

# Molecular Profiling in Common Cancers




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**ASCO-Recommended Pan-Tumor Markers and National Comprehensive Cancer Network® (NCCN®)-Recommended Predictive Biomarkers for the 5 Most Common Cancers<sup>1-7</sup>**

**PREDICTIVE BIOMARKER TESTING IN CARE FOR PATIENTS WITH METASTATIC CANCER**

- Many patients with advanced or metastatic cancer may benefit from biomarker testing and/or genomic sequencing. In fact, professional societies like ASCO recommend biomarker testing to identify appropriate treatment options for patients with metastatic cancer.<sup>1</sup>
- Pan-tumor markers are used to find options for patients who may benefit from tissue- and site-agnostic treatments that are FDA-approved across solid tumor types<sup>1</sup>
- Molecular panel-based approaches that use NGS enable testing for multiple markers simultaneously, allowing for the most efficient use of limited tissues.<sup>1</sup>
- There are several commercially available panel-based biomarker tests.

The NCCN Guidelines for NSCLC provide recommendations for individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories.




**All Solid Tumors<sup>1</sup>**

- NTRK Fusion**
- MSI**
- TMB**




**NSCLC<sup>3</sup>**

- ALK**
- BRAF**
- EGFR**
- ERBB2**
- KRAS**
- METex14**
- NTRK Fusion**
- RET**
- ROS1**
- PD-L1**




**Breast Cancer<sup>4</sup>**

- HER2**
- PIK3CA**
- BRCA1/2**
- NTRK Fusion**
- MSI**
- TMB**
- PD-L1**
- ER/PR**



**Colon Cancer<sup>5</sup>**

- BRAF**
- KRAS**
- NRAS**
- HER2**
- MSI or MMR**



**Cutaneous Melanoma<sup>6</sup>**

- BRAF**
- KIT**



**Prostate Cancer<sup>7</sup>**

- ATM**
- BRCA1/2**
- CDK12**
- CHEK2**
- FANCA**
- PALB2**
- RAD51D**
- MSI or dMMR**
- TMB**







Biomarkers listed are actionable and only recommended by NCCN for patients with metastatic disease; emerging biomarkers listed in NCCN are not included. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. To view the most recent and complete version of the guidelines, go online to [NCCN.org](http://NCCN.org).

# MULTI-GENE PANELS AND PROFILES FOR TESTING SOLID TUMORS

Number of NCCN-Recommended Biomarkers Tested

Sample Requirement

Tissue biopsy

Manufacturer Test Name	Testing Method	Genes	TAT							Sample Requirement
<b>Foundation Medicine</b> FoundationOne® CDx <sup>1,3-7,8-10</sup>	Hybrid capture NGS	324	≤12 days	3/3	9/10	7/10	5/5	2/2	10/10	FFPE block + 1 H&E slide <b>OR</b> 10 unstained slides + 1 H&E slide
<b>Caris Life Sciences</b> MI Profile™ <sup>1,3-7,11,12</sup>	NGS + IHC IHC tests vary by tumor type	22,000	8-14 days	3/3	10/10	10/10	5/5	2/2	10/10	FFPE block <b>OR</b> 10 unstained slides (≥20% tumor cells for DNA; ≥10% for RNA) Additional tissue required for IHC tests; varies by tumor type
<b>NeoGenomics</b> NeoTYPE® Precision Profile for Solid Tumors <sup>1,3-7,13</sup>	NGS + IHC IHC includes PD-L1 and Pan-TRK	79	14 days	3/3	9/10	8/10	5/5	2/2	10/10	FFPE solid tumor tissue (paraffin block preferred; please use positively-charged slides and 10% NBF fixative; do not use zinc fixatives)
MSK IMPACT™ <sup>1,3-7,14</sup>	DNA-based NGS	505	Information not publicly available	-	-	-	-	-	-	Information not publicly available
PENN PRECISION PANEL 2.0 <sup>1,3-7,15,16</sup>	DNA-based NGS	59	Information not publicly available	0/3	4/10	1/10	4/5	2/2	1/10	FFPE tissue, isolated Genomic DNA, or tissue or fluid in PreservCyt
MOFFITT STAR™ (TRUSIGHT® TUMOR 170) <sup>1,3-7,17</sup>	DNA- and RNA-based NGS	170	Information not publicly available	-	-	-	-	-	-	Information not publicly available

The select tests listed above represent the top 20 NGS solid tissue cancer tests by market share in Q1 2022. Tests are ordered by biopsy type, then by market share. This information is not exhaustive and is not intended to endorse a particular test. When testing for therapy selection, please consult product prescribing information and FDA-approved companion diagnostics.

For the most up-to-date information, please the website for the specific manufacturer. These websites are independently operated and not managed by Novartis Pharmaceuticals Corporation. Novartis assumes no responsibility for the content on the sites. Websites for the specific manufacturers are provided on page 14.



## MULTI-GENE PANELS FOR TESTING SOLID TUMORS WITH TISSUE SAMPLES (CONTINUED)

Number of NCCN-Recommended Biomarkers Tested

Sample Requirement



Tissue biopsy

Manufacturer Test Name	Testing Method	Genes	TAT	Brain	Lung	Colon	Stomach	Liver	Breast	Sample Requirement
HopeSeq Solid Tumors <sup>1,3-7,18-20</sup>	DNA- and RNA-based NGS	523	Information not publicly available	3/3	9/10	7/10	5/5	2/2	10/10	FFPE with highest tumor content, not exposed to decalcifying solutions OR 1 H&E and 15 USS
Johns Hopkins Solid Tumor Panel V6 <sup>1,3-7,21,22</sup>	DNA-based NGS	400+	14-21 days	0/3	4/10	4/10	4/5	2/2	7/10	Information not publicly available
<b>Natera</b> Empower™ Comprehensive Panel <sup>1,3-7,23</sup>	DNA- and RNA-based NGS	81	≤14 days	–	–	–	–	–	–	Information not publicly available
Stanford Actionable Mutation Panel for Solid Tumors (STAMP) <sup>1,3-7,24,25,*</sup>	DNA-based NGS	138	21 days	1/3	8/10	4/10	4/5	2/2	6/10	FFPE tissue blocks sent at room temperature, avoiding extreme heat or cold
OncoPanel (POPV3) <sup>1,3-7,26</sup>	Hybrid capture, DNA-based NGS	447	Information not publicly available	1/3	9/10	5/10	4/5	2/2	8/10	Fresh, frozen or formalin-fixed paraffin-embedded samples
<b>Exact Sciences</b> Oncotype MAP™ Pan-Cancer Tissue Test <sup>1,3-7,27</sup>	NGS + IHC IHC tests vary by tumor type	257	<7 days	3/3	10/10	8/10	5/5	2/2	10/10	3 mm <sup>2</sup> of tissue with ≥15% tumor content
Cleveland Clinic CC-SIGN™ Pan-Solid Tumor NGS Panel <sup>1,3-7,28</sup>	RNA-based NGS	59	14 days	1/3	4/10	1/10	0/5	0/2	0/10	FFPE tissue: 10 unstained, 4 μM sections of FFPE on charged, unbaked slides; one H&E stained slide with best tumor area circled by pathologist (minimum of 20% tumor content)
<b>Myriad Genetics</b> MyChoice® CDx <sup>1,3-7,29</sup>	DNA-based NGS	2	≤14 days	0/3	0/10	2/10	0/5	0/2	2/10	FFPE tumor blocks or slides that contain at least 40 microns of tumor (20% tumor by cellularity)

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\*Test only detects fusions in *NTRK1*.

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## MULTI-GENE PANELS FOR TESTING SOLID TUMORS WITH TISSUE SAMPLES (CONTINUED)

Number of NCCN-Recommended Biomarkers Tested

Sample Requirement

Tissue biopsy

Liquid biopsy

Manufacturer Test Name	Testing Method	Genes	TAT							Sample Requirement
<b>ThermoFisher Scientific</b> Ion AmpliSeq™ Cancer Hotspot Panel v2 <sup>1,3-7,30</sup>	Multiplex PCR	50	1 day	0/3	4/10	1/10	4/5	2/2	1/10	10ng of DNA for FFPE
<b>Strata Oncology</b> StrataNGS® <sup>1,3-7,31,32</sup>	DNA and RNA-based NGS	437	7 days (median)	3/3	9/10	7/10	5/5	2/2	9/10	FFPE (minimum >0.5mm <sup>2</sup> surface area), 10 x 5µm unstained air-dried slides with ≥20% tumor
<b>Illumina</b> TruSight™ Oncology 500 <sup>1,3-7,33</sup>	Hybrid capture NGS (DNA & RNA)	523	4-5 days	3/3	9/10	7/10	5/5	2/2	10/10	FFPE (DNA 40 ng, RNA 40 ng)
<b>ThermoFisher Scientific</b> OncoPrint™ Focus Assay <sup>1,3-7,34-36</sup>	DNA and RNA-based NGS	52	3 days	1/3	9/10	3/10	4/5	2/2	0/10	300-30,000 copies of DNA (10 ng of mammalian gDNA) from normal or FFPE tissue
<b>Guardant Health, Inc.</b> Guardant360® CDx <sup>1,3-7,37,38,*</sup>	Hybrid capture NGS	55	7 days	1/3	9/10	5/10	4/5	2/2	4/10	Plasma (Streck cell-free DNA blood collection tubes)
<b>TEMPUS</b> TEMPUS xF Gene Panel <sup>1,3-7,39,40,*</sup>	DNA sequencing	105	~7-10 days	2/3	9/10	6/10	5/5	2/2	5/10	Peripheral blood (2 Streck tubes, 8.5 mL each)

The select tests listed above represent the top 20 NGS solid tissue cancer tests by market share in Q1 2022. Tests are ordered by biopsy type, then by market share. This information is not exhaustive and is not intended to endorse a particular test. When testing for therapy selection, please consult product prescribing information and FDA-approved companion diagnostics.  
\*Test only detects fusions in *NTRK1*.

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## MULTI-GENE PANELS FOR TESTING LUNG CANCER

Manufacturer Test Name	Testing Method	Biomarkers	Number of NCCN-Recommended Biomarkers Tested	TAT	Sample Requirement
<b>NeoGenomics</b> Lung NGS Fusion Panel (Complete or Limited) <sup>3,41</sup>	NGS (RNA)	8	5/10	21 days	FFPE block <b>OR</b> 1 H&E slide + 5-10 unstained slides cut at ≥5 microns (Please use positively-charged slides and 10% NBF fixative; do not use zinc fixatives)
<b>NeoGenomics</b> NeoTYPE® Lung Tumor Profile <sup>3,42</sup>	NGS + 9 single gene assays (Single gene assays include MET exon 14 deletion analysis, FISH, and IHC)	49	10/10	14 days	FFPE block (please use 10% buffered formalin fixative; do not use zinc fixatives.)
<b>Quest Diagnostics™</b> Lung Cancer Mutation Panel (EGFR, KRAS, ALK) <sup>3,43</sup>	3 single gene assays (Single gene assays include mutation analysis + FISH)	3	3/10	NRPT	FFPE
<b>Thermo Fisher Scientific</b> Ion Torrent™ OncoPrint™ Dx Target Test <sup>3,44</sup>	Amplicon NGS	23	7/10	≤4 days	FFPE (DNA/RNA 10 ng)

*Ion Torrent™ OncoPrint™ Dx Target Test is an in house kit that can be ordered<sup>48</sup>*

The select tests listed above represent the top 20 NGS solid tissue cancer tests by market share in Q1 2022. This information is not exhaustive and is not intended to endorse a particular test. When testing for therapy selection, please consult product prescribing information and FDA-approved companion diagnostics.

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## MULTI-GENE PANELS FOR TESTING BREAST CANCER

Manufacturer Test Name	Testing Method	Biomarkers	Number of NCCN-Recommended Biomarkers Tested	TAT	Sample Requirement
<b>NeoGenomics</b> NeoTYPE® Breast Tumor Profile <sup>4,46</sup>	NGS, FISH, + IHC	60	8/10	14-17 days	FFPE block (Please use 10% buffered formalin fixative; do not use zinc fixatives)



## MULTI-GENE PANELS FOR TESTING COLORECTAL CANCER

Manufacturer Test Name	Testing Method	Biomarkers	Number of NCCN-Recommended Biomarkers Tested	TAT	Sample Requirement
<b>NeoGenomics</b> NeoTYPE® Colorectal Tumor Profile <sup>5,46</sup>	NGS + 7 single gene assays (Single gene assays include MLH1 promoter methylation analysis, FISH, and IHC)	44	5/5	14-17 days	FFPE block (Please use 10% buffered formalin fixative; do not use zinc fixatives)



## MULTI-GENE PANELS FOR TESTING MELANOMA

Manufacturer Test Name	Testing Method	Biomarkers	Number of NCCN-Recommended Biomarkers Tested	TAT	Sample Requirement
<b>NeoGenomics</b> NeoTYPE® Melanoma Profile <sup>6,47</sup>	NGS + 3 single gene assays (Single gene assays include FISH and IHC)	28	2/2	14 days	FFPE block (Please use 10% buffered formalin fixative; do not use zinc fixatives)

Test availability and other factors may impact test selection. The list of tests above is not a comprehensive list of all testing options and their inclusion in this chart does not imply that these are FDA approved. This information is not exhaustive and is not intended to endorse a particular test. When testing for therapy selection, please consult product prescribing information and FDA-approved companion diagnostics.

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**Manufacturer****Website**

Caris Life Sciences	<a href="https://www.carismolecularintelligence.com">https://www.carismolecularintelligence.com</a>
Exact Sciences	<a href="https://precisiononcology.exactsciences.com">https://precisiononcology.exactsciences.com</a>
Foundation Medicine	<a href="https://www.foundationmedicine.com">https://www.foundationmedicine.com</a>
Guardant Health, Inc.	<a href="https://guardant360cdx.com/">https://guardant360cdx.com/</a>
Illumina	<a href="https://www.illumina.com">https://www.illumina.com</a>
Myriad Genetics	<a href="https://myriad.com">https://myriad.com</a>
Natera	<a href="https://www.natera.com">https://www.natera.com</a>
NeoGenomics	<a href="https://neogenomics.com">https://neogenomics.com</a>
Quest Diagnostics™	<a href="https://www.questdiagnostics.com">https://www.questdiagnostics.com</a>
STRATA Oncology	<a href="https://strataoncology.com">https://strataoncology.com</a>
TEMPUS	<a href="https://www.tempus.com">https://www.tempus.com</a>
Thermo Fisher Scientific	<a href="https://corporate.thermofisher.com/us/en/index.html">https://corporate.thermofisher.com/us/en/index.html</a>

*ALK*, anaplastic lymphoma kinase; *ASCO*, American Society of Clinical Oncology; *ATM*, ATM serine/threonine kinase; *BARD1*, BRCA1-associated RING domain 1; *BRAF*, v-Raf murine sarcoma viral oncogene; *BRCA1/2*, breast cancer gene 1/2; *BRIP1*, BRCA1-interacting helicase 1; *CDK12*, cyclin-dependent kinase 12; *CDx*, companion diagnostic; *CHEK2*, checkpoint kinase 2; *dMMR*, deficient mismatch repair; *EDTA*, ethylenediaminetetraacetic acid; *EGFR*, epidermal growth factor receptor; *ER*, estrogen receptor; *ERBB2*, erythroblastic oncogene B 2; *FANCA*, FA Complementation Group A; *FDA*, US Food and Drug Administration; *FFPE*, formalin-fixed paraffin-embedded; *FISH*, fluorescence in situ hybridization; *H&E*, hematoxylin and eosin; *HER2*, human epidermal growth factor receptor 2; *Her2/Neu*, human epidermal growth factor receptor 2; *IHC*, immunohistochemistry; *KIT*, KIT proto-oncogene, receptor tyrosine kinase; *KRAS*, Kirsten ras oncogene homolog; *MET*, MET proto-oncogene, receptor tyrosine kinase; *MLH1*, mutL homolog 1; *MMR*, mismatch repair; *MSH2/6*, MutS homolog 2/6; *MSI*, microsatellite instability; *N/A*, not applicable; *NBF*, neutral buffered formalin; *NCCN*, National Comprehensive Cancer Network; *NGS*, next-generation sequencing; *NRAS*, neuroblastoma RAS viral oncogene homolog; *NRPT*, not reported; *NSCLC*, non-small cell lung cancer; *NTRK1/2/3*, neurotrophic receptor tyrosine kinase 1/2/3; *PALB2*, partner and localizer of BRCA2; *PD-L1*, programmed death-ligand 1; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha; *PMS2*, PMS1 homolog 2; *PR*, progesterone receptor; *PTEN*, phosphatase and tensin homolog; *RAD51D*, *RAD51* paralog D; *RAD54L*, *RAD54* like; *RET*, ret proto-oncogene; *TAT*, turnaround time; *TMB*, tumor mutation burden; *TRK*, tropomyosin receptor kinase.



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# SUMMARY



Many patients with advanced or metastatic cancer may benefit from biomarker testing and/or genomic sequencing



Professional societies like ASCO recommend testing for pan-tumor markers and/or tumor-specific predictive biomarkers to identify appropriate treatment options for patients with metastatic cancer



Molecular panel-based approaches that use NGS enable testing for multiple biomarkers simultaneously, allowing for the most efficient use of limited tissues



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