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: **AM** ◯ **PM** ◯
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

MISC TEST

GERMLINE TESTING

☐ 5-FLUOROURACIL (ARUP) **2012166**
☐ ALLOPURINOL(ZYLOPRIM) **H5801**
☐ CYTOCHROME P450 GENOTYPING PANEL **P450**
☐ CYP2D6 **CP2D6**

MELANOMA - *ALVERNO*

☐ BRAF **BRAFP**
☐ COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB **NGSCP** ***QUEST***
☐ 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 **EGFRP** ☐ BRAF **BRAFP** ☐ KRAS **KRAMT**
☐ EGFR WITH REFLEX TO ALK AND ROS1 FISH
☐ KRAS & EGFR WITH REFLEX TO ALK/ROS1 **LNCPK**
☐ ALK FISH **ALKF**
☐ ROS1 FISH **ROS1**
☐ PD-L1 (22C3) (KEYTRUDA) **AP REQUEST FORM**
☐ COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB **NGSCP** ***QUEST***
☐ PD-L1 (28-8) (OPDIVO) **PDLUN**
☐ PD-L1 (SP142) (TECENTRIQ) **PDLIA**
☐ PD-L1 (SP263), IHC WITH INTERP **94007**
☐ MET AMPLIFICATION FISH **METGA** ***NEOGENOMICS***
☐ MET EXON 14 SKIPPING
☐ RET FISH

GIST - *ALVERNO*

☐ BRAF **BRAFP** ***QUEST***
☐ KIT/PDGRFA PANEL **KITGI**

ESOPHAGUS/GASTRIC CARCINOMA - *ALVERNO*

☐ HER2 IHC WITH REFLEX TO FISH **AP REQUEST FORM**
☐ PD-L1 (22C3) (KEYTRUDA) **AP REQUEST FORM**
☐ MMR **AP REQUEST FORM**
☐ COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB **NGSCP**

OVARIAN CARCINOMA - *ALVERNO*

☐ EGFR **EGFRP** ☐ HER2 IHC ☐ KRAS **KRAMT**
☐ COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB **NGSCP** ***QUEST***
☐ BRCA Panel (BRACA1, BRACA2) **BRCAP**

BREAST CARCINOMA - *ALVERNO*

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

ENDOMETRIUM - *ALVERNO*

☐ HER2 BY FISH
☐ 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*

www.genomicstestingcooperative.com

☐ SOLID TUMOR PROFILE PLUS (434 DNA /1408 RNA Genes)
☐ LIQUID TRACE™ 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 **NGSCP** ***QUEST***
☐ NRAS **NRASA**
☐ RET/PTC REARRANGEMENT **REAGF**

CNS TUMORS - *QUEST*

☐ 1P19Q DELETION (FISH) **FO19Q**
☐ IDH 1/IDH2 **IDH12**
☐ MGMT PROMOTER METHYLATION **ARUP 3005956** ***ALVERNO***
☐ COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB **NGSCP**

OTHER ADVANCED SOLID TUMORS - *ALVERNO*

☐ COMPREHENSIVE NGS SOLID TUMOR PANEL WITH MSI/TMB **NGSCP**
☐ MSI FOR LYNCH SCREENING **MSILN**
☐ MSI FOR CHECKPOINT THERAPY **MSICP**
☐ PD-L1 (22C3) (KEYTRUDA) **PDL1** ☐ MMR ***QUEST***
☐ 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**

ALVERNO LABORATORIES

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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

Liquid Trace® Solid 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
- Pancreatic
- Ovarian
- Prostate
- HPV
- 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 conventional cfDNA.

Solid Tumor Profile Plus™	Liquid Trace® Solid Tumor
Genes: 434/>1600	Genes: 302/>1600
TAT: **7-10 Days**	TAT: **5-7 Days**
Indications	Indications
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)	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: **FFPE**	Sample Type: **Peripheral blood**
Sample Requirements	Sample Requirements
1 H&E slide and 6-8 unstained slides, 5-7 microns of tissue fixed with 10% NBF fixative	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**	Results Reported: **DNA + RNA**