



# Duke University Health System

## Molecular Diagnostics Laboratory

For questions regarding testing, please contact the laboratory

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<http://dukemolecular.org>

### 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 *EGFR*, *KRAS*, *BRAF*, *NRAS*, and *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

#### Lung

#### Melanoma

##### Colon Hotspot NGS Panel Includes:

##### Lung Hotspot NGS Panel Includes:

##### Melanoma Hotspot NGS Panel Includes:

**BRAF** - p.V600E/K  
**KRAS** - codons 12, 13, 61, 117, and 146 (p.G12, p.G13, p.Q61, p.K117, p.A146)  
**NRAS** - codons 12, 13, and 61 (p.G12, p.G13, p.Q61)

**EGFR** - known hotspot mutations in exons 3, 6, 15, 18, 19, 20, and 21  
**BRAF** - p.V600E/K  
**KRAS** - codons 12, 13, 61, 117, and 146 (p.G12, p.G13, p.Q61, p.K117, p.A146)  
**NRAS** - codons 12, 13, and 61 (p.G12, p.G13, p.Q61)

**BRAF** - p.V600E/K  
**NRAS** - codons 12, 13, and 61 (p.G12, p.G13, p.Q61)  
**KIT** - known hotspot mutations in exons 2, 9, 10, 11, 13, 14, 15, 17, and 18

#### Specimen

#### Test details

#### Reporting

- FFPE block (25mm<sup>2</sup> or ~40 µm of tissue) or 8 unstained slides + H&E
- The minimum recommended tumor content is ~20%.

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

- The report includes:
- Hotspot mutations related to tumor type
  - Additional disease-associated variants
  - Other variants
  - Regions without adequate coverage



Genes include:

<i>ABL1</i>	<i>EGFR</i>	<i>GNAS</i>	<i>KRAS</i>	<i>PTPN11</i>
<i>AKT1</i>	<i>ERBB2</i>	<i>GNAQ</i>	<i>MET</i>	<i>RB1</i>
<i>ALK</i>	<i>ERBB4</i>	<i>HNF1A</i>	<i>MLH1</i>	<i>RET</i>
<i>APC</i>	<i>EZH2</i>	<i>HRAS</i>	<i>MPL</i>	<i>SMAD4</i>
<i>ATM</i>	<i>FBXW7</i>	<i>IDH1</i>	<i>NOTCH1</i>	<i>SMARCB1</i>
<i>BRAF</i>	<i>FGFR1</i>	<i>JAK2</i>	<i>NPM1</i>	<i>SMO</i>
<i>CDH1</i>	<i>FGFR2</i>	<i>JAK3</i>	<i>NRAS</i>	<i>SRC</i>
<i>CDKN2A</i>	<i>FGFR3</i>	<i>IDH2</i>	<i>PDGFRA</i>	<i>STK11</i>
<i>CSF1R</i>	<i>FLT3</i>	<i>KDR</i>	<i>PIK3CA</i>	<i>TP53</i>
<i>CNNTB1</i>	<i>GNA11</i>	<i>KIT</i>	<i>PTEN</i>	<i>VHL</i>

### Frequently Asked Questions

- 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.
- What are the specimen requirements?** The lab accepts FFPE blocks containing 25mm<sup>2</sup> (or ~40µm) of tissue, as well as unstained slides (8 slides +1 H&E). The minimum recommended tumor content for this assay is 20%.
- How long will it take to get results?** TAT is 14 days from receipt of material in the laboratory.
- 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.
- What is the CPT code for this test?** 81445
- 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.
- 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
- 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>

