MyChoice® CDx Plus

HRD Companion Diagnostic Test

Pathologist guide

Improve patient outcomes with high-quality sample selection

Myriad genetics

Testing changes lives

Myriad Genetics' MyChoice CDx Plus Homologous Recombination Deficiency Test is the gold-standard HRD test for ovarian cancer.

Clinicians use it to help guide first-line treatment decisions which provide optimal outcomes to women with ovarian cancer.

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 CDx Plus 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

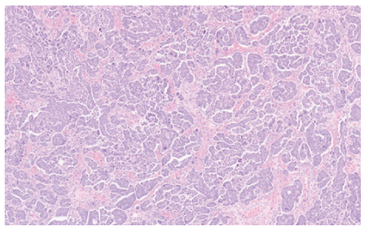
If only slides are available, follow these preparation instructions:

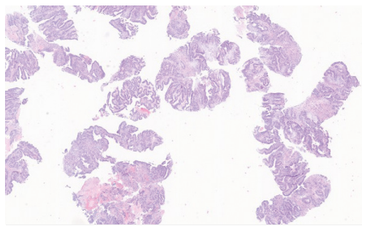
- Cut and label one 5µm section for H&E staining on a charged slide
- Cut and label 5µm sections on uncharged slides according to the table below

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





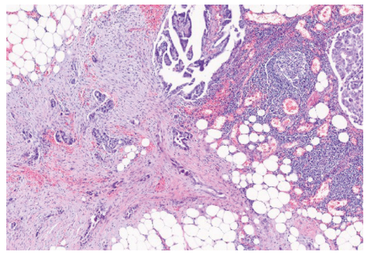
These examples illustrate high tumor percentage in comparison to normal tissue

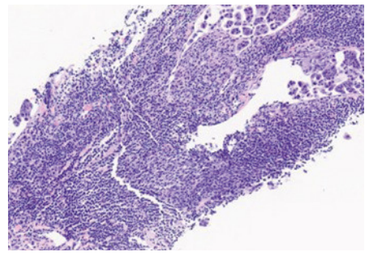
Low-quality sample selection affects patient outcomes

Myriad Genetics understands sample selection cannot always be optimal, but MyChoice CDx Plus 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 CDx Plus 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?

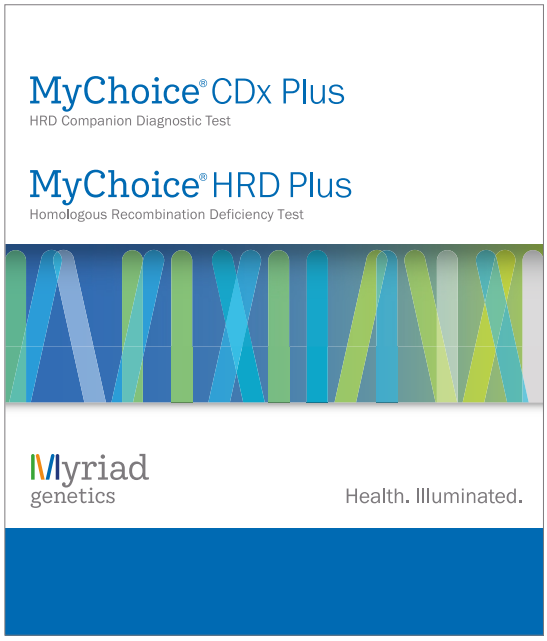
- Brain metastases
- Endometrial primary tissue
- Bone metastases treated with acid decalcification
- Extracted DNA

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

If the pathology team wants more advice on ensuring an optimal MyChoice CDx Plus sample, please contact Myriad Genetics



Intended use

Myriad Genetics MyChoice® CDx Plus is a next generation sequencing based in vitro diagnostic device that provides sequencing and large rearrangement analyses on a panel of genes and/or detects genomic instability using DNA extracted from tumor specimens. Homologous Recombination Deficiency (HRD) is determined by assessing the results of a subset of these genes and/or the Genomic Instability Score (GIS) Status.

The test may be used as a companion diagnostic to identify patients who are or may become eligible for treatment with specific therapies in accordance with the approved therapeutic product labeling. Results are to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with malignant solid tumors.

Myriad Genetics is committed to illuminating the treatment pathway for every woman

Myriad Genetics is a leading genetic testing and precision medicine company dedicated to advancing health and wellbeing for all, empowering individuals with vital genetic insights and enabling doctors to better detect, treat and prevent disease.

Myriad discovers and provides genetic and genomic tests that determine the risk of developing disease, assess the risk of disease progression, and guide treatment decisions across medical specialties where critical genetic insights can significantly improve patient care and provide access to the right treatments.

Myriad genetics

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The Myriad Genetics MyChoice® CDx Plus test was developed and performance characteristics were determined by Myriad Genetic Laboratories, Inc. and in compliance to In-Vitro Diagnostic Device Directive (98/79/EC) and is CE marked. Myriad is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing. Myriad is compliant with multiple international standards including, ISO 13485:2016 and ISO 15189: 2012 as applicable.

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