Molecular Diagnostics Solid Tumor NGS Panels

The Ion AmpliSeq Cancer Hotspot Panel (v2) is a highly sensitive assay that screens a broad range of gene targets. These targets consist of 2,855 “hotspot” variants from 50 different genes such as \textit{EGFR}, \textit{KRAS}, \textit{BRAF}, \textit{NRAS}, and \textit{TP53} that have been highly associated with various cancers. Each panel is tailored to focus analysis and reporting on those genes most relevant to disease prognosis and treatment.

### Colon

**Colon Hotspot NGS Panel**

- **Includes:**
  - \textit{BRAF} - p.V600E/K

### Lung

**Lung Hotspot NGS Panel**

- **Includes:**
  - \textit{EGFR} - known hotspot mutations in exons 3, 6, 15, 18, 19, 20, and 21
  - \textit{BRAF} - p.V600E/K

### Melanoma

**Melanoma Hotspot NGS Panel**

- **Includes:**
  - \textit{BRAF} - p.V600E/K
  - \textit{KIT} - known hotspot mutations in exons 2, 9, 10, 11, 13, 14, 15, 17, and 18

### Specimen

- FFPE block (25mm$^2$ or \(~40 \mu m \) of tissue) or 8 unstained slides + H&E
- The minimum recommended tumor content is \(~20\%\).

### Test details

- Minimum coverage of >250x for focus regions
- Targets consist of 2,855 variants from 50 genes
- TAT is 14 days from receipt of tissue

### Reporting

The report includes:

- Hotspot mutations related to tumor type
- Additional disease-associated variants
- Other variants
- Regions without adequate coverage
Frequently Asked Questions

1. **How do I order this test?** These tests can be ordered in EPIC as either the Lung, Colon or Melanoma Hotspot NGS Panels or by filling out a test requisition form and faxing it to 919-668-9173.

2. **What are the specimen requirements?** The lab accepts FFPE blocks containing 25mm$^2$ (or ~40µm) of tissue, as well as unstained slides (8 slides +1 H&E). The minimum recommended tumor content for this assay is 20%.

3. **How long will it take to get results?** TAT is 14 days from receipt of material in the laboratory.

4. **What genes are covered by the test?** This test covers clinically actionable mutations in 50 cancer-related genes present in multiple types of cancer, including lung, breast, colorectal, and skin, among others.

5. **What is the CPT code for this test?** 81445

6. **How much will this test cost?** The price for this assay is $2,500. For the true cost to the individual Duke patient, patients should contact a Duke financial care specialist.

7. **Do you offer this panel for solid tumors other than colon, lung, or melanoma?** Yes, additional tumor types will also be accepted. Please order the Solid Tumor NGS Hotspot panel

8. **What are the test limitations?** The assay will readily detect single nucleotide variants above a 5% allele frequency and insertion/deletion mutations above 10% allele frequency. Gene amplifications, translocation, and large insertion or deletions may not be detected by this assay.

For a complete list of regions covered and to download a test requisition form, scan the provided bar code or visit http://dukemolecular.org

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<tr>
<th>Genes include:</th>
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<tr>
<td><strong>ABL1</strong></td>
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<td><strong>CSF1R</strong></td>
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