Tissue Request Form

Delphi Diagnostics has received a test request for Endocrine Activity Index (EAIT) Testing for the patient below. Sufficient tumor must be present to complete testing, we request the specimen includes a minimum 10% tumor nuclei content. This analysis requires the pathologically staged paraffin-embedded tumor tissue.

REQUESTING LABORATORY

Laboratory Name: Delphi Diagnostics, Inc.
CLIA #: 45D2339502
Address: 8515 Fannin St. Suite 105
City, State, ZIP: Houston, TX 77054
Contact Name: Karla Alvarez, Lab Manager
Phone: 281.896.0056
Fax: 832.442.8762
Email: support@delphi-diagnostics.com

PATIENT INFORMATION

Patient Name: _____ Date of Birth:_____
Gender: _____

TISSUE INFORMATION

Institution/Hospital:_____
Specimen ID: _____ **Date of Collection:** _____
Tissue Site: Left Breast **OR** Right Breast
Specimen Type Requested: FFPE Tissue Block **OR** Unstained Slides

Please provide accompanying H&E Slide(s); see reverse for tissue specimen instructions

Requesting / Physician: _____
(see accompanying test requisition)

Statement of Intended Use:

This specimen is requested for clinical diagnostic testing to be performed in a CLIA-certified laboratory. Testing will be conducted in accordance with all applicable federal, state, and local regulations.

Tissue Request Form

Specimen Submission Instructions:

1. Select the formalin-fixed paraffin-embedded (FFPE) block with the highest amount of invasive breast carcinoma from core biopsy or surgical resection that is morphologically consistent with the submitting diagnosis.
    a. Please ensure the tumor area has at least 10% invasive tumor (using estimated number of invasive tumor cells divided by the total number of all cells with nuclei)
    b. Invasive carcinoma requires an area ≥ 5 mm in largest dimension (including any associated in situ disease, stroma, fat or fibrosis) and containing at least 25 cancer cells.
    c. A macrodissection will be performed at the lab to avoid large areas of ductal carcinoma in situ (DCIS), necrosis, adipose tissue, stroma, and/or hemorrhage, because these cellular elements will reduce the tumor cell percentage.
2. Use 10% neutral-buffered formalin for 6-72 hours to preserve nucleic acid integrity. DO NOT use other fixatives
3. DO NOT decalcify sample.
4. Samples with only ductal carcinoma in situ (DCIS), lobular carcinoma in situ (LCIS), or microinvasive carcinomas (one or more foci <0.1 cm) are not acceptable samples.
5. Send Block OR Prepare five 4-10 µm serial unbaked unstained slides with one serial section per slide. If sending slides:
    a. Mount sections onto charged glass slides (standard 1" x 3" or 25 mm x 75 mm size).
    b. Allow the slides to air dry. DO NOT place the slides on a hot plate.
    c. DO NOT cover slips the unstained slides.
    d. The EAI™ test needs a minimum area of 9mm2 per tissue section. Please submit additional slides if there is lower tumor content per slide.
6. Submit correlating H&E stained slide or one additional 4 or 5 µm unstained slide. The H&E slide is used to assess tumor cell percentage.

Labeling:

1. Label the blocks or slides with your pathology sample identification number and an additional patient specimen identifier (e.g. patient name, medical record number, etc).

Packing:

1. Pack the block or slides in a slide container to protect from breakage along with an ice pack
2. Please ensure clinical and/or pathological staging is provided on the requisition form
3. Ensure a copy of the pathology report has been sent or is included with the specimen
4. **If sending a block; please enclose block return information**

Questions: Contact Delphi Diagnostics Customer Service at 281.896.0056 or support@delphi-diagnostics.com

8515 Fannin St., Suite 105 Houston, TX 77054 | support@delphi-diagnostics.com | fax: 832.442.8762 | phone: 281.896.0056
CLIA ID#: 45D2339502 | Medical Director: Federico A. Monzon, M.D., FCAP