

# Shipping Instructions

1. Please prepare one Agendia Specimen Kit and Test Request Form (TRF) for each patient, or for each primary tumor of the same patient, if applicable. Apply one specimen barcode label on the TRF.
2. Before shipping, make a copy of the Agendia TRF and retain it for your records.
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 the Biohazard bag containing the specimen, associated 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 FedEx® shipping label to the FedEx Large Clinical Pack.
  - For customers outside of the United States, complete section 1 of the FedEx International Air Waybill and include 3 copies of the commercial invoice in the clear FedEx document pouch provided in the Agendia Specimen Kit.
6. Close the Agendia Specimen Kit box and place it in the FedEx Large Clinical Pack.
7. Seal the FedEx Large Clinical Pack 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 Customer Care team at [customer care@agendia.com](mailto:customer care@agendia.com) or visit [www.agendia.com](http://www.agendia.com)

M-USA-006-V5

For distribution in the US, Canada, Latin America, South Korea, Australia and New Zealand only

# Agendia Specimen Collection Kit Instructions for Use

Store and handle at ambient temperature

## Warnings and Precautions








- Make sure a suitable specimen is selected for the requested test procedure.
- Ensure the specimen is appropriately identified.
- Fill out the Test Request Form with the appropriate information.
- Follow your laboratory's standard practice guidelines:  
Store and handle at ambient temperature and wear appropriate personal protective equipment when handling patient samples.

## Intended use

This specimen collection kit, is a sample receptacle kit intended for professional laboratory use only. The device is intended for single use for transport of a formalin-fixed paraffin embedded (FFPE) female breast tumor tissue sample collected by the pathology laboratory and transported to Agendia's Diagnostic Service laboratory.

## Intended user

For professional laboratory use.

	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be defined
	Manufacturer	Indicates the medical device manufacturer
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed. Temperature is between 15 and 25 degrees Celsius



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## Specimen Selection Guidelines

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. Use standard fixation methods to preserve nucleic acid integrity. 10% neutral-buffered formalin for 6-72 hours is industry standard. DO NOT use other fixatives. DO NOT decalcify.
4. Samples with only ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), or microinvasive carcinomas (one or more foci <0.1 cm) are not acceptable samples.
5. Agendia's genomic assays need at least an area of 9mm<sup>2</sup> in one tissue section. Successful testing on specimens with a smaller surface area may be achieved when additional unstained slides or blocks are submitted.
6. 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.
7. If you do not have an Agendia Specimen Collection Kit, please label the blocks and slides with your pathology number and an additional patient specific identifier (e.g. patient name, medical record number, etc).

## Specimen Preparation Guidelines

### 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, along with the gel pack (preferably frozen), in the Biohazard bag.
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)

### B) Unstained Slides

1. Prepare ten (10) 5- $\mu$ m serial unstained slides with one 5- $\mu$ m serial section on each slide.
  - a. Use charged glass slides.
  - b. Ensure the sections on each slide are oriented similarly.
  - c. Allow the slides to dry at room temperature or in a slide dryer or oven.
  - d. 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 unstained slides (1 to 10) with serial sections 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 Biohazard bag.
6. Please proceed to Shipping Instructions.



(Figure 2)