ALVERNO LABORATORIES

HEMATOPATHOLOGY Patient Information Sheet

CLIENT INFORMATION

Account Name:	
Treating Physician (First, Last):	
Physician's Contact #:	

PATIENT INFORMATION

Last Name:	First Name:		M.I.
Date of Birth (mm/dd/yyyy):	Age:	Sex:	
Order Date:		Medical Record #:	
Physician's Signature:	**Physician's NPI #:**		

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 **Prior Authorization #:** _____

Bill To: ☐ Client Bill ☐ Insurance ☐ Medicare ☐ Medicaid ☐ Patient/Self-Pay ☐ Split Billing-Client(TC) & Insurance(PC) ☐ OP Molecular to MCR, all other testing to Client

☐Bill charges to other Hospital/Facility:

SPECIMEN INFORMATION

Collection Date mm_____ / dd_____ / yyyy_____ **Collection Time**_____ ☐ AM ☐ PM

☐ Peripheral Blood **(attach CBC result):** Green Top(s) _____ Purple Top(s) _____ Other _____ ☐ Fresh Tissue ☐ FNA in ☐RPMI ☐Other_____ (Site) _____

☐ Bone Marrow **(attach CBC result):** Green Top(s) _____ Purple Top(s) _____ Core Biopsy _____ Clot _____ ☐ Fluid: CSF_____ Pleural_____ Other:_____

CLINICAL INFORMATION

***** This section must be complete or report will be delayed. *****

Known Diagnosis:_____ **ICD-10 Code (Required)** _____

Pertinent History: ☐ Pancytopenia ☐ Thrombocytopenia ☐ Leukopenia ☐ Anemia ☐ Lymphocytosis ☐ Abnormal lymphocytes ☐ Monocytosis ☐ Atypical cells/blasts ☐ Eosinophilia ☐ Monoclonal gammopathy ☐ Plasmacytosis ☐ Lymphadenopathy ☐ Extranodal mass ☐ Splenomegaly ☐ Other _____

Diagnosis Under Consideration (Check All That Apply): ☐ non-Hodgkin Lymphoma ☐ Hodgkin Lymphoma ☐ Acute Leukemia ☐ Chronic Lymphoproliferative Disorder ☐ Myelodysplastic Disorder ☐ Myeloproliferative Neoplasms ☐ Multiple Myeloma ☐ Other _____

Status: ☐ New diagnosis ☐ Follow up ☐ Minimal residual disease ☐ Relapse ☐ BM Transplant

TEST MENU

Flow Cytometry - EDTA

☐ **Global** ☐ **Tech-Only**

☐ Lymphoma/Lymphocytosis Panel (For CLL, MM, and NHL studies) **FLWCY**

☐ Leukemia/Lymphoma Comprehensive Panel (For ALL, AML, CML and MDS studies) **FLWCY**

------ Reflex panels if indicated ------

☐ Plasma Cell
☐ Hairy Cell
☐ Acute Leukemia Intracellular Markers: (nTdT, cMPO, cCD3, cCD79a)
☐ T-cell Receptor
☐ PNH (QUEST) **PNHHS**

Cytogenetics (Chromosome Analysis)

(QUEST) - Sodium Heparin

☐ Chromosome Analysis, Hematologic Malignancy **CHABM**
Myelogenous- MDS,MPD,ALL,CML (blood or bone marrow)

☐ Chromosome Analysis, CLL/LPD **CHRCL**
Lymphoproliferative CLL,LPD (blood or bone marrow)

Fluorescence *in situ* Hybridization (FISH) - Sodium Heparin

☐ ***Process & hold** **RQFSH** *(all panels except Myeloma)*
☐ ***Plasma Cell Enrichment - process & hold** **RQPCE** *(all panels including Myeloma)*
**Call or email within 14 days of collection to add on panel.*

☐ **Global** ☐ **Tech-Only-**pathologist for interp: _____

Select a panel below: [FISH probes may be ordered individually by checking the box beside test]

☐ **ALL Panel (Adult)** **ALLFH**
- ☐ BCR/ABL t(9::22)
- ☐ MLL Rearrangement (11q23)

☐ **AML Panel** **AMLFH**
- ☐ Deletion 5q/Monosomy 5
- ☐ Deletion 7q/Monosomy 7
- ☐ Trisomy 8
- ☐ Deletion 20q
- ☐ Inv(3) 3q26
- ☐ RUNX1/RUNX1T1 (AML/ETO) t(8::21)
- ☐ PML/RARA t(15::17) (APL)
- ☐ MYH11/CBFB; inv(16), t(16::16)
- ☐ MLL Rearrangement (11q23)

☐ **CLL/SLL Panel** **CLLFH**
- ☐ Deletion 11q (ATM)
- ☐ Deletion 13q/Monosomy 13
- ☐ Deletion 17p *(TP53)*
- ☐ Trisomy 12
- ☐ IGH/CCND1, t(11::4)

☐ **MDS Panel** **MDSFH**
- ☐ Deletion 5q/Monosomy 5
- ☐ Deletion 7q/Monosomy 7
- ☐ Trisomy 8
- ☐ Deletion 20q

☐ **CML Panel** **CMLFH**
- ☐ BCR/ABL t(9::22)

☐ **Myeloma Panel** **MMYFH**
- ☐ Deletion 1p/1q Gain
- ☐ Deletion 13q/Monosomy 13
- ☐ Trisomy 3, 5, 9
- ☐ Deletion 17p *(TP53)*
- ☐ IGH Rearrangement (14q32) Reflex to
- ☐ IGH/CCND1, t(11::14)
- ☐ IGH/FGFR3, t(4::14)
- ☐ IGH/MAF, t(14::16)

☐ **NHL Panel** **NHLFH**
- ☐ ALK Rearrangement (2p23)
- ☐ BCL6 Rearrangement (3q27)
- ☐ MALT1 Rearrangement (18q21)
- ☐ MYC Rearrangement (8q24)
- ☐ IGH Rearrangement (14q32)
- ☐ IGH/BCL2, t(14::8)
- ☐ IGH/CCND1, t(11::14)
- ☐ IGH/MYC, t(8::14)

☐ **Eosinophilia Panel** (QUEST) **MPNEF**
PDGFR-α, (FIP1L1), PDGFR-β, FGFR1, and CBFB

☐ **Other** _____

Molecular Genetics - EDTA

***** Prior insurance authorization may be required.***

☐ Extract Nucleic Acid and Hold*
(* Call or email within 14 days to add NGSMY panel.)

☐ Myeloid Neoplasms Mutation Panel by NGS (40 DNA /29 RNA genes) **NGSMY**

GTC www.genomictestingcooperative.com

☐ Hematology Profile Plus
☐ Liquid Trace™Hematology

Quest Diagnostics www.questdiagnostics.com

☐ BCR/ABL1, Quantitative PCR **BCRGR**
☐ JAK2 V617F Mutation **JAVMA**
☐ JAK2 Exon 12 Mutation **JAKMA**
☐ MPN Panel w/JAK2, JAK2 Ex12, CALR, and MPL by NGS **JAKMN**
☐ B-Cell Clonality by PCR (IgH/IgK) **BCELL**
☐ T-Cell Clonality by PCR (TCRB, TCRG) **91445**
☐ MYD88 L265P Mutation **MYD88**
☐ NPM1 Mutation (Exon 12) **16158**
☐ FLT3 ITD&TKD Mutation **FLT3**
☐ CEBPA Mutation Detection **CEBPA**
☐ TP53 Somatic Mutation **16515**
☐ IgVH Mutation Status (CLL) **IGVMS**
☐ Other _____

LIS LABELS ONLY

ALVERNO LABORATORIES

HEMATOPATHOLOGY Patient Information Sheet

TEST MENU DETAILS

Genomic Testing Cooperative (GTC)

GTC-Hematology Profile Plus

GTC-Hematology Profile Plus combines expression and fusion with mutation analysis in DNA and RNA. The test covers 179 DNA genes and 1408 RNA genes. This is a comprehensive evaluation of all hematologic neoplasms. However, it is especially recommended for:

- Acute Lymphoblastic Leukemia (ALL): This comprehensive assay is designed to confirm the diagnosis of Ph-ALL and Ph-like ALL and distinguish them from other types of ALL. It can be used for diagnosis as well as for monitoring. Ph-like ALL is detected in 20% to 25% of adult ALL and in 15% of pediatric ALL. Diagnosis of Ph+-ALL and Ph-like ALL is very important because TKI therapy can be helpful in most of these patients. This assay can determine most of the mutations, translocations, and expression of genes (CRLF2) associated with Ph+ ALL and Ph-like ALL.
- Diffuse Large B-cell Lymphoma (DLBCL) and other Types of Lymphoma: This assay can provide very valuable information for the management and monitoring of patients with DLBCL. It can distinguish between ABC and GCB and can help in the diagnosis of double hit lymphoma. The assay is also useful for follicular lymphoma and T-cell neoplasms.
- Acute Myeloid Leukemia (AML): Translocations in AML are very important for diagnosis, prognosis and selecting therapy. This comprehensive testing can provide a complete evaluation of fusion mRNA and mutations. It also helps in determining a diagnosis in acute leukemia with ambiguous phenotype.
- Clonal Hematopoiesis of Indeterminate Potential (CHIP): Distinguish CHIP from clinically active and relevant hematologic neoplasm based on an internally developed algorithm using variant allele frequency, chromosomal structural abnormalities, clinical and laboratory data and longitudinal data. This distinction is particularly important when evaluating minimal residual disease and in the presence of other neoplastic process.
- IgVH Mutation Status: IgVH mutation status is very important for prognosis and selecting therapy in patients with chronic lymphocytic leukemia (CLL).
- VEXAS Syndrome: Recently described VEXAS (vacuoles, E1 enzyme, X-linked, autoinflammatory, somatic) is caused by mutations in the UBA1 gene. This is an adults-onset fatal disease that may present as myelodysplastic syndrome, aplastic anemia or multiple myeloma, but characterized by fevers, low white cell count, vacuoles in bone marrow cells, dysplastic bone marrow, pulmonary inflammation, chondritis, and vasculitis. Detecting the presence of mutations in the UBA1 gene is the only way for confirming the diagnosis of this syndrome.

Liquid Trace™ Hematology

Pan-Tumor Assay for Hematologic Malignancies
GTC's Liquid Trace Hematology 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.

GTC's Liquid Trace can significantly reduce the need for bone marrow biopsies for hematology patients. Furthermore, the test can detect, chromosomal abnormalities, translocations, and gene amplifications. Liquid Trace can detect all types if hematologic cancers including:

- Multiple myeloma
- Lymphoma
- Acute Lymphoblastic Leukemia
- Acute myeloid leukemia
- MDS
- CMML
- MPN
- MRD
- VEXAS syndrome
- EBV – related neoplasms
- Hypersinophilia

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.

Hematology Profile Plus	Liquid Trace™ Hematology
Genes: 179 /1408	Genes: 284/1501
TAT: 7-10 Days	TAT: 5-7 Days
Indications	Indications
All hematologic neoplasms including lymphoma Classification and diagnosis of lymphoma, multiple myeloma, acute lymphoblastic leukemia, and acute myeloid leukemia Includes IgVH Chromosomal abnormalities, and gene amplifications	All hematologic neoplasms including lymphoma multiple myeloma, acute lymphoblastic leukemia, acute myeloid leukemia, MDS, CMML, MPN, MRD, VEXAS syndrome, and EBV Chromosomal abnormalities, and gene amplifications
Sample Type	Sample Type
Bone marrow, Peripheral blood, Fresh tissue	Peripheral blood
Sample Requirements	Sample Requirements
Bone marrow: 2ml. Peripheral blood: 5 ml. EDTA tube preferred FFPE: 1 H&E slide and 6-10 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