LabPMM® GmbH
an invivoscribe company

Test Order Form

Patient Information:
Last Name:
First Name:
Date of Birth: DD/MM/YYYY
Sex: m ☐ f ☐ d ☐
Medical Record #:
Diagnosis:

Please see information on sample collection, specimen requirement and shipping on the back side of this page.

Place Patient Label Here if Required

Customer #:
Physician Information:
Name:
Telephone #:
Fax #:
Institution Name:
Address:

Specimen Information:
Collection Date: DD/MM/YYYY
DNA isolated from: Blood ☐ Bone Marrow ☐
Peripheral Blood: ☐
Bone Marrow: ☐

Tests Requested:

Molecular Diagnostic Tests (PCR):

- ☐ *NPM1* Mutation (qualitative)
- ☐ LeukoStrat® CDx *FLT3* Mutation Assay** (semi-quantitative)
  **Please note the special sample requirements on the back side

Minimal Residual Disease (NGS)‡:

- ☐ *FLT3* ITD Minimal Residual Disease (RUO)
- ☐ *NPM1* Minimal Residual Disease (RUO)

Gene Panel (NGS)[1]:

Signed Patient Consent Form Required

- ☐ MyAML®

Multiparametric Flow Cytometry Test ‡:

- ☐ AML MRD Assay (LLOQ = 0.01%) (RUO)

Clonality Tests (NGS):

☐ *IGH* FR1	☐ MRD (RUO) ‡
☐ *IGH* FR1, FR2, FR3	☐ MRD (RUO) ‡
☐ *IGHV* Leader (SHM)	☐ MRD (RUO) ‡
☐ *IGK*	☐ MRD (RUO) ‡
☐ *TRG*	☐ MRD (RUO) ‡
☐ *TRB*	☐ MRD (RUO) ‡

[1] Testing provided by our partner laboratory LabPMM LLC, San Diego, California, USA. LabPMM LLC is an ISO15189, CLIA/CAP accredited and New York State Licensed international reference laboratory.
‡ Tests are currently not accredited by DAkkS.

Costs for tests can be provided on request.

Physician Signature:	Date: DD/MM/YYYY

By signing this Test Order Form I declare that I have provided the privacy information to the patient and that I have informed the patient that the ordered tests are conducted at LabPMM GmbH or at LabPMM LLC, USA (for the MyAML assay), and for what purposes such tests are conducted.

PLEASE PLACE THE COMPLETED, SIGNED AND DATED FORM IN THE SHIPPING CONTAINER.

LabPMM GmbH Use Only:

Date Received:	Comments:
Time Received: Received By:	Volume:
LabPMM Accession Number:	Concentration:

LabPMM GmbH,
Zeppelinstraße 1, 85399 Hallbergmoos, Germany
Tel +49 89 904 299 800
Opening hours: Monday to Friday 8:00 to 16:30
Email: info@labpmm.de

CEO Jeffrey E. Miller, PhD
HRB 189049 München
USt-IdNr.: DE275782182
invivoscribe.com/clinical-services

DAkkS Deutsche Akkreditierungsstelle D-ML-18221-01-00

General Instructions

Sample Collection:

Peripheral blood and bone marrow samples to be collected using local standard protocols.
Label samples with **two patient identifiers** according to local procedures.

Specimen Requirements:

- 2 - 4 mL of Peripheral Blood in Sodium Heparin or EDTA (Gene Panels min. 3 mL)
- 2 - 4 mL of Bone Marrow in Sodium Heparin or EDTA

- Previously isolated DNA
  - *NPM1* testing: min. 250 ng
  - *FLT3* ITD, *NPM1* Minimal Residual Disease: 1 µg per assay
  - Clonality Tests: min. 500 ng per assay
  - Clonality Tests, MRD: 700 - 3500 ng per assay
  - Gene Panel: min. 1 µg per assay

LeukoStrat® CDx *FLT3* Mutation Assay

- 2 mL of Peripheral Blood in Sodium Heparin or EDTA tubes only
- 0.5 mL of Bone Marrow in Sodium Heparin or EDTA tubes only
- No isolated DNA accepted

Shipping:

- Blood and bone marrow samples should be shipped ambient or cooled. **DO NOT FREEZE!**
- Blood and bone marrow samples are stable at 2°C - 8°C for up to 7 days prior to testing.
- Note: FLOW SPECIMENS SHOULD ARRIVE WITHIN 48 HOURS OF COLLECTION.
- DNA can be shipped at ambient temperature, cooled or on dry ice.

LeukoStrat® CDx *FLT3* Mutation Assay:

- Samples must be shipped cooled (2°C - 8°C).
- Samples are stable at 2°C- 8°C for up to 7 days prior to testing.

Follow IATA regulations when shipping patient samples. Please refer to IATA Dangerous Goods Regulations for specific details. Do not ship any specimen defined as a Category A Biological Substance to LabPMM GmbH, these shipments will be returned. If there are any questions on shipping, please contact the laboratory.

Intended Use

LeukoStrat® CDx *FLT3* Mutation Assay:

This test is for both *FLT3* ITD and TKD mutations. The LeukoStrat CDx *FLT3* Mutation Assay was developed and its performance characteristics determined by Invivoscribe, Inc. It has been CE-marked (CE2797IVD) per the In Vitro Diagnostics Regulation (Regulation (EU) 2017/746). In regions where VANFLYTA® (quizartinib hydrochloride) is available, the LeukoStrat CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with *FLT3*-ITD+ AML for whom VANFLYTA® (quizartinib hydrochloride) treatment is being considered. In regions where XOSPATA® (gilteritinib fumarate) is available, the LeukoStrat® CDx *FLT3* Mutation Assay is used as an aid in the assessment of patients with AML for whom XOSPATA ® (gilteritinib fumarate) treatment is being considered.

General Information

Turnaround Time:

- *NPM1* Mutation (qualitative): 1 to 3 business days
- LeukoStrat® CDx *FLT3* Mutation Assay (semi-quantitative): 2 to 3 business days
- *FLT3* ITD Minimal Residual Disease (NGS): 12 to 14 business days
- *NPM1* Minimal Residual Disease (NGS): 12 to 14 business days
- Clonality Tests (NGS): 12 to 14 business days
- Clonality Tests, MRD (NGS): 14 to 21 business days
- AML MRD Assay: 1 business day

Complaint Procedure:

For complaints please contact LabPMM GmbH by phone or email. All complaints are registered within three business days in an internal electronic system and evaluated by the Quality Department. You will be contacted regarding complaint investigation as soon as reasonably practicable.