

SPECIMEN REQUIREMENTS

RADICAL PROSTATECTOMY / BIOPSY TISSUE

Block Selection:

For Radical Prostatectomy:

Select one (1) formalin fixed paraffin embedded (FFPE) tissue block with the highest Gleason score and at least 0.5cm² of tumor tissue by area, and a minimum of 60% tumor (by surface area).

For Biopsy:

Select one (1) formalin fixed paraffin embedded (FFPE) block of diagnostic needle core biopsy with at least 1mm in total linear length of tumor tissue with the highest Gleason grade of tumor, minimum of 25% tumor (by surface area), and ≤15% benign tumor.

Please select one of the following options below when submitting specimens for Decipher® testing

Option 1: Punch Submission (Preferred):

1. Identify an H&E slide that closely matches the block face.
 - a. If multiple sections have already been cut from the block, then cut and create a new H&E stained slide.
2. Circle the area with the highest Gleason grade on the corresponding H&E slide.
3. Using the punch tool provided in the specimen kit, take two (2) punches from the FFPE block which corresponds to the area circled on the H&E slide.
 - a. **For Radical Prostatectomy:** Two (2) x 1.5mm diameter cores are required.
 - b. **For Biopsy:** Two (2) x 1.0 mm or 1.5 mm diameter cores are required.
4. Place each core in a separate micro-centrifuge tube, close the caps and seal each tube with Para-film.
 - a. *Note: If the tissue gets stuck in the punch tool, then wrap the punch tool in foil and ship.*
5. Document that each punched core contains
 - a. **For Radical Prostatectomy:** ≥ 60% tumor content on the Specimen Profile Form.
 - b. **For Biopsy:** ≥ 25% tumor content, ≤ 15% benign glands, and at least 1 mm tumor length on the Specimen Profile Form.
6. Affix provided barcodes only to the tubes containing specimens and number each tube to correspond with the Specimen Profile Form.

Option 2: Block Submission:

Submit the selected FFPE block for punching.

Option 3: Slide Submission:

For Radical Prostatectomy:

Submit one (1) H&E slide and five (5) 5µm thick serially sectioned unstained slides. Label the serial sectioned slides (1-6) in the order in which they were cut for scraping.

For Biopsy:

Submit one (1) H&E slide and nine (9) 5µm thick serially sectioned unstained slides **or** ten (10) 5 µm thick serially sectioned unstained slides. Label the serial sectioned slides (1-10) in the order in which they were cut for scraping.

If you have any questions about specimen submission, please contact our Customer Support Team at (888) 792-1601 or email customersupport@genomedx.com

SHIPPING REQUIREMENTS

Punches:

1. Apply barcoded label(s) only to the tubes containing the punch specimen and number each tube to correspond with the Specimen Profile Form.
2. Place the labeled specimen tubes back into the foam insert.

Block:

1. Place a barcoded label on the block, then place the selected FFPE block into the small zip-lock bag.
2. Place the small zip-lock bag containing the block into the foam insert.

Slides:

1. Place slides into the two (2) slide holders (up to 5 slides each).
2. Apply barcoded labels to the two (2) slide holder(s) and place the labeled slide holder(s) back into the foam insert in the specimen kit.

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3. Apply barcoded labels to the test requisition, pathology report and Specimen Profile Form (if applicable).
 4. Fold (a) Test Requisition, (b) Pathology Report and (c) Specimen Profile Form (if applicable) and place all paperwork into the specimen kit, between the dividing flap and the foam insert.
 5. Fold down the dividing flap, place the provided cold pack on top of the flap and close the specimen kit.
 6. Place the closed specimen kit into the FedEx® Clinical Lab Pak and apply the shipping label provided.
 7. Ship via your regular scheduled FedEx® pickup or call Customer Support @ 888-792-1601 to schedule a pick up.

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