Featured NGS Panels

Lung Cancer NGS Panel

Test Usage

Molecular testing of non-small cell lung cancer (NSCLC) is currently the standard of care for guiding the use FDA-approved targeted therapies such as inhibitors of EGFR, ALK and ROS1. In addition, there is growing clinical evidence supporting the efficacy of other treatments such as BRAF and MEK inhibitors for BRAF V600E-mutated NSCLC, crizotinib for NSCLC with MET exon 14 skipping mutations or high level MET amplification, various tyrosine kinase inhibitors (TKI) for NSCLC with RET rearrangements and ERBB2 antibodies and TKI for NSCLC with ERBB2 mutations. The use FDA-approved drugs for an off-label indication, such as these, and enrollment in clinical trials based on molecular findings is an important aspect of the care of patients with advanced stage NSCLC. This assay is designed to provide comprehensive molecular results relevant for both standard of care and emerging/investigational clinical actions. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes). Detectable variants relevant for NSCLC include, but are not limited to, mutations of EGFR, KRAS, NRAS, BRAF, ERBB2, MET (including exon 14 skipping), MAP2K1, PIK3CA, AKT1, FGFR2, FGFR3, DDR2, ALK, ROS1 and RET; amplification of EGFR, FGFR1, ERBB2, KRAS, PIK3CA, and MYC; and rearrangements of ALK, ROS1, RET, NTRK1/2/3, BRAF, and FGFR3. Mlabs recommends ordering PD-L1 in conjunction with the lung cancer NGS panel to assist in the first line treatment decisions.

Melanoma Cancer NGS Panel

Test Usage

Molecular testing of metastatic melanoma is currently the standard of care for guiding the use FDA-approved targeted therapies such as BRAF, MEK and KIT inhibitors. In addition, more investigational clinical actions are often employed for patients with metastatic melanoma including the use FDA-approved drugs for an off-label indication and enrollment in clinical trials. This assay is designed to provide comprehensive molecular results relevant for both standard of care and emerging/investigational clinical actions. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes). Detectable variants relevant for melanoma include, but are not limited to, mutations of BRAF, NRAS, KIT, MAP2K1, CTNNB1, GNAQ and GNA11; amplification of CCND1 and KIT; and rearrangements of BRAF, NTRK1, ROS1, ALK and RET.

Colorectal Cancer NGS Panel

Test Usage

Molecular testing of colorectal cancer (CRC) is currently the standard of care for guiding the use FDA-approved targeted therapies such as anti-EGFR and anti-PDL1 antibodies. In addition, more investigational clinical actions are often employed for patients with advanced stage CRC including the use FDA-approved drugs for an off-label indication and enrollment in clinical trials. This assay is designed to provide comprehensive molecular results relevant for both standard of care and emerging/investigational clinical actions. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes). Detectable variants relevant for CRC include, but are not limited to, mutations of KRAS, NRAS, BRAF, PIK3CA, and AKT1; amplification of ERBB2, FGFR1, KRAS, and MYC; and rearrangements of ALK. Importantly, microsatellite instability testing is NOT included in this assay and must be ordered separately if clinically indicated.

Solid Tumor Cancer NGS Panel

Test Usage

Molecular testing of solid tumor neoplasms – particularly advanced-stage cancer – is currently the standard of care for indications such as guiding the use FDA-approved targeted therapies. In addition, more investigational clinical actions are often employed for patients with solid tumors including the use FDA-approved drugs for an off-label indication and enrollment in clinical trials. This assay is designed to provide molecular results relevant for both standard of care and emerging/investigational clinical actions for solid tumor neoplasms. This DNA and RNA based, next-generation sequencing test targets 50 genes to detect substitution and insertion/deletion mutations (35 genes), gene amplifications (19 genes), and gene fusions (21 genes).

A complete test listing is available at: mlabs.umich.edu

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN
LABORATORIES

mlabs.umich.edu
800.862.7284

CLINICALLY VALIDATED FOR ALL TYPES OF ALTERATIONS.

The NGS panels are designed to sequence selected cancer genes that can be used for detecting a number of genetic alterations including point mutations, copy number variants and gene fusions.

Mutations

AKT1	IDH2
ALK	JAK1
AR	JAK2
BRAF	JAK3
CDK4	KIT
CTNNB1	KRAS
DDR2	MAP2K1
EGFR	MAP2K2
ERBB2 (HER2)	MET
ERBB3	MTOR
ERBB4	NRAS
ESR1	PDGFRA
FGFR2	PIK3CA
FGFR3	RAF1
GNA11	RET
GNAQ	ROS1
HRAS	SMO
IDH1	

Copy Number Variants

ALK	FGFR3
AR	FGFR4
BRAF	KIT
CCND1	KRAS
CDK4	MET
CDK6	MYC
EGFR	MYCN
ERBB2 (HER2)	PDGFRA
FGFR1	PIK3CA
FGFR2	

Fusions

ALK	RAF11
RET	ERG
ROS1	ETV1
NTRK1	ETV4
NTRK2	ETV5
NTRK3	AXL
FGFR1	EGFRvIII
FGFR2	ERBB2 (HER2)
FGFR3	PDGFRA
MET	PPARB
BRAF	

MLabs recommends ordering PD-L1 in conjunction with the lung cancer NGS Panel to assist in the first line treatment decision.

LESS TISSUE, MORE RESULTS.

Specimen considerations are critical for molecular testing as the majority of specimens consist of small biopsies or aspirates. We have modified our procedures to address this concern with a **<3% QNS/failure rate**.

Versatility of Accepted Specimens

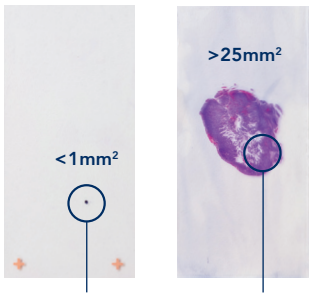
- Formalin-fixed, paraffin-embedded (FFPE) blocks
- FFPE tissue on slides
- Diff-Quik stained aspirate smears
- Pap stained aspirate smears
- H&E stained slides
- Previously extracted DNA/RNA*

	MLABS	OTHER LEADING LABORATORIES
Mean (TAT)	~10 days	~12 days
Tissue Requirement	<1mm^2	>25mm^2
Tumor Content	≥10%	≥20%
QNS/Failure Rate	<3%	15-20%

*RNA REQUIRED FOR DETECTING GENE FUSIONS

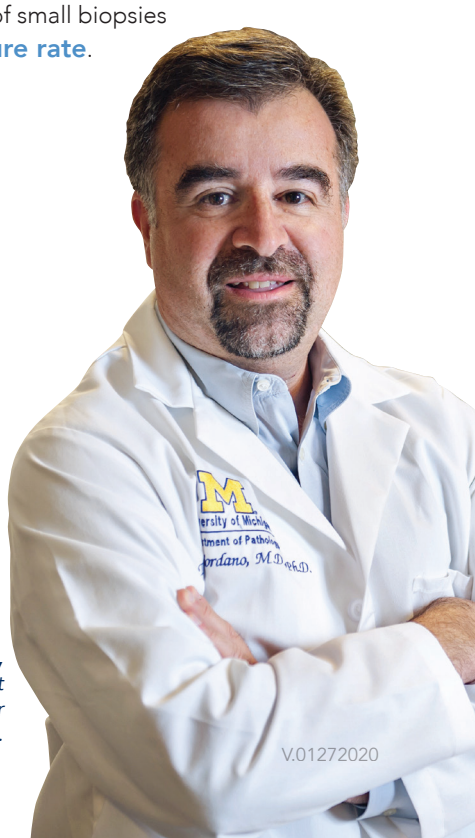
Input Requirements

- < 1 mm^2 of tissue
- As little as 100 tumor cells



MLabs Tissue Specimen

Leading Laboratory Tissue Specimen



*Director of the Division of Molecular Pathology, **Thomas Giordano, M.D., Ph.D.,** joined the faculty of the University of Michigan in 2001. His areas of interest include gene expression profiling and molecular diagnostics, molecular classification of human cancers, endocrine neoplasia, and thyroid carcinoma.*