

LymphoTrack® Dx Assays

CASE STUDY

Investigator and Institution

Dr. Sara Galimberti, University of Pisa

Location

Pisa, Italy

Type of Business

Education, Medical Research

Services

Scientific Sector, Specializing in Blood Disorders

ABOUT THE CLIENT

Dr. Sara Galimberti is an Associate Professor and the Chief of Hematology for the Department of Clinical and Experimental Medicine Disciplinary Scientific Sector at the University of Pisa, Italy.

For more: <http://www.medmcs.unipi.it/>



CHALLENGES

Doctors at the University of Pisa are focused on treating multiple forms of blood cancer, including acute and chronic leukemia, lymphoma, and myeloma. To support this endeavor, Dr. Galimberti's research lab was tasked with assessment of specific biomarker mutations and clonality, as well as monitoring minimal residual disease (MRD), with a focus on chronic lymphocytic leukemia (CLL) and acute myeloid leukemia (AML). The lab also needed a robust method to identify clonality in acute lymphoblastic leukemia (ALL) and assess immunoglobulin variable heavy chain (IGHV) SHM status in CLL patients.

For several years the medical and research teams had used alternative polymerase chain reaction (PCR) assays to assess IGH and TRG clonality. Due to the complexity and limited resolution of these methods, the team was seeking a new approach to simplify their workflow and enable them to accurately evaluate clonal shifts, which may appear in challenging ALL cases.

ABOUT INVIVOSCRIBE

Invivoscribe is an industry pioneer with over 25 years of experience developing and manufacturing diagnostic products and reagents for leukemia and lymphoma. All of our diagnostic tests generate actionable results allowing healthcare providers to stratify treatment for each patient.

LymphoTrack® Dx IGHV Leader Somatic Hypermutation (SHM) and LymphoTrack® Dx TRG Assay kits are *in vitro* diagnostic products intended for next-generation sequencing (NGS) based determination of immunoglobulin variable heavy chain gene (IGH) and T-cell receptor gamma (TRG) gene rearrangements in subjects suspected of having lymphoproliferative disease.





SOLUTION

Using a research grant, Dr. Galimberti's team began assessing the NGS-based LymphoTrack® Dx IGHV Leader SHM and LymphoTrack® Dx TRG Assay kits.

Her medical team was drawn to the LymphoTrack® Dx kits because they offer a complete solution, with ready-made master mixes, controls and an intuitive bioinformatics software. She was also pleased with the support provided by Invivoscribe during their evaluation, which enabled her team to become knowledgeable and proficient in LymphoTrack® Dx Assay interpretation. Her laboratory was able to rapidly transition from PCR to NGS clonality testing because the assays and software are intuitive and easy to use.

REFERENCES

LymphoTrack® Dx IGHV Leader Somatic Hypermutation Assay - MiSeq® INTENDED USE

The LymphoTrack® Dx IGHV Leader Somatic Hypermutation Assay for the Illumina® is an in vitro diagnostic product intended for next-generation sequencing (NGS) based determination of the frequency distribution of IGH gene rearrangements as well as the degree of somatic hypermutation of rearranged genes in patients suspected with having lymphoproliferative disease. This assay aids in the identification of lymphoproliferative disorders as well as providing an aid in determining disease prognosis.

LymphoTrack® Dx TRG Assay - MiSeq® INTENDED USE

The LymphoTrack® Dx TRG Assay for the Illumina® MiSeq® is an in vitro diagnostic product intended for next-generation sequencing (NGS) based determination of the frequency distribution of TRG gene rearrangements in patients suspected of having lymphoproliferative disease. This assay aids in the identification of lymphoproliferative disorders.

LymphoTrack® Dx Assays are in vitro diagnostic products and are available in regions that accept CE-IVD products.

M-0083 Rev 01

RESULTS

Dr. Galimberti's team adopted Invivoscribe's LymphoTrack® Dx Assay kits due to the simplified workflow and objective data analysis which streamlines patient care. Her team is now able to provide faster, more comprehensive answers for patients and their physicians, leading to a better informed choice of treatment.

In addition, the LymphoTrack® Dx IGHV Leader SHM and LymphoTrack® Dx TRG Assay kit has proven extremely valuable not only in determining the presence of clonality, but also as a tool to assess the degree of somatic hypermutation which may aid in disease stratification and patient prognosis.



More Comprehensive
INFORMATION



Objective Results for
FASTER DIAGNOSIS



Informed
TREATMENT DECISIONS



“I have to choose the best treatment for my patients. I need molecular answers and reports quickly. Invivoscribe's products have made this easier.”



“Invivoscribe's products are useful, modern, and update the diagnostic flow. They are also good at characterizing CLL.”



“I would recommend Invivoscribe because of their expertise and because they are able to help researchers, biologists and technicians.”

 **invivoscribe®**
Improving Lives with Precision Diagnostics™

 **LymphoTrack® Dx**
Assays

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