

SPECIMEN PREPARATION INSTRUCTIONS

The recovery of quality DNA and mRNA from FFPE (formalin-fixed, paraffin-embedded) specimens can be challenging. A number of factors can impact the overall quality and yield of nucleic acids isolated from these preparations. We make the following recommendations that address several key factors:

- **TISSUE PROCUREMENT AND PROCESSING:** Tissues should be fixed within one hour of surgical resection. The optimal total fixation time is 12-24 hours, using only neutral-buffered formalin. Fixed tissues should be thoroughly dehydrated prior to the embedding process.
- **BLOCK STORAGE:** Storage of blocks without cut faces prevents ongoing damage from exposure to oxygen, water, light and other environmental factors.
- **TISSUE TYPE, SIZE, AND CONTENT:** Excess non-malignant starting material will result in an effective dilution of targeted nucleic acids. When required, Paradigm employs Laser Capture Enrichment (LCE) to isolate and increase the specific microscopic subpopulations from FFPE tissue blocks.

PARADIGM CANCER DIAGNOSTIC (PCDX™) – SPECIMEN REQUIREMENTS

Formalin Fixed Paraffin Embedded (FFPE) Samples

PCDX™ TESTING	SAMPLE TYPE	SPECIMEN REQUIREMENTS	TUMOR CONTENT		SAMPLE SIZE	
			OPTIMAL	MINIMAL	OPTIMAL	MINIMAL
NGS Analysis	Paraffin Block	(1) FFPE block from most recent surgery or biopsy, containing the most amount of tumor, excluding bone.	40%	10%*	75 mm ³ (5 mm x 5 mm x 3 mm) or 4 to 6 needle biopsies	One (1) core needle with 10% tumor (10mm x 2mm x 1mm) * RISK THAT FULL PROFILE CANNOT BE PERFORMED
	Shaves/Curls	(6-10) 10 micrometer thick freshly cut curls along with H&E stained section of same block				
NGS Analysis & IHC	Paraffin Block	(1) FFPE block from most recent surgery or biopsy, containing the most amount of tumor, excluding bone.	40%	10%*	75 mm ³ (5 mm x 5 mm x 3 mm) or 4 to 6 needle biopsies	One (1) core needle with 10% tumor (10mm x 2mm x 1mm) * RISK THAT FULL PROFILE CANNOT BE PERFORMED
	Shaves/Curls & Unstained Slides	(6-10) 10 micrometer thick freshly cut curls along with H&E stained section of same block & (7-25) 4 micrometer, freshly cut, unstained, unbaked, sections on positively charged slides, or (1) Slide per IHC selected +1				

* PARADIGM CUSTOMER SERVICE WILL CONTACT THE ORDERING PHYSICIAN IF THE SPECIMEN RECEIVED FOR TESTING DOES NOT MEET OUR ESTABLISHED REQUIREMENTS.

TESTING PRIORITIZATION

In the case where the sample is inadequate to run the entire analysis, the default priority of testing will be

1.) DNA for mutations, copy number variations and chromosomal changes, 2.) RNA for mRNA expression and 3.) Protein by IHC

Paradigm will also customize the priority of testing based upon the ordering physicians request.

SHIPPING INSTRUCTIONS

1. Freeze the Polar Pack included in shipping kit for a minimum of 4 hours.
2. Place FFPE Block with Paradigm Requisition Form and all patient insurance materials and pathology reports into Specimen Kit.
3. Place the Paradigm Specimen Kit into the pre-addressed shipping pack provided and seal.
4. Complete the pre-printed FedEx shipping label and affix to shipping pack.
5. Ship completed Specimen Kit (FFPE sample, requisition form, other documents) "Priority Overnight" to:

Paradigm PCDx
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(844) 232-4719

