality sample selection affects patient outcomes

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
- Endometrial primary tissue
- Bone metastases treated with acid decalcification
- 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