Decipher® Prostate Genomic Classifier

FFPE Specimen Instructions

Veracyte Labs SD
Fax: 1.858.766.6575
specimenprocurement@veracyte.com

Ice packs will be provided to all accounts throughout the year.
Include one fully frozen ice pack per specimen collection kit.

SPECIMEN REQUIREMENTS

- **Minimum Tumor Content (Quality Requirement)**
  - Selected tissue must contain tumor tissue enriched for analysis.
  - Specimens should contain ≥25% tumor content within the selected area after histologic review and macrodissection, when applicable.
  - Specimens composed predominantly of benign tissue may fail quality control even if length/area minimums are met.
- **Please select one of the following options below when submitting specimens for Decipher Prostate testing**

Biopsy Tissue

OPTION 1: BLOCK

1. Submit one (1) formalin fixed paraffin embedded (FFPE) block of diagnostic needle core biopsy with at least 0.5 mm in total linear length of tumor tissue with the highest Grade Group (Gleason score) of tumor.

OPTION 2: SLIDES

(Note: Though both charged and uncharged slides are accepted, charged slides are preferred)

1. Submit ten (10) 5µm thick serially sectioned unstained slides.
2. Label the serial sectioned slides (1-10) in the order in which they were cut.
3. Air dry slides overnight or until no water is visible under the paraffin section and store unstained slides at 4 degrees C until shipping.

Radical Prostatectomy Tissue

OPTION 1: BLOCK

1. Submit one (1) formalin fixed paraffin embedded (FFPE) block of radical prostatectomy tissue with the highest Grade Group (Gleason score) and at least 0.5 mm^2 of tumor tissue by area.

OPTION 2: SLIDES

(Note: Though both charged and uncharged slides are accepted, charged slides are preferred)

1. Submit six (6) 5µm thick serially sectioned unstained slides.
2. Label the serial sectioned slides (1-6) in the order in which they were cut.
3. Air dry slides overnight or until no water is visible under the paraffin section and store unstained slides at 4 degrees C until shipping.

SPECIMEN SELECTION WORKFLOW (IF REQUESTED BLOCK IS UNAVAILABLE)

Follow this workflow to prevent submission of benign tissue and to keep selection aligned with Decipher Prostate acceptance criteria.

1. Locate the requested Block ID listed on the Decipher Specimen Procurement Letter.
2. Confirm the block contains prostate adenocarcinoma (tumor present). Do NOT submit benign tissue.
3. If the requested block is unavailable or does not meet tumor content or length/area minimums:
   a. Select the block with the next highest Grade Group (one Grade Group lower) that contains tumor.
   b. Do not select a block more than one Grade Group lower without contacting Veracyte.
      i. When contacting Veracyte about the lower Grade Group, please confirm if there is enough tissue to send following the tissue content above.
4. Document the actual Block ID being sent on the procurement letter and include the pathology report.
5. If no qualifying tumor block is available, submit slides per specimen type using the highest available Grade Group tumor.

Gleason Grade Group Quick Reference

Grade Group	Gleason Score
1	3+3 = 6
2	3+4 = 7
3	4+3 = 7
4	4+4 = 8 (also includes 3+5 or 5+3)
5	9-10 (4+5, 5+4, 5+5)

ADDITIONAL INFORMATION

- If an FFPE block arrives melted at Veracyte Labs SD, we will re-embed the tissue. If you prefer that we do not re-embed the tissue, please contact our Procurement team at specimenprocurement@veracyte.com.
- If multiple samples are submitted within a kit, the blocks/slides sent should be documented on the provided manifest.

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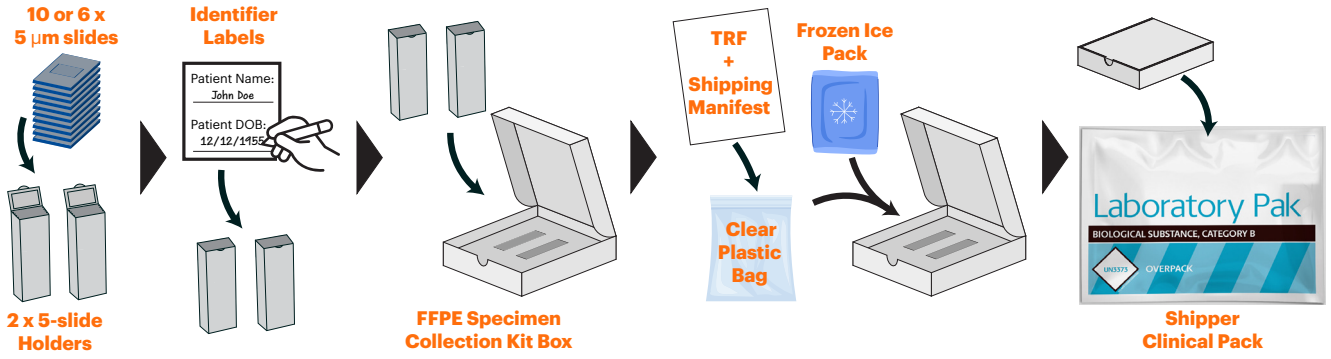
Veracyte Labs SD
Fax: 1.858.766.6575
specimenprocurement@veracyte.com

SHIPPING INSTRUCTIONS

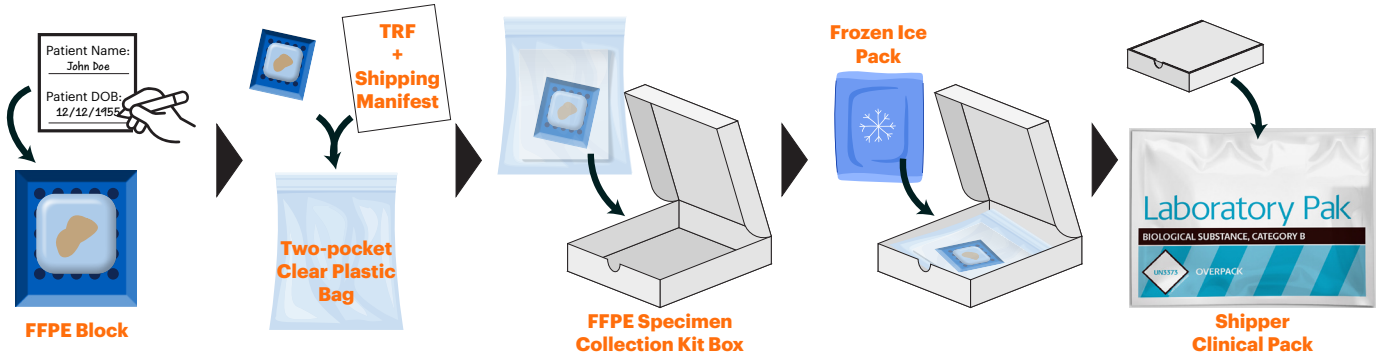
1. Begin packing specimen:
   a. For **FFPE slides** place the selected slides into the 5-place slide holders provided.
   b. For **FFPE block** proceed to step 2.
2. Label each slide holder or selected block with a unique identifier label provided. Enter the patient's name and date of birth in the designated fields on the label. Specimens must include a minimum of two unique patient identifiers (e.g., patient name or date of birth). Specimens that do not meet this requirement may not be able to be processed.
3. Continue packing specimen:
   a. For **FFPE slides** place the slide holders into the cardboard holder within the kit box.
   b. For **FFPE block** place the block in the clear resealable plastic bag provided.
4. Place a copy of the completed **Decipher Test Requisition Form** (provided by the Veracyte Procurement Team), **shipping manifest**, and **any other paperwork** in the outer sleeve of the resealable plastic bag.
5. Fold the plastic bag and place on top of the cardboard holder inside the kit box.
6. Place the frozen ice pack on top of the plastic bag and close the kit box securely.
7. Insert the specimen collection kit into the shipper clinical pack and affix the shipping label provided.
8. Ship via your regularly scheduled pickup **- OR -** contact 1.866.279.4205 and provide the client key: VeracyteDecipher to schedule a pick-up.

SHIPPING ADDRESS: 6925 Lusk Boulevard, San Diego, CA 92121

How to pack FFPE Slides



How to pack an FFPE Block



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Shipping Manifest

PLEASE PROVIDE THE BELOW INFORMATION AND INCLUDE IT IN THE SPECIMEN SHIPMENT

Number of block(s)/slides enclosed: _____

Specimen ID: _____

Block ID(s): _____

Has the specimen been relabeled or does the specimen ID differ from the pathology report or procurement request?

☐ **No - Specimen IDs match**

☐ **Yes - Specimens have been re-labeled or have a different ID than originally requested**

Please specify original and current identifiers: _____

_____

_____

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