

# 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.

<b>Fixation Method</b>	Formalin-Fixed Paraffin-Embedded (FFPE) tissue is recommended for all testing services. Recommended fixative is 10% Neutral Buffered Formalin
<b>Specimen Type</b>	Testing can be performed on primary tumor or a site of metastasis. The following are acceptable specimen types: <ul style="list-style-type: none"> <li>• Surgical Resections</li> <li>• Fine Needle Aspiration (FNA)</li> <li>• Excisional Biopsies</li> <li>• Cell Blocks (pleural effusions, ascites)</li> <li>• Core Needle Biopsies</li> <li>• Bone Marrow Biopsies (decalcified in Formic Acid, not HCl)</li> </ul>
<b>CancerTYPE ID®</b> <i>Molecular Cancer Classifier</i>	<b>Minimum Requirement: 300–500 viable tumor cells. Specimen options:</b> <ul style="list-style-type: none"> <li>• Formalin-fixed, paraffin embedded blocks (highly recommended for optimal testing) and 1 H&amp;E slide, <b>OR</b></li> <li>• 3–4 unstained, 7 micron sections on Leica Membrane slides (if FFPE block not available) and 1 H&amp;E slide.</li> </ul> <i>Note: Laser micro-dissection CANNOT be performed on regular glass slides. To request complimentary Leica Membrane slides, please contact bioTheranostics Client Services.</i>
<b>breastcancerindex<sup>SM</sup></b> <i>Risk of 10-Year Distant Recurrence</i>	<b>Minimum Requirement: 50% tumor. Specimen options:</b> <ul style="list-style-type: none"> <li>• Formalin-fixed, paraffin embedded blocks (highly recommended for optimal testing) and 1 H&amp;E slide, <b>OR</b></li> <li>• 3–4 unstained, 10 micron sections on glass slides (if FFPE block not available) and 1 H&amp;E slide.</li> </ul>
<b>PRÉCIS</b> Precision Medicine by bioTheranostics <sup>SM</sup>  <b>NSCLC Biomarker Profile</b> <i>Predictive Testing for Non-Small Cell Lung Cancer</i>  <b>CRC Biomarker Profile</b> <i>Predictive Testing for Colorectal Cancer</i>  <b>Individual Biomarkers</b>	<b>Minimum Requirement: 40% to 50% viable tumor with minimum tumor area 25 mm<sup>2</sup></b>  <b>Includes EGFR, ALK, KRAS, c-MET, BRAF, PIK3CA, &amp; 10q23 Deletion. Specimen options:</b> <ul style="list-style-type: none"> <li>• Formalin-fixed, paraffin embedded blocks (highly recommended for optimal testing) and 1 H&amp;E slide, <b>OR</b></li> <li>• 21 total unstained slides (if FFPE block not available) and 1 H&amp;E slide. <ul style="list-style-type: none"> <li>– 12 unstained, 10 micron sections on plus (+) slides.</li> <li>– 9 unstained, 4 micron sections on plus (+) slides.</li> </ul> </li> </ul> <b>Includes KRAS, BRAF, PIK3CA, &amp; 10q23 Deletion. Specimen options:</b> <ul style="list-style-type: none"> <li>• Formalin-fixed, paraffin embedded blocks (highly recommended for optimal testing) and 1 H&amp;E slide, <b>OR</b></li> <li>• 12 total unstained slides (if FFPE block not available) and 1 H&amp;E slide. <ul style="list-style-type: none"> <li>– 9 unstained, 10 micron sections on plus (+) slides.</li> <li>– 3 unstained, 4 micron sections on plus (+) slides.</li> </ul> </li> </ul> <b>ALK, 10q23 Deletion, &amp; c-MET specimen options:</b> <ul style="list-style-type: none"> <li>• Formalin-fixed, paraffin embedded blocks (highly recommended for optimal testing) and 1 H&amp;E slide, <b>OR</b></li> <li>• 3 unstained, 4 micron sections on plus (+) slides required for each assay and 1 H&amp;E slide.</li> </ul> <b>EGFR, KRAS, BRAF, &amp; PIK3CA specimen options:</b> <ul style="list-style-type: none"> <li>• Formalin-fixed, paraffin embedded blocks (highly recommended for optimal testing) and 1 H&amp;E slide, <b>OR</b></li> <li>• 3 unstained, 10 micron sections on plus (+) slides required for each assay and 1 H&amp;E slide.</li> </ul>
<b>Storage Conditions</b>	Store specimen at room temperature (15-30° C).
<b>Stability of Specimen</b>	Recommend shipping within 1 week of preparation. Do not freeze slides.
<b>Transportation</b>	Ambient kit. Use cold pack for transport. Do not place cold pack in direct contact with specimen during transport.
<b>Questions</b>	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.
<b>Additional Information</b>	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 also 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](http://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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