

# FFPE Specimen Handling for KRAS and BRAF Mutation Testing

**Table 1: FFPE Specimens**

<b>SPECIMEN TYPE</b>	<b>Formalin-fixed paraffin-embedded (FFPE) tissue or cell block, sectioned (unstained slides) or uncut.</b>
<b>SHIPPING CONTAINER</b>	<ul style="list-style-type: none"> <li>• Slides: plastic slide cassette.</li> <li>• Uncut FFPE blocks: small zip-lock bag. Additional charges will apply for sectioning, H&amp;E stained slide preparation, specimen review and enrichment by a pathologist.</li> </ul>
<b># SLIDES</b>	<ul style="list-style-type: none"> <li>• Slides: a minimum of one unstained slide with 10µm tissue section <math>\geq 1\text{cm}^2</math> surface area plus one (1) H&amp;E stained slide. Additional charges will apply for H&amp;E slide preparation and specimen enrichment.</li> <li>• Sections should be representative of <math>\geq 40\%</math> of the tumor area.* Include one (1) H&amp;E stained slide sectioned immediately prior to unstained sections.</li> <li>• Samples with <math>&lt;40\%</math> tumor will require enrichment prior to testing.</li> <li>• FFPE core needle biopsy slides/blocks accepted, however, the smaller amount of tissue usually present in these specimens can affect the number of mutations tested. Several unstained slides may be needed to recover sufficient amount of DNA for testing. Contact the Laboratory manager for more guidance. Additional charges will apply for sectioning, H&amp;E stained slide preparation, specimen review and enrichment by a pathologist.</li> </ul>
<b>STORAGE CONDITIONS</b>	Room temperature (15 to 30 °C).
<b>STABILITY OF SPECIMEN</b>	Recommended shipping within 1 week of sectioning.
<b>TRANSPORTATION CONDITIONS</b>	Ambient, protect from direct light.

\* FFPE blocks may be sent in place of slides. However, this will likely increase turnaround time.

**ADDITIONAL INSTRUCTIONS:**

1. Specimens should be labeled with identifiers that match the test requisition form, such as patient case number, and/or specimen number.
2. Specimens should be placed in a plastic slide cassette (slides) or a zip-lock bag (FFPE blocks). Do not place glass slides with tissue facing one another during shipment.
3. Preferably, shipment notification, including tracking information, should be sent to Asuragen CLIA Laboratory (CLIAServices@asuragen.com) on the day of specimen shipment. Failure to do so may result in significant delays in specimen processing.
4. Specimens should be shipped overnight with a completed, signed and dated requisition form. Diagnosis/ICD9 code(s) and billing information must be included. No testing will be performed if the physician signature is missing.
5. Shipments to Asuragen can be received only Monday through Friday. Asuragen does not accept deliveries on Saturday, or Sunday.
6. Asuragen cannot accept specimens for testing if the:
  - a. Test requisition form is missing, incomplete, incorrectly filled, or illegible. Common errors include missing patient information, collection date, mismatched specimen identifiers between slides/blocks and the information provided on the test requisition form, lack of physician's signature, etc.
  - b. Improper specimen type is submitted for the test requested.
  - c. Specimen shipment guidelines were not followed (e.g., slides shipped on dry ice).
  - d. Specimen and/or slide(s) is (are) irreparably broken or damaged.
  - e. Insufficient number of slides/FFPE tissue slices was shipped.
  - f. The inclusion criteria for tissue sections presenting  $\geq 40\%$  of the tumor area are not met or specimen enrichment to at least 40% tumor cannot be achieved.

**The Laboratory Director or Laboratory Supervisor will contact the physician/customer in the event that a specimen is determined to be unacceptable for testing.**