Rigshospitalet

Center for Genomic Medicine

Rigshospitalet, Copenhagen University Hospital

Myriad – My Choice CDx Plus

Must be filled out in capital letters

Patient	Requester
Date of birth: _____ Patient- or Block ID: _____ First name: _____ Last name: _____	Requesting doctor: Name: _____ Position: _____ Department: _____ Address: _____ Country: _____ Phone number: _____ Mail: _____
REMEMBER to include a copy of the pathological description	The requesting doctor hereby confirms that the patient has consented to the analysis: Date: _____ Signature:_____

Billing information

Name:

Address:

VAT-no:

E-mail address:

Reference:

Results should be sent to: (secure e-mail address)

Mail address:_____

Test requested

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Intended use – Myriad My Choice CDx Plus is used to detect Homologous Recombination Deficiency (HRD) by assessing the GIS status and the Tumor mutation *BRCA1/BRCA2* status in genomic DNA extracted from tumor specimens. Results are used as an aid to determine the eligibility of patients with ovarian cancer treatment with certain Poly-ADP Ribose Polymerase (PARP) inhibitors with the approved therapeutic product labeling.

When ordered as a panel, sequencing and large rearrangement analyses are also performed on all analyzable regions of the following genes that have been analytically validated using multiple cancer types: *ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, PPP2R2A, RAD51B, RAD51C, RAD51D* and *RAD54L*. Results from these genes are provided for informational purpose only and have not been clinically validated for use with Poly-ADP Ribose Polymerase (PARP) inhibitors. Follow-up germline testing may be appropriate for mutations in genes associated with hereditary cancer risk.

Test option:

□ **Analysis of GIS + *BRCA1/2***

□ **Analysis of GIS + *BRCA1/2* + 13 additional genes**

Clinical information: For more information about the specimen please see appendix 1	□ Ovarian cancer (ovaries, fallopian tube, peritoneum □ Breast cancer Age at the operation: _____ Biopsy/operation date: _____	□ Tissue is formalin fixed (FFPE) * * Only fixed tissue can be tested using myChoice HRD. Formalin Fixed Paraffin Embedded (FFPE) blocks are preferred when available, however other fixatives can also be tested. Estimated TCP (tumor cell percentage)*:_____% *a minimum of 30% tumor cell is required (for more information please see appendix 1)
Return address for the FFPE:	Pathology dept: _____	Address: _____ _____

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For further questions	
MGA group Center for Genomic Medicine, Rigshospitalet. +45 5160 7324 Genomiskmedicin.rigshospitalet@regionh.dk	Consultant Maria Rossing + 45 3545 3016 / +45 3435 2223 caroline.maria.rossing@regionh.dk
Requisition notes	**Samples should be sent to:**
https://www.rigshospitalet.dk/afdelinger-og-klinikker/diagnostisk/genomisk-medicin/rekvirering/Sider/Rekvisitionssedler.aspx	Center for Genomic Medicine, GM 4113 Att.: Sample reception Rigshospitalet Blegdamsvej 9 2100 København Ø. Phone number: +45 5162 8535

Appendix 1: Selection of optimal tissue specimens*:

1. Specimens with at least 30% tumor cells in tissue or fluid samples by pathologic review.

    1. The tumor percentage can be found by dividing the number of malignant nuclei by the total number of nuclei. However, in samples where there is poor DNA quality, the assay may require a higher tumor percentage. If there is more than one block to choose from, the tissue from the block with the highest tumor percentage possible should be sent for testing.

2. A tissue block is preferred over slides when available.

    1. At least one tumor block with a cross sectional area ≥ 25mm² that contains at least 40 microns of tumor should be chosen for testing.

    2. If only tumor slides are available, preparation instructions below should be followed: Cut and label one 5µm section for H&E staining on a charged slide.

    3. Cut and label 5µm sections on uncharged slides according to the table.

Area of tumor (mm²)	# of 5µm unstained slides
20-25	8
15-19	12
10-14	16
5-9	20

3. Specimens that have been fixed >6 hours and <72 hours.

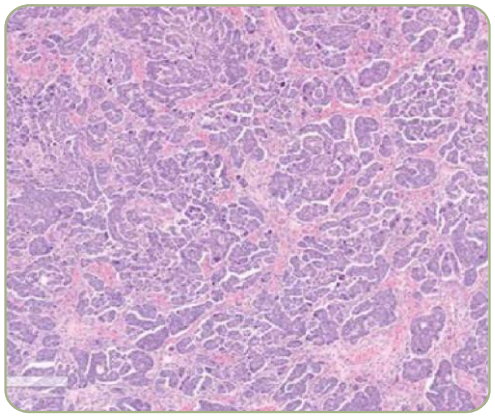
    (Under-fixation and over-fixation can result in DNA quality failures)

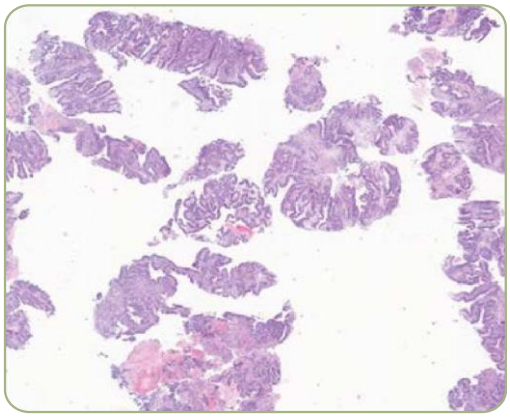
Specimens that do not meet these criteria will be accepted but run a higher risk of failure.

- The submitted tissue cannot be from brain, bone (depending on the decalcification method), or endometrium.
- Cell blocks from cytology samples such as ascites fluid are acceptable, as long as the tumor percentage is >30%.

THE FOLLOWING EXAMPLES ILLUSTRATE SPECIMEN FEATURES THAT ARE IDEAL

These specimens show high tumor percentage in comparison to normal tissue:





NOTE: Tumor percentage is calculated as the number of malignant nuclei/number of all nuclei.

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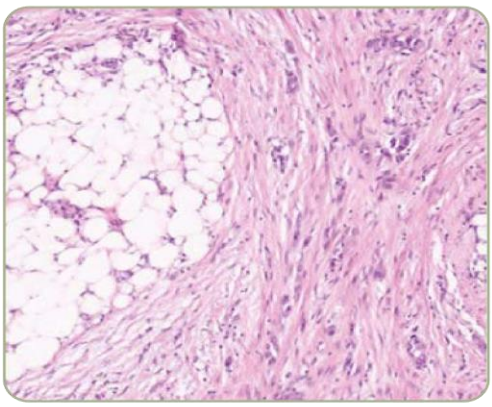
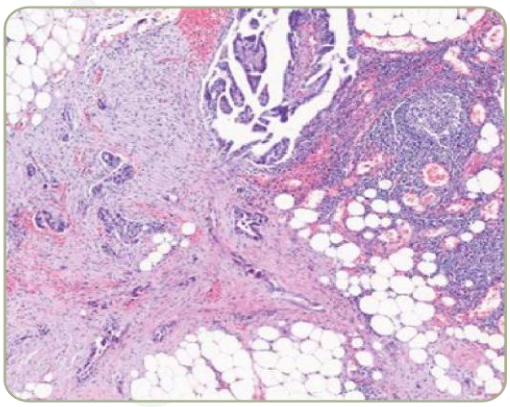
Switzerland

THE FOLLOWING EXAMPLES ILLUSTRATE SPECIMEN FEATURES THAT ARE NOT RECOMMENDED

Omentum with marked stromal response



Omentum with marked inflammation and stromal response



Lymph nodes with lymphocytes that greatly outnumber tumor cells