

reliability of NGS assay for the detection of rearrangements compared to the results obtained using FISH and IHC.

Methods: 86 FFPE samples, primary tumors or micro biopsies of patients with NSCLC, were analyzed in 7 European labs for this study. All samples were qualified by a senior pathologist prior to analysis. DNA and RNA were extracted from FFPE samples using Qiagen AllPrep kit. TruSight™ Tumor 15 and INCa panel kits were used for DNA library preparation and Archer® FusionPlex® panel kit for RNA library preparation. Both libraries were finally pooled and analyzed using illumina MiSeq sequencing system. Data were finally analyzed using Variant Studio software or Biomedical Genomics Workbench and Ingenuity Variant Analysis for SNV or indel and Archer Analysis software for rearrangements. SNV, indel and rearrangements found for each sample were finally compared to FISH and IHC results and previous DNA sequencing data when available in the labs.

Results: 86 DNA and RNA libraries were sequenced. Among 86 samples 8 failed fusion quality control, due to too low amount or too degraded input RNA. No FISH and IHC results were available for 12 samples. Rearrangements were found for 28 samples, 22, 5 and 1 with an ALK, ROS1 and RET rearrangements respectively. Among 74 samples with previously known rearrangements, all samples showed full concordance with previous methods.

Conclusions: RNA based NGS is a suitable and reliable alternative to FISH and/or IHC for the detection of rearrangements of ALK, RET, ROS1, NTRK1 and MET genes for the theragnostic management of patients with NSCLC. Further investigations are needed to determine if an “all NGS strategy” is more likely cost-effective and faster than a “FISH and NGS strategy”.

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35P Detection of ALK, RET, ROS1, NTRK1 and MET rearrangements and actionable mutations using next generation sequencing in patients with non-small cell lung cancer

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Background: Targeted therapies have been developed this last decade and considerably improved PFS and OS of patients with NSCLC. Next-Generation Sequencing (NGS) is commonly used for the detection of actionable mutations in a panel of genes and FISH or IHC are the gold-standard assay for the detection of rearrangements of ALK, RET, ROS1, NTRK1 and MET. The aim of this study is to evaluate the suitability and