GENE PROFILING ASSAYS
Brentwood, TN: (800) 874-8532  fax: (615) 370-8074
Phoenix, AZ: (800) 710-1800  fax: (800) 481-4151
New York, NY: (800) 447-5816  fax: (212) 698-9532

Patient, client, and billing information is requested for timely processing of this case. Medicare and other third party payors require that services be medically necessary for coverage, and generally do not cover routine screening tests. Refer to Determining Necessity of ABN Completion on reverse.

**SPECIMEN LABEL INSTRUCTIONS**

1. Complete the requisition with all requested information.
2. Label specimen with two unique identifiers.
3. Remove the required number of labels from the front of this sheet.
4. Place one (1) label on each specimen container (not on the lid).
   Please dispose of unused labels.
IntelliGEN® Gene List

|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| ABL1 | BRAF | EGFR | FGFR1 | GNAQ | IDH2 | KRAS | NPM1 | PTEN | SMO | TERT | ATM | B2A | C2orf58 | CEP7 | CNOT1 | DAX1 | FH | FBXW7 | GNA11 | IDH1 | KIT | NOTCH1 | P16 | SMARCB1 | TP53 | VRK1 | ATM | CTNNB1 | FBXW7 | GNA11 | IDH1 | KIT | NOTCH1 | P16 | SMARCB1 | TP53 | VRK1 |

IntelliGEN® Specimen Requirements

Solid Tumor (excision, core, FNA or endoscopic biopsies)

Formalin-fixed paraffin embedded tissue. Fixative should be neutral buffered formalin. For solid tumor metastatic bone samples submit a non-decalcified FFPE sample. Decalcified bone biopsies are not acceptable sample types for this test.

- **Block**
  - Tumor surface area of ≥ 4 mm² and tumor content ≥ 10%; ≥ 50% is preferred.
  - (SEE NOTE)
  - Unstained slides
  - See table below as a guide to the number of slides required to meet the DNA input requirements

<table>
<thead>
<tr>
<th>Measured tumor surface area (mm²)</th>
<th>Tumor content %</th>
<th>Number of slides needed (each slide cut at 10 μm sections)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 4</td>
<td>≥ 50%</td>
<td>5 unstained slides and 1 H&amp;E</td>
</tr>
<tr>
<td>1-4</td>
<td>≥ 10%</td>
<td>10 unstained slides and 1 H&amp;E</td>
</tr>
</tbody>
</table>

**NOTE:**

1. Tumor surface areas between 1-4 mm² with ≥ 10% tumor content are less likely to meet the DNA input requirements.
2. Tumor surface areas between 1-4 mm² and < 10% tumor or below <1 mm² will be considered NOS for analysis.
3. If sending a core biopsy, if tumor is less than < 0.5 cm in length it is less likely to meet the DNA input requirements.
4. If sending a cell block aspirate, at least eight tumor cell clusters providing 400-800 intact tumor cells is needed or it is less likely to meet the DNA input requirements.

Bone Marrow Aspirates

- 1-2 ml fresh aspirate in a Lavender top (EDTA) or a green top (sodium heparin) tube.
- Fresh Tumor Aspirates (FNAs)
  - 5-10 ml tumor in RPMI or CytoLyt® container. FNAs require sufficient tumor cells for DNA extraction.

Determing Necessity of Advance Beneficiary Notice of Noncoverage (ABN) Completion*

1. **Diagnose.** Determine your patient’s diagnosis.
2. **Document.** Write the diagnosis code(s) on the front of this requisition.
3. **Verify.** Determine if the laboratory test(s) ordered for the patient is subject to the Local Coverage Determination or National Coverage Determination. This information can be located in the policies published by Medicare Administrative Contractor (MAC), CMS, or the “Documenting Medical Necessity of Laboratory Services” booklet provided by your LabCorp representative.
4. **Review.** If the diagnosis code for your patient does not meet the medical necessity requirements set forth by Medicare or the test is being performed more frequently than Medicare allows, an ABN should be completed.

*An ABN should be completed for all tests that are considered investigational (experimental or for research use) by Medicare.

How to Complete an Advance Beneficiary Notice of Noncoverage (ABN)

Medicare is very specific in requiring that all of the information included on the ABN must be completed. Additionally, LabCorp requests that the specimen number or bar code label be included on the form. To be valid, an ABN must:

1. Be executed on the CMS approved ABN form (CMS-R-131).
2. Identify the Medicare Part B Beneficiary, using the name as it appears on the patient’s red, white, and blue Medicare card.
3. Indicate the test(s)/procedure(s) which may be denied within the relevant reason column.
4. Include an estimated cost for the test(s)/procedure(s) subject to the ABN.
5. Have “Option 1”, “Option 2”, or “Option 3” designated by the beneficiary.
6. Be signed and dated by the beneficiary or his/her representative prior to the service being rendered.