

Specimen Collection and Handling Procedures

PLEASE NOTE: Laboratory test result quality is highly dependent upon proper specimen collection and handling procedures. The specimen requirements and handling procedures for tests processed in the bioTheranostics laboratory are listed below. All samples must be labeled with the patient name and date of collection. Unlabeled specimens will not be accepted for testing.

FIXATION METHOD	Formalin-Fixed Paraffin-Embedded (FFPE) tissue is recommended for all testing services. Recommended fixative is 10% Neutral Buffered Formalin.
SPECIMEN TYPE	Testing can be performed on primary tumor or a site of metastasis. The following are acceptable specimen types: <ul style="list-style-type: none"> • Surgical Resections • Excisional Biopsies • Core Needle Biopsies • Fine Needle Aspiration (FNA) • Cell Blocks (pleural effusions, ascites) • Bone Biopsies decalcified in EDTA or Formic Acid (not HCl)
CancerTYPE ID[®]	Minimum Requirement: 300-500 viable tumor cells. Specimen options: <ul style="list-style-type: none"> • FFPE block (preferred) OR • 3-4 unstained 7 micron sections on Leica Membrane slides and 1 H&E slide. <i>Note: Laser micro-dissection CANNOT be performed on regular glass slides. To request complimentary Leica Membrane slides, please contact bioTheranostics Client Services.</i>
breastcancerindex[™]	Minimum Requirement: 50% tumor. Specimen options: <ul style="list-style-type: none"> • FFPE block (preferred) OR • 3-4 unstained 10 micron sections on glass slides and 1 H&E slide.
PRÉCIS[™] Precision Medicine	Minimum Requirement: 40% to 50% viable tumor with minimum tumor area 25mm². NSCLC Biomarker Profile specimen options: <ul style="list-style-type: none"> • FFPE block (preferred) OR • 26 total unstained slides and 1 H&E slide. <ul style="list-style-type: none"> - 12 unstained, 10 micron sections on plus (+) slides. - 14 unstained, 4 micron sections on plus (+) slides. CRC Biomarker Profile specimen options: <ul style="list-style-type: none"> • FFPE block (preferred) OR • 14 total unstained slides and 1 H&E slide. <ul style="list-style-type: none"> - 10 unstained, 10 micron sections on plus (+) slides. - 4 unstained, 4 micron sections on plus (+) slides. Individual Biomarkers specimen requirements: PCR Mutation Analysis <ul style="list-style-type: none"> • 2 unstained, 10 micron sections on plus (+) slide required per assay and 1 H&E slide. IHC and FISH <ul style="list-style-type: none"> • 2 unstained, 4 micron sections on plus (+) slide required per assay and 1 H&E slide.
STORAGE CONDITIONS	Store specimen at room temperature (15-30°C).
STABILITY OF SPECIMEN	Recommend shipping within 1 week of preparation. Do not freeze slides.
TRANSPORTATION	Ambient kit. Use cold pack for transport. Do not place cold pack in direct contact with specimen during transport.
QUESTIONS	Medical and scientific staff are available to answer questions about specimen and sample viability prior to sending blocks or slides for testing - call Toll Free (877) 886-6739 between 7am and 5pm Pacific Time.
PATHOLOGY REPORT	Please enclose a copy of the pathology report with the specimen.

Please label sample blocks or slides with identifiers that are also written on or affixed to the Test Requisition, such as patient name, case number, and/or sample number. We regret that we cannot accept samples for testing if the identifiers used on the blocks or slides do not match those listed on the Test Requisition submitted with the samples. We are unable to accept sample blocks or slides that are not labeled. Blocks will be returned immediately following test completion.

TRANSPORTATION: Place specimen blocks or slides in a plastic slide cassette. Place the cassette and the completed Test Requisition in a FedEx envelope or bioTheranostics Specimen Shipping Kit. Send specimens via FedEx "Priority Overnight" service. A pickup may be scheduled online at www.fedex.com or by calling (800) 463-3339.

NOTE: Shipping kits and bioTheranostics' FedEx account information may be obtained from Client Services at Toll Free (877) 886-6739.



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