SpaceGen 飞朔生物 | 飞朔医学 SPACESEQ | 朔幸医学 SPACESEQ

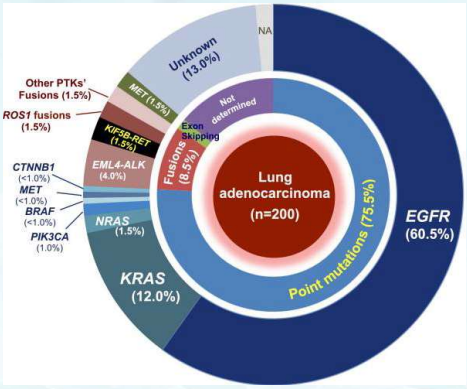
# Oncology Multi-Gene Mutations Detection Kit (Next Generation Sequencing)

## GENE MUTATION AND TUMOR

Tumor is the neoplasm of normal tissue, of which cancer is malignant neoplasm driven by various of tumorigenesis factors. Gene mutations caused by environment and heredity (including point mutation, deletion, insertion, copy number gain, gene fusion and so on) may lead to the division and growth of normal cells out of control and finally induce the formation of tumors.

Targeted drugs are able to target the pathologic molecules in cancer cells caused by specific gene mutations, which will maximize the drug efficacy and minimize the side effects. Therefore, the detection of the patient's gene status can contribute the clinicians to select suitable targeted drugs.

The initiation of the tumor is usually caused by activation proto-oncogenes or inactivation suppressor oncogenes. Studies had shown that 87% of Asian patients with lung adenocarcinoma have carried known kinds of driver genes mutations, 81% of which had clear target inhibitors, thus, 66% of patients can be treated with personalized target treatments.




Seo JS, et al. Genome Res 2012;22:2019–2119.

## DETECTED GENES

| NO. | GENE | Nucleic Acid Type | Mutation Type | Covering Exons |
|---|---|---|---|---|
| 1 | EGFR | DNA | Gene Mutation | 18,19,20,21 |
| 2 | KRAS | | | 2,3,4 |
| 3 | BRAF | | | 15 |
| 4 | PIK3CA | | | 10,14,21 |
| 5 | NRAS | | | 2,3 |
| 6 | HER2 | | | 19,20,21 |
| 7 | MET | | | 2,14,16,19 |
| 8 | AKT1 | | | 2 |
| 9 | KIT | | | 9,11,13,17 |
| 10 | PDGFRA | | | 12,18 |
| 11 | ALK | RNA | Fusion Mutation | EML4-ALK(21kinds) |
| 12 | RET | | | KIF5B, CCDC6, NCOA4, PCM1, GOLGA5, HOOK3, KTN1(15 kinds) |
| 13 | ROS1 | | | CD74, GOPC, SDC4, SLC34A2, EZR, LRIG3, TPM3-ROS1(15 kinds) |
| 14 | MET | | Skipping Mutation | 14 exon skipping mutation |

## PRODUCT INFORMATION

| Product Name | Core Technology | Pack Size | Instruments Validated | Sample Type |
|---|---|---|---|---|
| Oncology Multi-Gene Mutations Detection Kit | RingCap® | 16 Tests/Kit<br>32 Tests/Kit | IonTorrent<br>Illumina<br>MGISEQ | Tumor tissue<br>Peripheral blood<br>Pleural effusion |

## DETECTION SIGNIFICANCE

- Personalized treatment: Select suitable targeted drugs for the patients based on the gene detection information to improve the efficacy of the drugs, thus realize personalized treatment.
- Monitoring drug efficacy and resistance: Analyze the drug resistance mechanism, adjust the treatment plan according to the gene variation information after drug resistance.

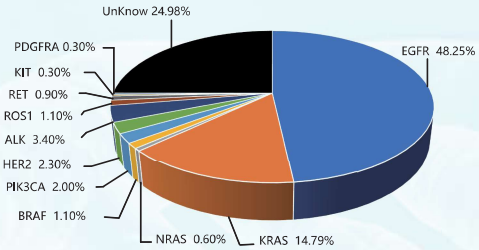
## CLINICAL DATA

This double blind trial adopted a comparative design to the Oncomine DX Target Test(NGS), which is one FDA-approved test kit of Thermo Fisher Scientific

Results comparison of the two methods

| | | Control reagent: Oncomine DX Target Test Detection Result | | |
|---|---|---|---|---|
| | | Mutation Type | Wild Type | Total |
| Results of Spacegen oncology panel | Mutation Type | 660 | 0 | 660 |
| | Wild Type | 1 | 518 | 519 |
| | Total | 661 | 518 | 1179 |

Gene mutations of 1267 FFPE clinical samples




The total coincidence rate of the two methods for detecting genes was 99.92%

## FEATURES & ADVANTAGES

Ease of Use: Based on the independent patent technology RingCap®, library preparation in 2 steps.

Fast Results: The library preparation takes only 3.5 hours.

High Sensitivity: Tissue sequencing depth up to 5000X, cell-free DNA sequencing depth up to 20,000X, sensitivity up to 0.1%.

Comprehensive Coverage: Covers and detect relevant hotspot mutations in 13 genes , applicable for non-small cell lung cancer, colorectal cancer, malignant melanoma, gastrointestinal stromal tumor.

Multiple Instruments: Reagents are compatible with three NGS platforms: Ion Torrent, Illumina and MGISEQ.

## DETECTION PROCESS

Nucleic Acid Extraction > Library Preparation (3.5 hours total time) > Sequencing > Auto-data Analysis > Report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