Human EGFR Gene Mutation Detection Kit

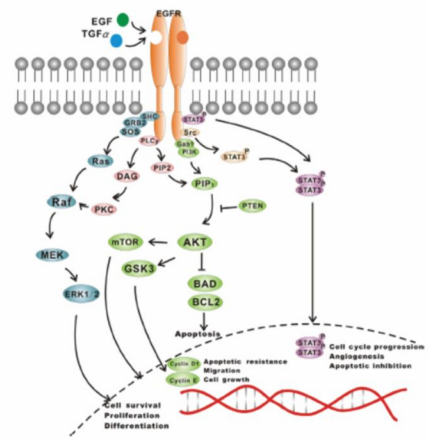
(PCR -Fluorescent Probe Method)

National Medical Device Registration and Approval No: 20173401245

PRODUCT DESCRIPTION

The human EGFR Gene Mutation Detection Kit is used to qualitatively detect 11 common mutations of human EGFR gene in DNA samples of clinical tumor patients for targeted drug therapy.

Typically embedded in the cell membrane on the cell surface, EGFR (Epidermal Growth Factor Receptor) is a membrane protein that plays an essential role in the proliferation, growth, repair and survival of tumor cells. The positive rate of EGFR-sensitive mutation in lung adenocarcinoma patients in Asia is 40%-50%. There are multiple mutations in the tyrosine kinase region of the EGFR gene, mainly concentrated in exons 18-21, among which deletion mutations in exon 19 and L858R mutations in exon 21 are the most common ones.



Types of EGFR Gene Mutation Detected by This Kit

Exon region	Mutation type	Mutation probability	Clinical guidance
18	G719A/G719S/G719C	3-5%	Sensitivity
19	Glu746-Ala750del	45%	Sensitivity
20	S768I	3-5%	Sensitivity
	T790M，Ins		Insensitive to EGFR TKIs Generation I & II, EGFR mutation and drug resistance patients are sensitive to EGFR-TKI Generation III, oseltinib and ametinib.
21	L858R、L861Q	45%	Sensitivity

Overview of Molecular Typing of EGFR Mutation of NSCLC and corresponding Targeted Drugs

Molecular typing	Corresponding targeted medicine	Enter the Chinese market or not	Included in medical insurance or not
EGFR Mutation	Geofitinia, Elotini, Ektinia Afatini, Dachtini, Oshtini	Yes	Yes
	Ametinib (Second-line medication)	Yes	Yes

CLINICAL GUIDELINES

Version 2022 of NCCN Guidelines for Non-small Cell Lung Cancer(NSCLC)

Retain sufficient tissue specimens for molecular testing after pathologic diagnosis to guide treatment based on molecular typing ; For non-squamous tissue specimens: EGFR mutation , ALK fusion and ROS1 fusion testing;

For patients resistant to EGFR-TKIs, a repeat biopsy for EGFR T790M testing is recommended.

EGFR mutation detection for N1 and or N2 positive non-squamous cancers after operation shall guide the auxiliary targeted therapy

EGFR mutation, ALK fusion and ROS1 fusion testing are recommended for non-smoking patients with squamous or mixed adenocarcinoma components diagnosed by small specimen biopsy

Postoperative targeted therapy for operable NSCLC in stages I to III

EGFR mutation testing for N1 and or N2 positive non-squamous cancers to guide the auxiliary targeted therapy.

Targeted therapy for inoperable NSCLC in stages III & IV

Retain sufficient tissue specimens for molecular testing after pathological diagnosis to guide the targeted therapy based on molecular typing.

Treatment of EGFR-mutated NSCLC in stage IV with extensive progression after drug resistance

First-line treatment failure using TKI Generation I/II requires a repeat biopsy.

T790M positive patient: axitinib ;T790M negative patients after a repeat biopsy or those who failed with the treatment of TKI therapy Generation III: platinum-based dual-drug chemotherapy ± bevacizumab (non-squamous cancer)

Re-biopsy to assess the mechanism of other medicine resistance； Retest the T790M positive: platinum-based dual-drug chemotherapy or + bevacizumab (non-squamous cancer); amatinib.

APPLICABLE POPULATION

1.All NSCLCs with an adenocarcinoma component

2.Non-smoking squamous or lung cancer with mixed adenocarcinoma diagnosed by the biopsy of small specimens

SAMPLE TESTING TYPE

Paraffin sections, fresh tissue， samples originated from primary tumors and metastases are acceptable.

PRODUCT FEATURES

High Sensitivity: **accurately detect 1% of mutant DNA from 10ng of the wild-type gene**

High Specificity: **effectively improve the testing specificity by ARMS-PCR detection technology**

High Accuracy: **closed tube reaction effectively prevent false negative and false positive results through the standard internal system and UNG enzyme system**

Quick & Easy: **easy to operate with reliable results analysis, 90 mins to complete**

APPLICABLE MODEL (REAL-TIME FLUORESCENCE QUANTITATIVE PCR DEVICE)

ABI7500， Agilent MX3000p/3005, Roche LightCycle 480/cobas z 480， QIAGEN Rotor-Gene Q， Bio-Rad CFX 96, SLAN, Bori

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