



mammaprint®

decoding breast cancer.

Sampling Instructions


1.

Before surgery

The fresh, unfixed tumor specimen must be delivered to pathology immediately following surgical removal



- A. Notify all parties involved in the surgical procedure, including pathology, that a tissue sample of the patient's fresh, unfixed tumor specimen will be required for MammaPrint gene expression profiling.
- B. Confirm that a pathologist will be available to obtain a fresh tissue sample from the tumor within 60 minutes of surgical removal.
- C. Confirm that the MammaPrint specimen collection and transportation kit is readily accessible within the pathology department.
- D. Upon surgical removal, the tumor specimen should be placed in a non-formalin carrier for immediate transport to pathology.
- E. If tissue sampling is performed by the operating surgeon, please place the sample of the tumor into the RNA*Retain*[™] vial and follow the shipping instructions provided.



Please do not place specimen in formalin until after the punch biopsy has been obtained for MammaPrint[®] testing

2.

Before you prepare the sample

Sample must be obtained within 60 minutes of surgical removal



- A. Remove large specimen tube from kit and open it.
- B. Place large screw cap with small specimen vial on table and open small specimen vial.
- C. Remove biopsy punch tool from package, unless using a scalpel, to obtain the tissue sample.



3a.

Preparing the surgical sample

Within 60 minutes of surgical removal

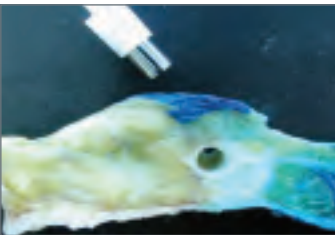
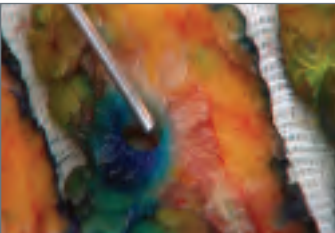


- A. Preliminary gross analysis is performed as needed and surgical specimen is inked for margin analysis.
- B. Specimen is bisected exposing the tumor for MammaPrint tissue sampling using a scalpel, or the optional punch biopsy tool provided within the kit.
- C. Using a scalpel, the tissue sample should be at least 3mm^3 (height, width, length) and at least one side of the biopsy should not exceed 5mm to allow penetration of the RNARetain™ fixative. If using the optional punch tool provided in the kit, the tissue sample will be 3mm in diameter and should be at least 3-5mm in length.
- D. Some clients serially section the specimen using a "bread-loafing" technique and tumor sections are exposed for MammaPrint sampling.
- E. Upon completing any sampling procedure, immediately place the tissue sample into the specimen vial containing RNARetain™ and close the specimen vial lid securely.

3b.

Preparing the surgical sample

Sampling tips



- A. Occasionally there is more than one lesion; be sure to biopsy the larger tumor.
- B. For ideal testing material, the tissue sample should include as much tumor as possible.
- C. Do not take the punch from areas with necrosis or hemorrhage.
- D. For soft lumpectomy specimens, placing the specimen in the freezer for 5-10 minutes adds rigidity, but will not damage the specimen; however, do not freeze the specimen.
- E. To minimize the compression distortion of surgical margins, use an elongated scalpel.
- F. Immediately place the tissue sample into the specimen vial containing RNA*Retain*[™] and close the specimen vial lid securely.

4.

Preparing the surgical sample

Instructions for using the biopsy punch tool



- A. The punch tool is held between the thumb and index finger and placed upon the cut surface of the tumor.
- B. Roll the punch between the index finger and thumb in a "screwing or rotary" motion applying moderate pressure to the specimen surface.



- C. Once the desired depth is attained, remove the punch from the incision site and extract the tissue sample from the "window" using tweezers or hemostats.

- D. If the tissue sample is not fully excised from the primary specimen, it should be carefully grasped and raised with a set of tweezers, avoiding any crushing, then separated with scissors or a scalpel at the base.



- E. If the specimen is lodged within the punch tool chamber, eject the specimen by inserting a stylus type device down the chamber of the tool and gently pushing the specimen out.

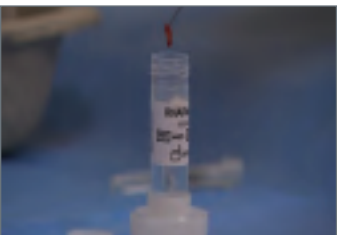
5.

Preparing the core needle sample

Imaging guidance dramatically improves tumor yield



- A. When submitting core needle biopsies for MammaPrint testing, please use a 14 gauge or larger needle. Please provide two core tissue samples to ensure sufficient tumor cells are obtained.
- B. The use of imaging guidance, even if tumors are large and easily palpated, will improve tumor yield. Therefore, it is recommended for all core needle procedures.
- C. Immediately place the tissue samples into the specimen vial containing RNA*Retain*[™] and close the specimen vial lid securely.



6.

Packaging the sample for shipment

Ship at room temperature, do not freeze the sample



- A. Place a barcode label from the completed requisition form onto the specimen vial.
- B. Replace the small specimen vial into the large specimen tube and place the tube into the specimen safety bag.
- C. Place the sealed specimen bag into the shipping kit along with the completed test requisition form.



- D. Package the kit into the FedEx shipping pak and attach the pre-printed label for shipment to Agendia.
- E. Please call FedEx and/or Agendia for pickup.



7.

Completing the test requisition form

Please provide as much information as possible

- Record specimen collection date.
- Complete the healthcare provider's information including the National Provider Identifier number (NPI), and an email address and/or a fax number for the MammaPrint test result.
- Complete patient information, including name and date of birth.
- Ensure appropriate clinical information is provided, including the diagnosis code (ICD-9 code).
- Ensure payment option is selected in the method of payment section.
- If the insurance billing option is being selected, ensure all patient contact information is complete, including telephone number and the following:
 1. Completely fill out insurance information section
 2. Legible photocopies of the front and back of insurance card(s)
 3. When applicable, patient's signed ABN or AOB
- If patient payment option (self pay) is selected, information must include either credit card information or check/money order.
- Ensure the ordering physician and/or submitting pathologist has signed and dated the form.
- Retain a copy of the test requisition form for your records; if possible, please fax a copy of the requisition to Agendia Customer Care at 888.669.3292, thereby providing advanced notice.

8.

Results

You will receive the MammaPrint test result within 7-10 working days by your specified means of reporting: email, fax, hard copy and/or secure intranet account.

9.

Questions

If you have any questions regarding the tumor sampling procedure, or if you require additional MammaPrint® shipping kits, please contact Agendia Customer Care at **(888) 321-2732** or email us at **customer care@agendia.com**.

RNA*Retain*[™] MSDS: Per OSHA 29CFR1910.1200 and the latest amendments to the European Union Directives 67/548/EC and 1999/45/EC the following product does not require a Material Safety Data Sheet (MSDS). Therefore Asuragen does not provide an MSDS for the following product.

RNA*Retain*[™] does not contain more than 1% of a component classified as hazardous and does not contain more than 0.1% of a component classified as carcinogenic. However, when working with this or any chemical reagent, we recommend the use of gloves, laboratory coats, and eye protection. Asuragen assumes no liability for damage resulting from handling or contact with this product.

For *in vitro* Diagnostic Use.

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17742 Beach Boulevard | Suite 250 | Huntington Beach | CA 92647
phone: 1.888.321.2732 | fax: 1.888.669.3292
customer care@agendia.com | www.agendia.com

