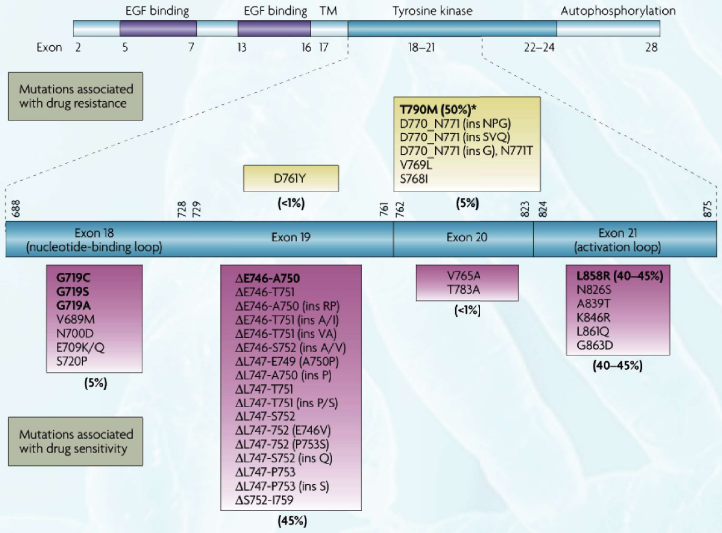
EGFR Gene Mutations Detection Kit (Real-Time PCR assay)

GENE MUTATION AND TUMOR

Epidermal growth factor receptor (EGFR) is a receptor tyrosine kinase, expressed in 50% of non-small cell lung cancer (NSCLC) [1], which is closely related to the occurrence and development of tumors. EGFR is the most frequently mutated driver gene in NSCLC patients in East Asian population, with a mutation frequency of 38.4%, among which East Asian female NSCLC patients have a mutation frequency of 51.1% [2]. EGFR gene mutation is the most important predictor of the efficacy of EGFR Tyrosine Kinase Inhibitor (TKI) and is a prerequisite for clinically determining whether patients can use EGFR-TKI therapy. Both the National Comprehensive Cancer Network (NCCN) and the Chinese Society of Clinical Oncology (CSCO) guidelines include EGFR mutation detection as a category 1 recommendation [3] [4].

COMMON MUTATIONS

The carcinogenic mutations of EGFR mostly occur in exons 18-21, of which 19 del and L858R account for 85% to 90% of EGFR mutations [1], which are also the most common EGFR-TKI sensitive mutations. The T790M mutation suggests resistance to the first and second generation of EGFR-TKI while sensitive to the third generation of EGFR-TKI. For 20 ins mutation， which is not sensitive to traditional EGFR-TKI, suggesting the use of EGFR 20 ins inhibitor.



Common mutations in the EGFR gene [1]

DETECTED GENES

Gene	Covering Exons	Medication
EGFR	19 del, L858R	EGFR-TKI
	G719X, S768I, L861Q	EGFR-TKI（Except for Befotertinib）
	T790M	Osimertinib, Almonertinib, Furmonertinib, Befotertinib
	20 ins	Amivantamab, Mobocertinib

[1] Nat Rev Cancer. 2007 Mar;7(3):169-81.
[2] Oncotarget. 2016 Nov 29;7(48):78985-78993.
[3] NCCN Clinical Diagnosis and Treatment Guidelines NSCLC 2023 V3
[4] CSCO NSCLC Diagnosis and Treatment Guidelines 2023

PRODUCT INFORMATION

Product Name	Core Technology	Pack Size	Instruments Validated	Sample Type
EGFR Gene Mutations Detection Kit	PAP-ARMS®	10 Tests/Kit	Stratagene Mx3000P™ ABI7500 etc.	Tumor tissue Peripheral blood Pleural effusion

DETECTION SIGNIFICANCE

- EGFR mutation detection in resectable stage IB-IIIA NSCLC patients to guide adjuvant targeted therapy.
- The detection of EGFR mutation for unresectable stage III and IV NSCLC patients, can help guide the treatments according to molecular classification.
- For patients with EGFR-TKI resistance, it is recommended to perform another biopsy for EGFR gene mutation detection.

FEATURES & ADVANTAGES

Accuracy and Reliability: Use pre-load PCR tube to effectively avoid cross-contamination.

High Sensitivity: Sensitivity can reach as low as 1%in 10 ng DNA.

Ease of Use: Based on technology PAP-ARMS®, one step detection in 90 mins.

Great versatility: Validated on the most common qPCR machines with stable results.

DETECTION PROCESS

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