

Specimen requirements and collection instructions - FFPE

Genome Insight’s CancerVision™ is for multiple tumor types. Information generated by this test aid in the identification of patients who are most likely to benefit from associated therapeutic products.

Kit components

- 1 Test requisition form
- 1 Specimen instructions
- 1 FFPE slide mailer (for 10 unstained slides)
- 1 FFPE slide mailer (for 1 H&E slide)
- 10 Microscope slides
- 1 Biohazard plastic bag
- 1 FedEx® ClinPak with “Exempt Human Specimen” label

Specimen requirements

Tissue sample size

- 10 FFPE unstained slides for NGS (positively charged and unbaked at 4–5 microns thick)
- 1 H&E stained slide*
- Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6–72 hours is industry standard.

Surface Area

- Minimum: 25mm² (Area 25mm² and thickness 5 μm on glass slide)

Tumor Content

- Optimum: 30% TN
- Minimum: 20% TN
- Storage: Room temperature (15-25°C)

***On the H&E slide, circle the area with the greatest tumor content.** Failure to follow these instructions will lead to delayed processing of the samples and delayed turnaround time.

Prepare specimen:

1. FFPE slides: prepare 10 consecutive unstained FFPE sections and 1 H&E stained slide both at 5 μm thick, on glass slides. 30% or higher malignant tumor content is required. Please hand-number the serially sectioned unstained slides (1-10) to indicate the order in which they were cut. Each slide must be properly numbered and labeled and placed into slide mailers.
2. Per CAP guidelines, patient material must be labeled with two identifiers.

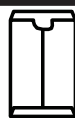
Collection and shipping instructions



Place completed test requisition form (TRF)



Prepare and label each specimen



Package



Ship

1. Place completed test requisition form (TRF) and any other attachments into the Genome Insight Specimen Shipping Kit.
2. Place the specimen shipping kit (including samples and paperwork) into the provided clinical shipping pack, first ensuring that primary specimen containers (e.g. EDTA tube) is labeled with two patient-specific identifiers. Seal the shipping pack. Confirm “Exempt human specimen” label checked on FedEx® ClinPak. Genome Insight’s FedEx Account Number is 685142600. Call 800.463.3339 to request a pick-up or drop the package at your site’s designated FedEx pick-up location and ship sealed shipping pack

Checklist and list of items

Before you ship your specimens, please ensure that you have prepared all the items listed below. For additional kits, please contact support@genomeinsight.net

- Test requisition form (TRF) - 1 sheet FFPE slide mailer
- 1 mailer for 10 unstained FFPE slides, 1 mailer for 1 H&E stained FFPE slide*
- Previous molecular diagnostic records (*optional*)

***On the H&E slide, circle the area with the greatest tumor content.** Failure to follow these instructions will lead to delayed processing of the samples and delayed turnaround time.

For further questions please contact our Customer Service at 858.665.2120