

To minimise test failure, following these requirements is important to assist in successful genomic profiling. For other specimen types, contact us before submitting.

Specimen Requirements

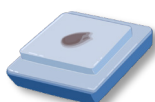
- ✓ FFPE specimens, including cell blocks (core needle biopsies, fine-needle aspirates, and effusion cytologies).
- ✓ Chemotherapy-naïve cancer types are preferred.
- ✗ Unfixed cytology specimens are NOT appropriate for genomic profiling.
- ✗ Decalcified and bleached tissues are NOT accepted.

ONLY ovarian, fallopian tube and primary peritoneal cancer types are accepted for HRD* genomic profiling.

Sample Preparation & Submission

Block Selection

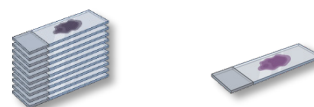
Select a block with the most invasive carcinoma that is morphologically consistent with the submitting diagnosis.



FFPE Tissue/Cell Block (preferred)

Optional: Include one (1) H&E stained slide if tumour purity has not been pre-determined.

OR



Unstained FFPE Slides + 1 H&E Stained Slide

Serial adjacent sections of 5µm on **uncoated** (coated for IHC) slides, labelled according in the order they were cut.

DNA/RNA is more stable in blocks than slides. Therefore, sending block is much preferred for genomic profiling, especially for Fusion panels, as RNA is known to degrade faster than DNA. A minimum surface area of 5 x 5mm² is required for slide preparation. For smaller tissue area lesser than 5 x 5mm², additional five to ten (5 – 10) slides is required.

Genomic Profiling FFPE Slides Preparation

OncoStrands® NGS Panel	No. of Genes#	No. of Slides Required	Slide Surface	Tumour Purity		
Essential Combined	50 DNA + Fusion RNA	10 x 5µm per panel	Uncoated	Minimum 10%		
Essential DNA	45 DNA					
Essential RNA	18 Fusion RNA					
DNA 68	68 DNA	15 x 5µm per panel		Uncoated	Minimum 20%	
DNA 68 + Essential RNA	68 + 18 Fusion RNA					
Extended	109 DNA					
Extended + Essential RNA	109 + 18 Fusion RNA					
Comprehensive	523 DNA + Fusion RNA	Uncoated	Minimum 20%			
Comprehensive + HRD*						
Comprehensive Fusion						
HRD*	2 (<i>BRCA1</i> & <i>BRCA2</i>)			10 x 5µm tumour tissue 10 x 5µm normal tissue (if any)	Uncoated	Minimum 10%
Promoter Methylation Test	No. of Slides Required					
MLH1						
MGMT		10 x 5µm tumour tissue				

*HRD reported in GIS and t*BRCA1/2* status, based on Myriad Genetics' proprietary algorithm and is available for Ovarian cancer ONLY. *Full gene list available upon request.

Immunohistochemical (IHC) FFPE Slides Preparation

IHC Test	Clone/Genes	No. of Slides Required	Slide Surface
PD-L1	SP263	4 x 5µm per test	Coated
ALK	-		
ROS1	-		
MMR	MLH1, PMS2, MSH2, MSH6	5 x 5µm	

Storage Conditions & Documentation Requirements

- ✓ Store specimens at room temperature (between 15 – 25°C).
- ✗ DO NOT Freeze, and keep away from direct sunlight.

All OncoStrands® genomic profiling tests need to be submitted together with the following:

- A copy of the histology report.
- Completed Test Requisition Form (TRF) with the treating physician's signature.

Packing & Shipping Instructions



Submit either FFPE block OR prepared unstained slides.

For Block submission:
Pack FFPE block into a small plastic Ziplock bag. If a H&E stained slide is included, insert the slide into a separate slide holder.

For Slides submission:
Insert slides into the slide holder box, leave a space in between the unstained slides and H&E stained slide.

Place the specimen into the Biohazard bag provided together with completed TRF in the kangaroo pouch. Include a copy of the histology report.

Place the items packed from Step 3 into the original OncoStrands® collection kit. Close the kit and place into a mailing bag.

Include laboratory accession no./specimen ID and label the block and/or slides with patient's information; full name and at least two unique identifiers (e.g. ID & D.O.B.). DO NOT pack slides face to face.

IMPORTANT: Ordering physician MUST sign and date the TRF and all sections of the form must be filled out completely. Store specimen at room temperature (15-25°C) and ship at ambient within the same day if possible. DO NOT freeze and keep away from sunlight.

Contact your local distributor for pick-up/shipping information. For direct shipping, contact LifeStrands Genomics for shipping information or send it through the pre-paid mailing bag provided within the collection kit (if any).

Sample Rejection Criteria

- Incomplete or absence of TRF.
- Absence or incomplete patient identifiers on the specimen.
- Patient information on the specimen does not match the information provided on TRF.
- Incorrect specimen type, i.e. submitting a specimen type that is not within the stipulated requirement.
- Tumour content is less than the specified minimum requirement.
- Less than the specified number of slides for each test.
- Specimen container and/or slides are damaged.
- Melted FFPE specimens.

Turnaround Time (TAT)

TAT is estimated upon sample receipt in our laboratory, reflected in working days Monday to Friday, excluding public and national holidays. Genomic profiling tests are generally unavailable for STAT testing. For urgent cases, contact us before submitting.

OncoStrands® NGS Panel	TAT	IHC Tests	TAT
Essential Combined Essential DNA Essential RNA	7 – 10 days	PD-L1	5 – 7 days (for standalone submission; concurrent TAT with OncoStrands® NGS panels)
DNA 68 DNA 68 + Essential RNA		ALK	
Extended Extended + Essential RNA		ROS1	
Comprehensive Comprehensive + HRD*		MMR	
Comprehensive Fusion HRD*	12 – 15 days	Promoter Methylation Tests	
		MLH1	
		MGMT	

*HRD is reported in GIS and tBRCA1/2 status, based on Myriad Genetics' proprietary algorithm and is available for Ovarian cancer ONLY.

Results will be available through your preferred means of reporting; email, fax, hard copy and/or secured LIMS provider account. Additional three to five (3 – 5) working days will be expected for hard copy reporting.

For further enquiries, or to order additional kits, TRFs and other supplies, please contact us at enquiry@lifestrands.com or visit our website at www.lifestrands.com.