

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 larger 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. 1. **Within the US**, package the kit into the FedEx shipping pak and attach the pre-printed label for shipment to Agendia. Please call FedEx® at 800-goFedEx (800.463.3339) for specimen pickup.

- 2. **For outside the US**, put the specimen collection and transportation kit into the TNT pak. Please call your local TNT office to schedule a package pickup.



7. Completing the test requisition form

Please provide as much information as possible.

- A. If you use our customer portal for ordering, please enter your test request at customers.agendia.com.
- B. Record specimen collection date.
- C. Complete the healthcare providers information including the National Provider Identification Number (NPI) for US specimen. Include an email address and/or fax number for where the Agendia test result(s) should be sent.
- D. Complete patient information, including name and DOB.
- E. Ensure appropriate clinical information, including the diagnosis code (ICD-9 code for US specimens).
- F. If insurance billing is applicable, ensure all payment contact information is complete, including telephone number and the following:
 - 1. Completely fill out insurance information section or provide a copy of patient face sheet
 - 2. Legible photocopies of the front and back of insurance card(s)
- G. Ensure the ordering physician and/or submitting pathologist has signed and dated the form.
- H. Retain a copy of the test requisition form for your records.

8. Results

You will receive the Agendia test result(s) within 10 working days by your specified means of reporting: email, fax, hard copy and/or secure intranet account once the patient's specimen is received at Agendia.

9. Questions

If you have any questions regarding the tumor sampling procedure, or if you require additional Agendia Specimen Kits, please contact Agendia or visit www.agendia.com.

US Specimens:

Email: customercare@agendia.com
Ph: 888.321.2732

Non- US Specimens:

Email: customerservice@agendia.com
Ph: +31 20 462 1510

10. Material Safety Data Sheet

Asuragen's RNARetain® 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.

Asuragen's RNARetain® 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.

Agendia®, MammaPrint®, TargetPrint®, Blueprint™, TheraPrint™, and ColoPrint® are trademarks of Agendia Inc., Irvine, CA and NV, Amsterdam, The Netherlands. Agendia test microarrays are manufactured by Agilent Technologies, Inc. RNARetain® is a trademark and product of Asuragen, Inc. and available pursuant to a licensing agreement with Asuragen, Inc.



SYMPHONY™ Colon Cancer Profile

Personalized Colon Cancer Genomic Profile



Specimen Sampling Instructions

US Specimens:
Agendia, Inc.
22 Morgan
Irvine | CA 92618
p: 888.321.2732
f: 866.756.7548
e: customercare@agendia.com
u: www.agendia.com

Non-US Specimens:
Agendia NV
Science Park 406
1098 XH Amsterdam
The Netherlands
p: +31 20 462 1510
f: +31 20 462 1505
e: customerservice@agendia.com
u: www.agendia.com



1. Pre-surgery preparations

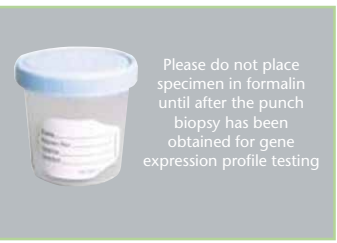
The fresh, unfixed tumor specimen must be delivered to pathology immediately following surgical removal.



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 Agendia's gene expression profiling test ColoPrint®.



B. Confirm that a pathologist or other qualified person is available to obtain a fresh tissue sample from the tumor within 1 hour of surgical removal.



C. Confirm that the Agendia Specimen Collection and Transportation kit ("Specimen Kit") is readily available at the location where the specimen will be obtained.

2. Specimen collection and transportation kit

The sample must be obtained within 1 hour of surgical removal.



A. The specimen kit contains essential items for obtaining and preserving the tissue sample (for packaging and shipping instructions see Sections 6 and 7).

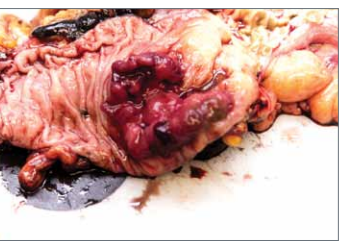


B. The specimen sample should be placed in the inner vial labeled RNARetain® (attached to the inside of the screw cap of the larger plastic tube).



C. The sampling tool may be used to obtain a punch biopsy sample from a surgical specimen. For instructions on how to use the punch biopsy tool see Section 4.

3. Obtaining a sample from a surgical specimen



A. Preliminary gross examination is performed as needed and the surgical specimen is inked for assessment of margins.



B. Tumor is cross-sectioned to expose cut surface of viable, invasive tumor for Agendia tissue sampling. The sample may be excised with a scalpel or with the optional punch biopsy tool provided in the sampling kit.



Note: Prevent extended exposure of the tumor surface to air to avoid air drying of tumor tissue. If necessary, keep wet with normal saline.

4. Instructions for using the punch biopsy tool

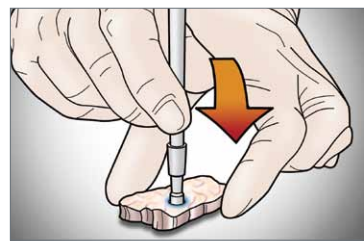
C. Obtain the specimen. **Send two samples per specimen when possible:**

1. If using a scalpel, the tissue sample should be 3 to 4 mm in thickness (maximum of 4 mm) and between 5 and 10 mm in diameter. This size allows timely and thorough perfusion of the RNARetain® preservative.

2. If using a punch biopsy tool, the tissue core will measure 6 mm in diameter and should be approximately 5 mm in length.
a. For instructions on how to use the punch biopsy tool see Section 4.

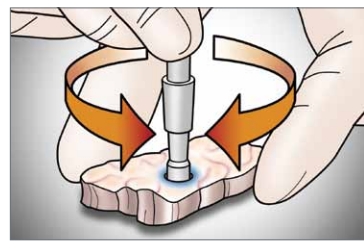
Note: There is a higher probability of the sample being analyzable if the punch tool is used.

D. Place the sample immediately into the RNARetain® specimen vial. The sample is stable in this preservative solution for 7 days at room temperature. Please ship the specimen to Agendia to arrive before the 7th day.



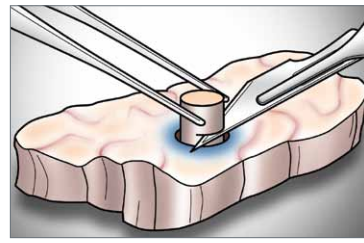
A. The punch tool is held between the thumb and index finger with its cutting end placed perpendicular to the tumor surface.

B. Under moderate pressure, roll the punch between the thumb and index finger in a screwing or rotary motion pressing gently into the tumor. Once a depth of approximately 5 mm has been reached, angle the punch tool at 45 degrees while still rotating in order to sever the tissue core at its base.



C. Withdraw the punch tool with the biopsy core contained within and extract the core with tweezers through the side window within the tip of the punch tool. Do not crush the tissue.

D. If the tissue core slips out of the punch tool because its base is still attached to the main specimen, the core should be carefully grasped and raised with tweezers and separated at its base with scissors or a scalpel. Do not crush the tissue.



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

F. Once the tissue sample has been obtained, place the sample immediately into the RNARetain® specimen vial.

5. Sampling tips and choosing the sampling site

A. Tumors are very often covered or surrounded with adenoma or normal mucosa. To minimize the presence of this tissue in the sample for Agendia, it is necessary to make a deep and central cut into the tumor tissue to reach the invasive part of the fresh tumor before taking a sample.

B. Avoid areas with obvious necrosis or hemorrhage.

C. Very soft surgical specimens may be difficult to bisect without distorting the surface margins. These specimens may be "firmed up" by being chilled in the freezer for about 10 minutes after the outer margins have been inked. Be careful not to freeze the tissue.