

Shipping Instructions

1. Please, register the sample for each patient, or if applicable for each primary tumor of the same patient, via the ordering portal (<https://agendia.com/ordering-portal/>). Or use the Test Request Form (TRF).
2. If you use the Agendia TRF, retain the carbon copy for your records and place the original copy in the kit. If you ordered online, you don't need to use the TRF. A PDF is available in the 'view orders' section.
3. Any unused specimen barcode labels should be left in the Agendia Specimen Kit and should NOT be used for another patient or a second primary tumor.
4. Place (if applicable) the TRF, a copy of the pathology report, and any relevant documents (such as patient insurance information) inside the Agendia Specimen Kit.
5. Adhere the provided courier shipping label to the Large Clinical Pak. Complete section 1 of the FedEx® International Air Waybill and include 3 copies of the commercial invoice.
6. Close the Agendia Specimen Kit box and place it in the Large Clinical Pak.
7. Seal the Large Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
8. Place the package in the designated courier pickup location at your site.
9. If your site does not have standard pickup, please contact the appropriate courier service.



To order any additional supplies or for any questions relating to reimbursement in your country, please contact our customerservice team at:

- www.agendia.com/ordering-portal/
- +31-(0)20 462 1510
- customerservice@agendia.com or visit
- www.agendia.com.



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Agendia Specimen Collection Kit

Instructions for Use

This kit is intended for collection and transport of formalin-fixed paraffin-embedded (FFPE) breast tumor tissue to Agendia's central laboratory, where the tissue is further subjected to *in vitro* diagnostic testing.

For professional and laboratory use.

This kit contains:

- 10 Microscopic slides
- 2 Five-slide carrier
- Small and large Zip Style Plastic Bag
- Specimen sampling Instructions
- Test Request Form
- Label sheet with barcode labels
- Shipping materials



Specimen Selection

1. Select the formalin-fixed paraffin embedded (FFPE) block with the highest amount of invasive carcinoma that is morphologically consistent with the submitting diagnosis.
2. FFPE specimens, including unstained slide specimens, are acceptable.
3. For successful analysis of your sample, It is recommended to use neutral buffered 10% formalin. Follow your laboratory's standard practice guidelines for the processing of FFPE tissue.
4. Agendia's genomic assays need at least an area of 9 mm² in one tissue section. Successful testing on specimens with a smaller surface area may be achieved when additional unstained slides or blocks are submitted.
5. Agendia will perform H&E stain using submitted material, which is used to assess tumor cell percentage. At least 30% invasive tumor (using estimated number of invasive tumor cells divided by total number of all cells with nuclei) is required to run the assay. When needed and feasible, a microdissection will be performed to avoid large areas of DCIS, necrosis, adipose tissue, stroma, and/or hemorrhage, because these cellular elements will reduce the tumor cell percentage.

Specimen Preparation Instructions

A) FFPE Blocks

1. For each block, apply 1 specimen barcode label that is provided on the inner top lid of the Agendia Specimen Kit (See Figure 1).
2. Place the tumor block in the small plastic bag and seal the bag.
3. Secure the specimen in the provided styrofoam insert and place it in the kit. If you need gel packs, please contact our customer service team.
4. It is not necessary to provide an H&E slide with submitted testing specimen because Agendia will perform H&E stain using submitted material.
5. Please proceed to Shipping Instructions.



Figure 1



Figure 2

B) Unstained Slides

1. Prepare ten (10) 5- μ m serial unstained slides with one 5- μ m serial section on each slide.
 - Use charged glass slides.
 - Ensure the sections on each slide are oriented similarly.
 - Allow the slides to dry at room temperature or in a slide dryer or oven.
 - Do not place cover slips on the unstained slides.
2. For each slide, apply one specimen barcode label that is provided on the inner top lid of the Agendia Specimen Kit.
3. Label the serially-sectioned unstained slides (1 to 10) to indicate the order in which they are cut.
4. When the unstained slides are dry, insert them into slide carriers and place one specimen barcode label on the outside of each slide carrier (See Figure 2).
5. Secure the slide carriers in the provided styrofoam insert and place it in the kit.
6. Please proceed to Shipping Instructions

**Follow your laboratory's standard practice guidelines:
Store and handle at room temperature.
Wear appropriate personal protective equipment
when handling patient samples.**