

Select optimal tissue specimen for a successful Precise™ Tumor or MyChoice® CDx test

Specimen selection

		MyChoice CDx	PreciseTumor	PD-L1
Cancer type	Ovarian, fallopian tube, and primary peritoneal cancer	✓	✓	✓
	All other tumor types	Ø	✓	✓
Fixative	10% neutral buffered formalin	✓	✓	✓
	Formalin and alcohol mixture	✓	✓	✓
	Any other fixative	✓	Ø	Ø
Specimen types	Frozen section tissue	✓	Ø	Ø
	Cytology cell block	✓	✓	✓
	Most recent procedure recommended	Ø	✓	✓
Exclusions	Brain tissue	Ø	✓	✓
	Acid decalcification	Ø	Ø	Ø
	EDTA decalcification	✓	✓	✓
	Endometrium	Ø	✓	✓

1

Chemotherapy-naïve

Ideal specimen are chemotherapy-naïve tumors from primary debulking surgery or biopsy.

2

Chemotherapy-treated*

If patient has received neoadjuvant therapy, chemotherapy-treated tumors from primary debulking surgery may be submitted, but chemotherapy-naïve tumor from biopsy is preferred.

*Pre-treatment biopsy samples should be considered in patients with complete or near-complete treatment response.

3

Biopsy

If debulking doesn't provide sufficient tumor, pre-treatment biopsy samples should be considered.

4

Cytology

Cytology cell blocks (e.g., ascites fluid) are acceptable but tumor content must exceed 30%. Unfixed cytology samples are not appropriate for genomic testing.



Single test order

Blocks*

At least one tumor block with a cross-sectional tumor area of **25mm² containing at least 40 µm of tumor** should be chosen for testing

Slides

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
- Cut and label 5 µm sections on **uncharged** slides:

Area of tumor (mm ²) with ≥ 30% tumor	# of 5µm unstained slides
20-25	8
15-19	12
10-14	16
5-9	20

- If cutting 10 µm sections, **please label** on slide "10µm"

PD-L1 Specimen

Can be performed on the tumor specimen FFPE block if provided, or:

- Additional 1-2 sections of 4-5 microns thickness provided on unstained, unbaked, **positively charged** slides
- A minimum of 50-100 tumor nuclei present

Biopsy

For small biopsies, try to submit at least 15 to 20 sections from 6 to 8 cores



Multiple test order

At least one tumor block with a cross-sectional tumor area of **25mm² containing at least 80µm of tumor** should be chosen for testing

If only tumor slides are available, preparation instructions below should be followed:

- Cut and label **two 5µm sections** for H&E staining on a **charged** slide.
- Cut and label 5µm sections on **uncharged** slides:

Area of tumor (mm ²) with ≥ 30% tumor	# of 5µm unstained slides
20-25	16
15-19	24
10-14	32
5-9	40

- If cutting 10µm sections, **please label** on slide "10µm"

For small biopsies, try to submit at least 15 to 20 sections from 6 to 8 cores

Preparation and fixation of samples

Fixative		10% neutral buffered formalin (NBF) is preferred, but others will be accepted.
		Fixation time should not exceed 72 hours.
		Fixative should be freshly diluted from stock within the previous 24 hours.
		Fixation should take a suggested minimum of 6 hours and a maximum of 72 hours. This will help reduce fixative artifacts from over fixation which can adversely affect the success of genetic testing.
		Fixative penetrates tissue at a rate of -1mm/hr. Large specimens should be opened or incised to promote formalin penetration and reduce autolysis, which can adversely affect the success of testing.
		Cytology samples must be spun, embedded into cell blocks and fixed in formalin. They can then be assessed for neoplastic cell content the same way as tissue samples.
Collection	Specimen Handling	Specimens should be handled using a 'genome-friendly' protocol that minimizes nucleic acid damage, but maximizes nucleic acid recovery while also preserving tissue morphology.
	Resection Specimen	Resection specimens should be delivered to pathology and undergo sample selection ideally within 1 hour of surgical excision.
	Biopsy specimen	Recommended to obtain additional core with a dedicated block for Myriad testing.
	Biopsy to fixative time	Tissue should go directly into fixative or degradation can occur.
	Ratio of fixative to tissue	30% ideal, 20% minimum
	Type of tissue	Ensure normal tissue is sampled before abnormal tissue to minimize contamination. Previously frozen tissue is accepted.
	Fixation before processing time	At least 8 hours but less than 36 hours is optimal for DNA* *Fixation times longer than 72 hours should only be used when characteristics of the specimen demand it.
Processing	Chemical 1 on processor	10% NBF preferred. Time here counts against time in fixative (less than 36 hours total).
	Chemical 2 on processor	Alcohol is standard in increasing strengths to dehydrate tissue.
	Chemical 3 on processor (Clearing agent)	Xylene is preferred. (Let Myriad AP lab know if substitute is used.)
	Processor run time	Typically runs overnight. Less than 4 hours not optimal.
MyChoice® CDx prep	Slides or blocks	DNA is more stable in blocks than slides, so blocks preferred.
	Slide prep	Uncharged slides preferred makes it easier for macro dissection.
	Refrigeration	Ice block must be sent to prevent the wax in the blocks/slides from melting. Heat can also damage DNA.
	Labeling	Sample containers must be clearly labeled according to institutional standards with an acceptable set of unique identifiers corresponding to information on the accompanying test request form.

If you have any questions about your specimen submission or to obtain additional kits, please call our dedicated Precise Oncology Solutions Customer Service at **877-283-6709** or email helpmed@myriad.com.

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