

ALVERNO LABORATORIES

Precision Medicine Requisition

CLIENT INFORMATION

ACCOUNT NAME: ACCOUNT #:

STREET ADDRESS:

CITY, ST, ZIP:

PHONE: FAX:

REQUSITION COMPLETED BY: DATE:

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.

AUTHORIZED SIGNATURE: DATE:

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 STAGING: 0 I II III IIIA IIIB IV

NOTE:

PATIENT INFORMATION

LAST NAME: 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:

Slides # Unstained Stained H&E
Paraffin Block(s) #: Choose best block

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: Yes No Unknown

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

CIRCULATING TUMOR CELL COUNT

ARU

BREAST COLORECTAL PROSTATE

CANCER ORIGIN: **GERMLINE TESTING**

5-FLUOROURACIL

ALLOPURINOL(ZYLOPRIM)
CYTOCHROME P450 GENOTYPING

PANEL CYP2D6

ARIIP

MELANOMA - ALVERNO

BRAF

52 GENE NGS SOLID TUMOR PANEL

COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

ARUP

NRAS (2003123) KIT (2002674)

PD-L1 (28-8) (OPDIVO)

NON-SMALL CELL LUNG (LOW STAGE) - ALVERNO

EGFR BRAF KRAS
EGFR WITH REFLEX TO ALK AND ROS1 FISH

ALK FISH ROS1 FISH

PD-L1 (22C3) (KEYTRUDA)

KRAS WITH REFLEX TO EGFR/ALK/ROS1

ARUP

PD-L1 (28-8) (OPDIVO)

QUEST

PD-L1 (SP142) (TECENTRIQ)

NON-SMALL CELL LUNG CANCER (ADVANCED STAGE) - ALVERNO

52 GENE GS SOLID TUMOR PANEL

COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

ARUP

MISC TEST

MET AMPLIFICATION FISH (3001313)

RET FISH (3001312)

NEOGENOMICS

NEOGENOMICS

MET EXON 14 SKIPPING

GIST - ALVERNO

BRAF

ARUP

KIT/PDGRFA PANEL (2002674)

ESOPHAGUS/GASTRIC CARCINOMA - ALVERNO

HER2 IHC WITH REFLEX TO FISH PD-L1 (22C3) (KEYTRUDA)

MMR

52 GENE NGS SOLID TUMOR PANEL

COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

OVARIAN CARCINOMA - ALVERNO

EGFR HER2 IHC KRAS
COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

NEOGENOMICS

BRCA1/2

BREAST CARCINOMA - ALVERNO

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

ENDOMETRIUM - ALVERNO

MMR WITH MLH1 METHYLATION REFLEX (ALVERNO/

ARUP) MSI

COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

ARUP

MLH1 METHYLATION STUDIES (2202499)

GTC *See PAGE 2 FOR DETAILS

SOLID TUMOR PROFILE PLUS (434 DNA /1408 RNA Genes) LIQUID TRACE $^{\rm IM}$ SOLID TUMOR (284 DNA /1501 RNA Genes)

COLORECTAL CARCINOMA - ALVERNO

BRAF MSI KRAS

MMR WITH REFLEX TO BRAF/MLH1 METHYLATION

STUDIES 52 GENE NGS SOLID TUMOR PANEL

COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

ARUP NRAS (2003123)

MLH1 METHYLATION STUDIES (2202499)

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THYROID - ALVERNO

BRAF KRAS

COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

ARUP

NRAS (2003123) RET FISH (3001312)

CNS TUMORS

ARUP

1P19Q DELETION (FISH)

IDH 1/IDH2 (2014188)

MGMT PROMOTER METHYLATION (2009310)
COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

ADVANCED SOLID TUMOR (TUMOR TYPE) - ALVERNO

MMR MS

52 GENE NGS SOLID TUMOR PANEL

PD-L1 (22C3) (KEYTRUDA)

COMPREHENSIVE SOLID TUMOR PANEL WITH MSI/TMB

ARUP

PD-L1 (28-8) (OPDIVO) **NEOGENOMICS**

PD-L1 (SP142) (TECENTRIQ) PD-L1 (SP263) (IMFINZI)

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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[™] Soli</u>d 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 subclones not present in the tissue sample (heterogeneity).

Types of solid tumors Liquid Trace can detect:

- Lung
- Breast
- Thyroid
- Colon
- Oropharyngeal tumors
- PancreaticOvarian
- Prostate
- ProstaHPV
- 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 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