

OncoDefender™ – CRC SAMPLE COLLECTION & PREPARATION GUIDELINES



GENERAL SPECIMEN REQUIREMENTS FOR UNSTAINED SLIDES

1. Confirm American Joint Committee on Cancer (AJCC) Stage I or Stage II colon carcinoma, or Stage I rectal carcinoma (CRC).
2. **For submission of tissue sample slides**, prepare 15 tissue slides containing an amount of unstained formalin-fixed, paraffin-embedded (FFPE) tissue (5 microns thick) that, when taken together, provide a total of at least 375 sq mm of CRC tumor foci (i.e., ≥ 25 sq mm tumor/slide). Follow detail guidelines and instructions below for collection, preparation, and shipment of unstained slides.
3. The amounts indicated above are sufficient to perform one test and any necessary quality control procedures, along with one repeat or confirmatory test if necessary. If an insufficient amount of sample is received for testing, there may be delays and the test request may be referred to the Laboratory Director for issuance of a Specimen Rejection report.

NOTE: For submission of tissue block samples, select an FFPE tissue block with the greatest amount of invasive cancer. Everist Genomics will return any unused tissue from this block to the Pathologist. Refer to separate detail guidelines and instructions for collection, preparation, and shipment of blocks.

DETAIL GUIDELINES FOR UNSTAINED SLIDES

1. Choose a block with the greatest amount of invasive cancer.
2. Minimize hemorrhage, necrosis, and adipose tissue.
3. Stained slides are not required. An H&E slide will be prepared by and reviewed at Everist Genomics.

DETAIL PREPARATION AND SHIPPING INSTRUCTIONS FOR UNSTAINED SLIDES

1. Preparation materials:
 - FFPE colon or rectal cancer tissue block
 - OncoDefender™ – CRC Specimen Collection and Shipping Kit
 - OncoDefender™ – CRC Test Requisition Form
 - Glass slides (not included in Kit) and slide carriers (included in Kit)

(NOTE: Prior to shipment, the 3-ounce ice pack included in the OncoDefender™ – CRC Specimen Collection and Shipping Kit should be frozen overnight.)
2. Follow your laboratory's standard procedures for processing FFPE tissue.
3. Discard the first three slices from the tumor block and then prepare 15 FFPE tissue slides containing unstained FFPE tissue (5 microns thick) that, when taken together, provide a total of at least 375 sq mm of CRC tumor foci (i.e., ≥ 25 sq mm tumor/slide).
 - Be sure sections on each slide are oriented alike.
 - Clearly label each slide consecutively and with patient name and/or ID. **(NOTE: Use reagent resistant ink or pencil.)**

- Allow slides to air dry. NO OVEN. NO PLUS + + SLIDES.
 - Do not use cover slips on slides.
4. Label slides:
 - Affix one bar code label from the inside lid of the OncoDefender™ – CRC Specimen Collection and Shipping Kit to each slide.
 - Number the slides (1-15) in the order in which they were cut. **(NOTE: Use reagent resistant ink or pencil.)**
 5. Insert dry slides into the slide carriers provided in the OncoDefender™ – CRC Specimen Collection and Shipping Kit.
 6. Place a bar code label from the inside lid of the OncoDefender™ – CRC Specimen Collection and Shipping Kit on the outside of each slide carrier and put the slide carriers in the foam block slots in the Kit.
 7. Insert the foam block with slide carriers and the frozen 3-ounce ice pack into the inner large secondary plastic bag and place the bag with foam block and slide carriers in the Kit box.
 8. Seal the inner large secondary plastic bag with the zip lock.
 9. Complete the OncoDefender™ – CRC Test Requisition Form
 - Affix a bar code label from the inside lid of the OncoDefender™ – CRC Specimen Collection and Shipping Kit in the space provided at the top of the Requisition Form. **(NOTE: Use only one form and one collection kit per patient. DO NOT USE any leftover bar code labels in the kit box for another patient or specimen.)**
 - Make a copy of the OncoDefender™ – CRC Test Requisition Form for your records.
 10. Insert the OncoDefender™ – CRC Test Requisition Form, any patient insurance documentation, and a copy of the Pathology report into the OncoDefender™ – CRC Specimen Collection and Shipping Kit. Place these materials between the box and the inner large secondary plastic bag.
 11. Close the kit box with the lid tab.
 12. Shipping materials:
 - OncoDefender™ – CRC Specimen Collection and Shipping Kit box that contains the specimen, the OncoDefender™ – CRC Test Requisition Form, and other required documentation.
 - FedEx® shipping materials, including pre-printed Domestic Airbill with Everist Genomics address and account number, large Clinical Pak, and adhesive Airbill pouch.
 13. Put the OncoDefender™ – CRC Specimen Collection and Shipping Kit box in the Clinical Pak.
 14. Complete the Domestic Airbill with your “From” information. **(Note: In Section 6 on the Domestic Airbill, Special Handling, under the question “Does this shipment contain dangerous goods?” please check “No”. The FFPE specimens are considered “non-infectious” and are not classified as dangerous goods.)**
 15. Seal the Clinical Pak.
 16. Affix the adhesive Airbill pouch to the outside of the Clinical Pak and insert the completed Domestic Airbill.
 17. Place the Clinical Pak in a designated FedEx® pickup location, OR, if your facility does not have routine FedEx® pickup, call 800-463-3339 to arrange for pick up.