

# ALVERNO LABORATORIES

# **Precision Medicine Requisition**

# **CLIENT INFORMATION**

ACCOUNT #: ACCOUNT NAME:

STREET ADDRESS:

CITY, ST, ZIP:

FAX: PHONE:

DATE: **REQUSITION COMPLETED BY:** 

ORDERING PHYSICIAN (LAST, FIRST):

NPI#:

TREATING PHYSICIAN (LAST, FIRST):

NPI#:

THE UNDERSIGNED CERTIFIES THAT HE/SHE IS LICENSED TO ORDER THE TEST(S) LISTED BELOW AND THAT SUCH TEST(S) ARE MEDICALLY NECESSARY FOR THE CARE/TREATMENT OF THIS PATIENT.

DATE: **AUTHORIZED SIGNATURE:** 

## **BILLING INFORMATION**

REQUIRED: PLEASE INCLUDE FACE SHEET AND FRONT/BACK OF PATIENT'S INSURANCE CARD

PATIENT STATUS: Hospital Patient (in) Hospital Patient (out) Non-Hospital Patient

BILL TO: Client Bill Insurance Medicare Medicaid Patient/Self-Pay

Split Billing- Client(TC) and Insurance (PC) OP Molecular to MCR, all other testing to Client

Bill charges to other Hospital/Facility:

PRIOR AUTHORIZATION #:

## **CLINICAL FORMATION**

REQUIRED: PLEASE ATTACH PATIENT'S PATHOLOGY REPORT (REQUIRED), CLINICAL HISTORY, AND OTHER APPLICABLE REPORT (S).

ICD-10 (DIAGNOSIS) CODE/NARRATVE (REQUIRED):

REASON FOR REFERRAL:

**New Diagnosis** Relapse In Remission Monitoring IV STAGING: Ш IIIA IIIB

KRAS KRAMT

NOTE:

#### PATIENT INFORMATION

LAST NAMF: MALE FEMALE FIRST NAME: M.I. D.O.B.: OTHER PT ID/ACCT #: MED. RECORD #:

CLIENT REPRESENTS IT HAS OBTAINED CONSENT FROM PATIENT TO PERFORM THE SERVICES DESCRIBED HEREIN.

# SPECIMEN INFORMATION

SPECIMEN ID: **BLOCK ID:** 

FIXATIVE/PRESERVATIVE:

**COLLECTION DATE: COLLECTION TIME:** 

**RETRIEVED DATE:** 

**HOSPITAL DISCHARGE DATE:** 

BODY SITE:

Primary Metastasis- If Metastasis, list Primary:

Peripheral Blood: Green Top(s) Purple Top(s) Other

FNA cell block:

Stained H&E Slides # Unstained Choose best block Paraffin Block(s) #: Perform tests on all blocks

Other (Please contact the lab before sending.)

# Breast Marker & GI HER2 Fixation (CAP/ASCO Requirement for Breast and Non-Breast)

Cold ischemic time ≤ 1 hour: Yes No Unknown 10% neutral buffered formalin: Unknown Yes No

HER2/ER/PgR Fixation duration 6 to 72 hours: Unknown Yes No

MISC TEST

# **GERMLINE TESTING**

5-FLUOROURACIL (ARUP) 2012166 ALLOPURINOL(ZYLOPRIM) H5801 CYTOCHROME P450 GENOTYPING

AM

PM

PANEL P450 CYP2D6 CP2D6

#### **MELANOMA - ALVERNO**

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMBNGSCP

OUEST

FGFR FGFRP

ALK FISH ALKF

NEOGENOMICS

**GIST - ALVERNO** 

**OUEST** 

BRAF BRAFP

KIT/PDGRFA PANEL KITGI

**RET FISH** 

MET EXON 14 SKIPPING

ROS1 FISH ROS1

NRAS NRASA KIT CKIT

PD-L1 (28-8) (OPDIVO) NLUPD

PD-L1 (22C3) NON-LUNG (PEMBROLIZUMAB), IHC PDL1 PD-L1 (SP142) NON-LUNG (ATEZOLIZUMAB), IHC 94047

**NON-SMALL CELL LUNG CANCER - ALVERNO** 

EGFR WITH REFLEX TO ALK AND ROS1 FISH

PD-L1 (28-8) (OPDIVO) PDLUN

PD-L1 (SP142) (TECENTRIQ) PDLIA

MET AMPLIFICATION FISH METGA

PD-L1 (SP263), IHC WITH INTERP 94007

BRAF BRAFP

KRAS WITH REFLEX TO EGFR/ALK/ROS1 LNCPK

PD-L1 (22C3) (KEYTRUDA) AP REQUEST FORM

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCP

EGFR EGFRP HER2 IHC KRAS KRAMT

ESOPHAGUS/GASTRIC CARCINOMA - ALVERNO

PD-L1 (22C3) (KEYTRUDA) AP REQUEST FORM

HER2 IHC WITH REFLEX TO FISH AP REQUEST FORM

BRCA Panel (BRACA1, BRACA2) BRCAP

# **OVARIAN CARCINOMA - ALVERNO**

MMR AP REQUEST FORM

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCP

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCI

# **BREAST CARCINOMA - ALVERNO**

PD-L1 (SP142) (TRIPLE NEGATIVE) (TECENTRIQ) COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCF

# **ENDOMETRIUM - ALVERNO**

MMR WITH MLH1 METHYLATION REFLEX (ALVERNO/QUEST) MSI FOR CHECKPOINT THERAPY MSICP MSI FOR LYNCH SCREENING MSILN COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCP

QUEST MLH1 METHYLATION STUDIES MLH1M

#### **GTC** \*See PAGE 2 FOR DETAILS

SOLID TUMOR PROFILE PLUS (434 DNA /1408 RNA Genes) LIQUID TRACE<sup>TM</sup>SOLID TUMOR (284 DNA /1501 RNA Genes)

# **COLORECTAL CARCINOMA - ALVERNO**

MSI FOR LYNCH SCREENING MSILN BRAF BRAFP MSI FOR CHECKPOINT THERAPY MSICP KRAS KRAMT MMR WITH REFLEX TO BRAF/MLH1 METHYLATION

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCP QUEST

NRAS NRASA

MLH1 METHYLATION STUDIES MLH1M

# THYROID - ALVERNO

BRAF BRAFP KRAS KRAMT

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCI QUEST

NRAS NRASA

RET/PTC REARRANGEMENT REAGE

# **CNS TUMORS - QUEST**

1P19Q DELETION (FISH) FO19Q IDH 1/IDH2 IDH12

MGMT PROMOTER METHYLATION MGMT

**ALVERNO** 

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB NGSCF

# OTHER ADVANCED SOLID TUMORS - ALVERNO

COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMRNGSCE MSI FOR LYNCH SCREENING MSILN

MSI FOR CHECKPOINT THERAPY MSICP

PD-L1 (22C3) (KEYTRUDA) PDL1 MMR

**OUEST** 

PD-L1 NON-LUNG (28-8) (NIVOLUMAB), IHC NLUPD PD-L1 LUNG (28-8) (NIVOLUMAB), IHC PDLUN PD-L1 (SP142) NON-LUNG (ATEZILIZUMAB), IHC 94047

PD-L1 (SP263), IHC WITH INTERP 94007

## **TEST MENU DETAILS**

# Genomic Testing Cooperative (GTC)

#### Solid Tumor Profile Plus

The Solid Tumor Profile Plus test combines the analysis of DNA with targeted transcriptome sequencing (RNA) to provide a comprehensive evaluation of cancer that includes detection of single nucleotide variation, copy number variation, gene expression levels and fusions irrespective of their partner genes. This includes testing of DNA abnormalities in 434 genes and targeted transcriptome analysis of 1408 genes. In addition, the test is designed to detect microsatellite instability (MSI), tumor mutation burden (TMB), homologous recombination repair (HRR) and homologous recombination deficiency (HRD). Other notable features include RNA levels of CTLA4, PD-L1, PD-L2, MET Exon 14 skipping, EGFRvIII, AR-V7 and DYPD gene polymorphism and prediction of toxicity to fluoropyrimidine therapy. The provided information helps in determining prognosis, designing a therapeutic approach and predicting response to immunotherapies, targeted therapies, and precision medicines.

Targeted transcriptome sequencing can also detect:

- · Gene expression levels that correlate to immunophenotype
- · Gene amplifications
- Exon skipping
- Alternative splicing
- Biomarker discovery

# <u>Liquid Trace<sup>™</sup> Solid</u> Tumor

#### Pan-Tumor Assay for Solid Tumors

GTC's Liquid Trace Solid Tumor is a pan-cancer highly sensitive test evaluating cfRNA and cfDNA providing highly informative data that can be used for diagnoses, evaluating the host immune response, and identifying biomarkers for predicting responses to various therapies.

Liquid Trace Solid Tumor may provide additional information not detected by tissue biopsies including information on the presence of germline mutations or mutations in the subciones not present in the tissue sample (heterogeneity).

# Types of solid tumors Liquid Trace can detect:

- Lung
- Breast
- Thyroid
- Colon
- Oropharyngeal tumors
- PancreaticOvarian
- Prostate
- ProstateHPV
- Cancer of unknown primary (CUP)

Liquid biopsy in its current form is dependent on cfDNA analysis; this method likewise presents multiple challenges. These include variations in DNA shedding between tumors as well as low sensitivity (especially in early-stage cancer), difficulty in detecting fusion genes (i.e., chromosomal translocations leading to the expression of chimeric mRNA from two genes), and inability to reflect the numerous biological processes that modify RNA expression levels, such as alternative splicing, stability, and allele-specific methylation. The latter limitation is critically important as recent studies have shown that RNA testing provides another level of biological information regarding the tumor and its microenvironment.

#### The Benefits of cfRNA

RNA sequencing has proven to be more sensitive for some types of mutations. Cancer cells typically contain one copy of mutated DNA but numerous copies of RNA. This research is consistent with GTC's findings that cfRNA has increased sensitivity over cfDNA alone. More specifically, cfRNA allowed GTC's Liquid Trace to detect more mutations and fusions in hematologic and solid tumor samples, which may be undetected by

# Solid Tumor Profile Plus

Genes: **434/1408** TAT: **7-10 Days** 

All solid tumors

Fusions: ALK, ROS1, RET, NTRK1/2/3, and more. BRAF, CIC, EWSR1, PD-L1, MET exon 14 skipping and various alternative splicing, MET, HER2, EGFR, Gene amplifications, PIK3CA, PTEN, AKT1, RAS and HRD Cancer of unknown primary (CUP)

Sample Type: **FFPE**Sample Requirements

1 H&E slide and 6-8 unstained slides, 5-7 microns of tissue fixed with 10% NBF fixative

Results Reported: **DNA + RNA** 

# Liquid Trace™ Solid Tumor

Genes: **284/1501** TAT: **5-7 Days** 

#### Indications

All solid tumors
Chromosomal abnormalities,
gene amplifications, HRR, MRD,
Fusions: ALK, ROS1, RET,
NTRK1/2/3, and more.
BRAF, CIC, EWSR1, PD-L1, MET exon
14 skipping and various alternative
splicing, MET, HER2, PIK3CA, PTEN,
Gene amplifications, AKT1, RAS,
HER2, MYC, EGFR,
Cancer of unknown primary (CUP)
HPV

# Sample Type: Peripheral blood

Sample Type. Perpireral blood
Sample Requirements
8-10 mL. EDTA tube is required
RNA stability is 48-72 hours from
blood draw. DNA stability is 7
days from blood draw. Samples
received beyond 72 hours may
include only DNA results.
Results Reported:
DNA + RNA