

Agendia Specimen Collection Kit

Instructions for Use



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Manufactured for: Agendia Inc. 22 Morgan Irvine, CA 92618

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 9mm² 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 macrodissection 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 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- μ m serial unstained slides with one 5- μ 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 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 Biohazard bag.
6. Please proceed to Shipping Instructions.



(Figure 2)

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 Pak.
 - o 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 Pak.
7. Seal the FedEx 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 Customer Care team at customercare@agendia.com or visit www.agendia.com

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