

	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
	<i>In vitro</i> diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> 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
	Use-by date	Indicates the date after which the medical device is not to be used
	Manufacturer	Indicates the <i>medical device manufacturer</i>
	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 <i>medical device</i> can be safely exposed. Temperature is between 15 and 25 celcius

Advisory Notice:

Report any serious incident related to the Specimen Collection Kit to the manufacturer and to the competent authority of the Member State. The manufacturer will report the serious incident to the competent authority of the Member State in which the user/patient is established.



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

- www.agendia.com/order-a-test
- +31-(0)20 462 1510
- customerservice@agenda.com or visit
- www.agendia.com.



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MKT-067-V10

Modifications to previous version
Release v9 Feb 2023
Release v10 March 2026
Modification details:
Updated Specimen Preparation Guidelines



Instructions for Use Agendia Specimen Collection Kit

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.



This kit contains:

2 carriers with each 5 slides
Small and large Zip Style Plastic Bag
Specimen sampling Instructions
Test Request Form
Label sheet with barcode labels
Shipping materials

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.

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 assay¹. 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.

1. MicroArray MP and BP IFU MKT-517 (M-ROW-387) and MKT-518 (M-ROW-388)

Specimen Preparation

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-µm serial unstained slides with one 5-µm 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. Clearly write the Pathology Number on each slide. Ensure the Pathology Number is legible and clearly visible and not placed in an area that will be covered by a barcode label.
3. For each slide, apply one specimen barcode label that is provided on the inner top lid of the Agendia Specimen Kit.
4. Label the serially-sectioned unstained slides (1 to 10) to indicate the order in which they are cut.
5. 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).
6. Secure the slide carriers in the provided Styrofoam insert and place it in the kit.
7. Please proceed to Shipping Instructions.

Shipping Instruction

1. Please register the tissue sample of the primary tumor. In case of a multi focal tumor, register the other tissue sample of the same patient separately. Register via the ordering portal (<https://agendia.com/order-a-test>) or use the Test Request Form (TRF).
2. If you use the 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 copy of your order 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. Close the Agendia Specimen Kit and put it in the Clinical Pak or Flyer.
5. If you use FedEx: Complete section 1 of the FedEx® International Air Waybill and put it into the FedEx Clinical Pak including 4 copies of the electronic trade documents.
6. If you use DHL: Adhere DHL Waybill on the DHL Flyer and include electronic trade documents in the pouch, if applicable.
7. If you use MRW: Fill in Shipment Details with the online submission or send email to request pickup.
8. Seal the Clinical Pak or Flyer by removing the plastic adhesive protector from the white stripe and secure.
9. Place the package in the designated courier pickup location at your site.
10. If your site does not have standard pickup, please contact the appropriate courier service or Agendia Customer Service.