

Myriad – My Choice CDx Plus Version 4

Skal udfyldes med blokbokstaver eller elektronisk

Patient

Fødselsdato: _____

Fornavn: _____

Efternavn: _____

Rekvirent**Rekvirerende læge:**

Navn: _____

Titel: _____

Afdeling: _____

Adresse: _____

Land: _____

Telefonnummer: _____

Mail: _____

Underskrift

Hermed bekræfter rekvirerende læge at patienten har samtykket til analysen:

Dato: _____

Underskrift: _____

Betalingsinformation (Skal udfyldes for at analysen kan udføres)

Navn:

Adresse:

EAN-nummer:

Omkostningssted:

Vat nummer:

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

Mailadresse: _____

Ønskede analyse

Intended use – Myriad My Choice CDx Plus is used to detect Homologous Recombination Deficiency (HRD) by assessing the GIS status and the Tumor mutation *BRAC1/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, 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 mulighed: Analyse af GIS + BRAC1/2 Analyse af GIS + BRAC1/2 + 13 yderligere gener

Der skal vælges en pakke, der kan ikke kun bestilles HRD.

Udfyldes af patologi afdeling

HUSK at vedlægge en kopi af patologibeskrivelsen

Hvis en blok eller et glas ommærkes, skal begge beskrivelser vedlægges og det nye nummer skal fremgå af begge patologi beskrivelser.

Patologibeskrivelsen anonymiseres inden afsendelse til Myriad, prøven tildeles et eksternt Myriad nummer.

Der skal derfor være en tydelige sammen hæng mellem det medsendte materiale og beskrivelsen.

Block ID:

Kontakt oplysninger ved spørgsmål til det tilsendte:

Mail eller telefon nummer:

Klinisk information:

For krav til prøvematerialet, se bilag 1

- Ovariekræft (Æggestokke, Æggeledere, bughinde)
- Brystkræft

Vævstype:

Alder ved operation: _____

Dato for biopsi/operation:

- Væv er formalin fikseret (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.

Estimeret tumor indhold i procent*: _____%

*minimum 30% tumorcelleindhold (se bilag 1 for yderligere information)

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Retur adresse til FFPE blok:

Patologi afdeling:

Adresse:



Spørgsmål	
MGA gruppen Afdelingen for Genomisk Medicin, Rigshospitalet +45 5160 7324 Genomiskmedicin.rigshospitalet@regionh.dk	Overlæge Maria Rossing + 45 3545 3016 caroline.maria.rossing@regionh.dk
Rekvissionsedler	Prøven sendes til
https://www.rigshospitalet.dk/afdelinger-og-klinikker/diagnostisk/genomisk-medicin/rekvirering/Sider/Rekvissionsedler.aspx	Afdeling for Genomisk Medicin, GM 4113 Att.: Prøvemodtagelsen Rigshospitalet Blegdamsvej 9 2100 København Ø. Tlf. +45 5162 8535

Bilag 1: Selection of optimal tissue specimens*:

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

- b.** 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 microns of tumor should be chosen for testing.
- If only tumor slides are available, preparation instructions below should be followed: Cut and label one $5\mu\text{m}$ section for H&E staining on a charged slide.
- Cut and label $5\mu\text{m}$ sections on uncharged slides according to the table.

Area of tumor (mm^2)	# of $5\mu\text{m}$ unstained slides
20-25	8
15-19	12
10-14	16
5-9	20

- c.** Specimens that have been fixed >6 hours and <72 hours.

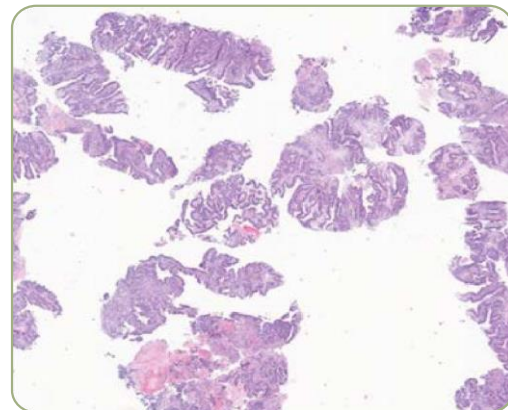
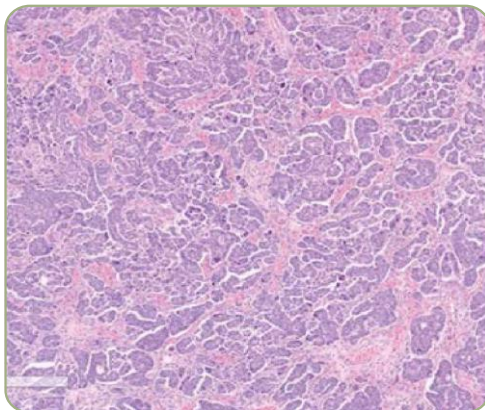
(Under-fixation and over-fixation can result in DNA quality failure)

**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

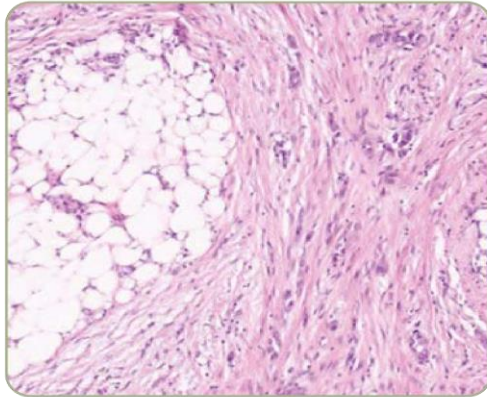
These specimens show high tumor percentage in comparison to normal tissue:



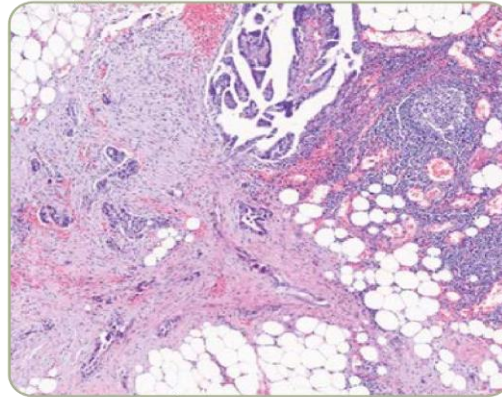
NOTE: Tumor percentage is calculated as the number of malignant nuclei/number of all nuclei.

THE FOLLOWING EXAMPLES ILLUSTRATE
SPECIMEN FEATURES THAT ARE NOT RECOMMENDED

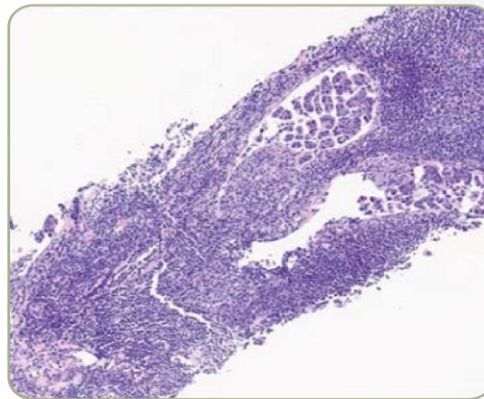
Omentum with marked stromal response



Omentum with marked inflammation and stromal response



Lymph nodes with lymphocytes that greatly outnumber tumor cells



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