LEGNID

Lung canc**E**r fusi**O**n ge**N**es: a new d**I**agnostic **D**evice

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GENETIC LAB

Lung cancer is the 1st cancer among men in terms of both incidence and mortality, and among women has the 3rd highest incidence, and is 2nd in mortality. Non Small Cell Lung Carcinoma (NSCLC) accounts for 85% of all lung cancer cases.

From 1% to 7% of NSCLC cases show chromosomal translocations involving ALK, ROS1 or RET genes and conferring sensitivity to TKI therapy.

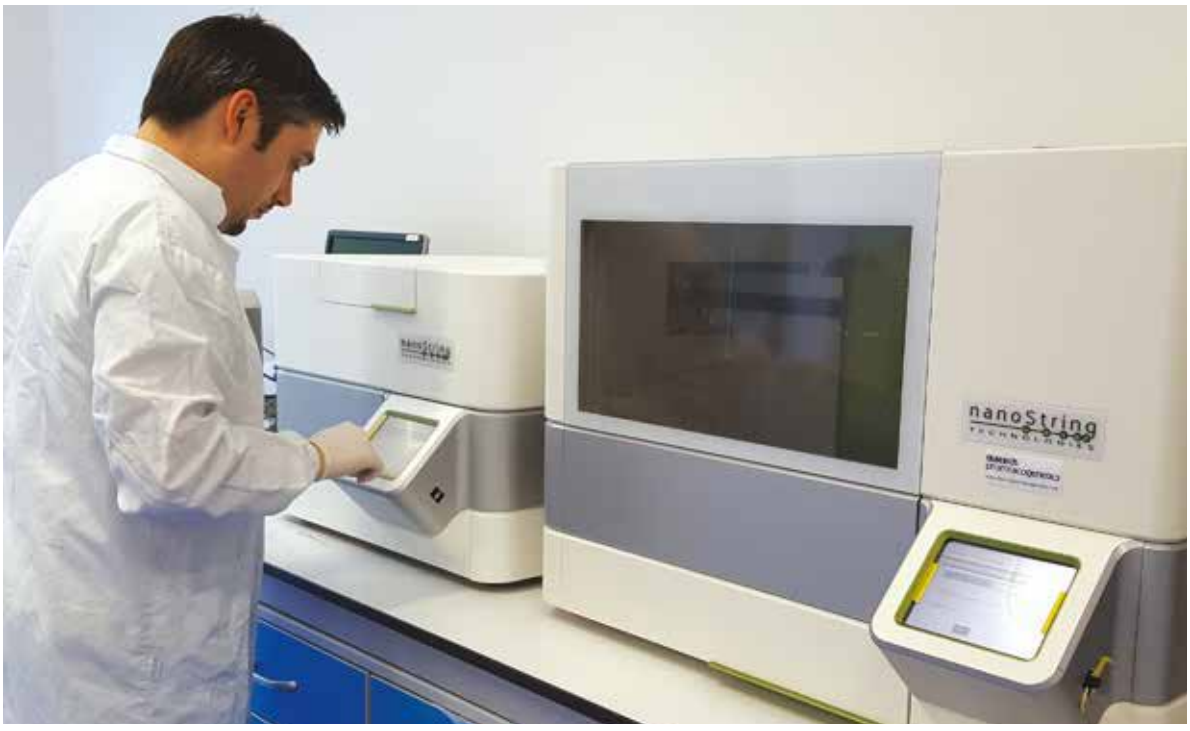
Several clinically validated methods are available for the detection of fusion genes. Fluorescence in situ hybridization (FISH) is complex, requires specialized technical expertise and has limitations in terms of costs and throughput. Immunohistochemistry (IHC) requires highly sensitive and specific antibodies and the involvement of trained pathologists to interpret the staining results. Real Time PCR needs multiple primer sets and PCR reactions to reliably detect all possible fusion isoforms and the availability of good-quality RNA.

Objectives

- Development of a new diagnostic device able to detect and quantify with the NanoString® platform transcripts of fusion genes involving ALK, ROS1 and RET in lung cancer.
- Validation of the clinical performance of the new diagnostic device against existing standards for in vitro diagnostic use under the 98/79/EC directive.
- Correlation of IHC/FISH data, tissue morphology signatures, with molecular results from NanoString® and patient outcomes after treatment with tyrosine kinase inhibitors (TKI), in order to better stratify patients and improve both treatment decision and sample selection.
- Clinical validation of ALK, ROS1 and RET fusion genes as predictive biomarkers of response to specific TKIs.

Leonid's product and impacts

- RealQuant® Lung Fusion Genes, medical device validated for in vitro diagnostic use under the 98/79/EC directive.
- One test for multiple biomarkers detection and quantification (ALK, ROS1 and RET gene rearrangements in the same reaction) >>> reduction of costs.
- Identification of the main fusion genes in the same well.
- Standardized results without personal interpretation and simplification of the medical report thanks to a dedicated software for secondary analysis of NanoString® output data >>> reduction of data decoding errors.
- Easy-of-use (only 4 pipetting steps) >>> reduction of hands-on-time and manual errors.
- Higher throughput (up to 10 samples per run).
- Faster workflow (from FFPE tissue to data in less than 2 days).
- Quality control of pre-analytical and analytical steps.
- Performance validated in a multicenter clinical study at Dipartimento di Patologia Chirurgica, Medica, Molecolare e dell'Area Critica, Università di Pisa - Azienda Ospedaliero Universitaria Pisana (Pisa) and at Laboratorio di Bioscienze, Diagnostica Molecolare di III livello - Biomarcatori e Medicina Personalizzata, Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori (I.R.S.T.) IRCCS (Meldola).



Partners of the project: three Italian SMEs

1. Diatech Pharmacogenetics - R&D-production CE IVD

2. BiMind - Software development

3. Geneticlab - MDx service lab

Programme/Call: H2020-SMEINST-2-2014
Funding scheme: SME instrument
Topic: PHC-12-2014/2015 - Clinical validation of biomarkers and/or diagnostic medical devices

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No° 673953

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