

TRUPCR® EGFR Mutations Detection Kit

NEED

Non-small-cell lung cancer (NSCLC) is the most common form of lung cancer. Epidermal growth factor receptor (EGFR) mutations are regarded as the strongest predictor of effectiveness for the treatment of lung cancer. Unfortunately, lung cancer patients eventually develop resistance to drugs after 10 months.

Mutations associated with enhanced sensitivity to EGFR tyrosine kinase inhibitors (TKI) are found in exons 18–21 of the TK domain of EGFR. T790M mutation is the most common mechanism for resistance to first and second generation TKI.

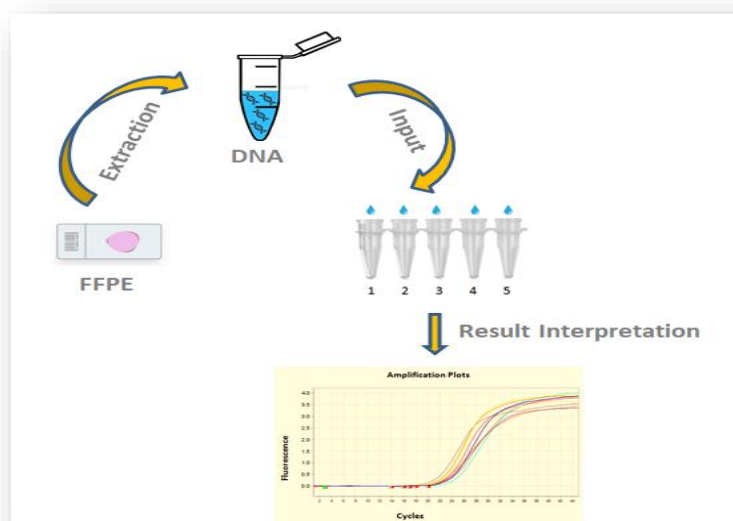
Mutations in the EGFR gene in the DNA of the tumor cells helps to determine whether someone with non-small cell lung cancer (NSCLC) may benefit from targeted therapy with tyrosine kinase inhibitors (TKIs) such as osimertinib, gefitinib & erlotinib.

SOLUTION BY TRUPCR®

The TRUPCR® EGFR Mutations Detection Kit is an in vitro diagnostic test intended for the qualitative detection of 59 somatic mutations exons 18-21 of epidermal growth factor receptor (EGFR) gene from tumor tissue DNA extracted from fresh, frozen or formalin fixed paraffin-embedded (FFPE) tissue or liquid biopsy.

This assay is based on allele specific amplification and is achieved by nested ARMS PCR. The detection is achieved in multiplex reaction using fluorescent probes labeled with FAM, VIC/HEX and ROX/Texas Red. It comprises of five separate PCR amplification reaction mixes where mutation-specific reactions (exons 18, 19, 20 & 21 of the EGFR gene) and a reference (wild type control in exon 2 without any known polymorphism/mutation) is amplified simultaneously in each tube.

TEST PROCEDURE



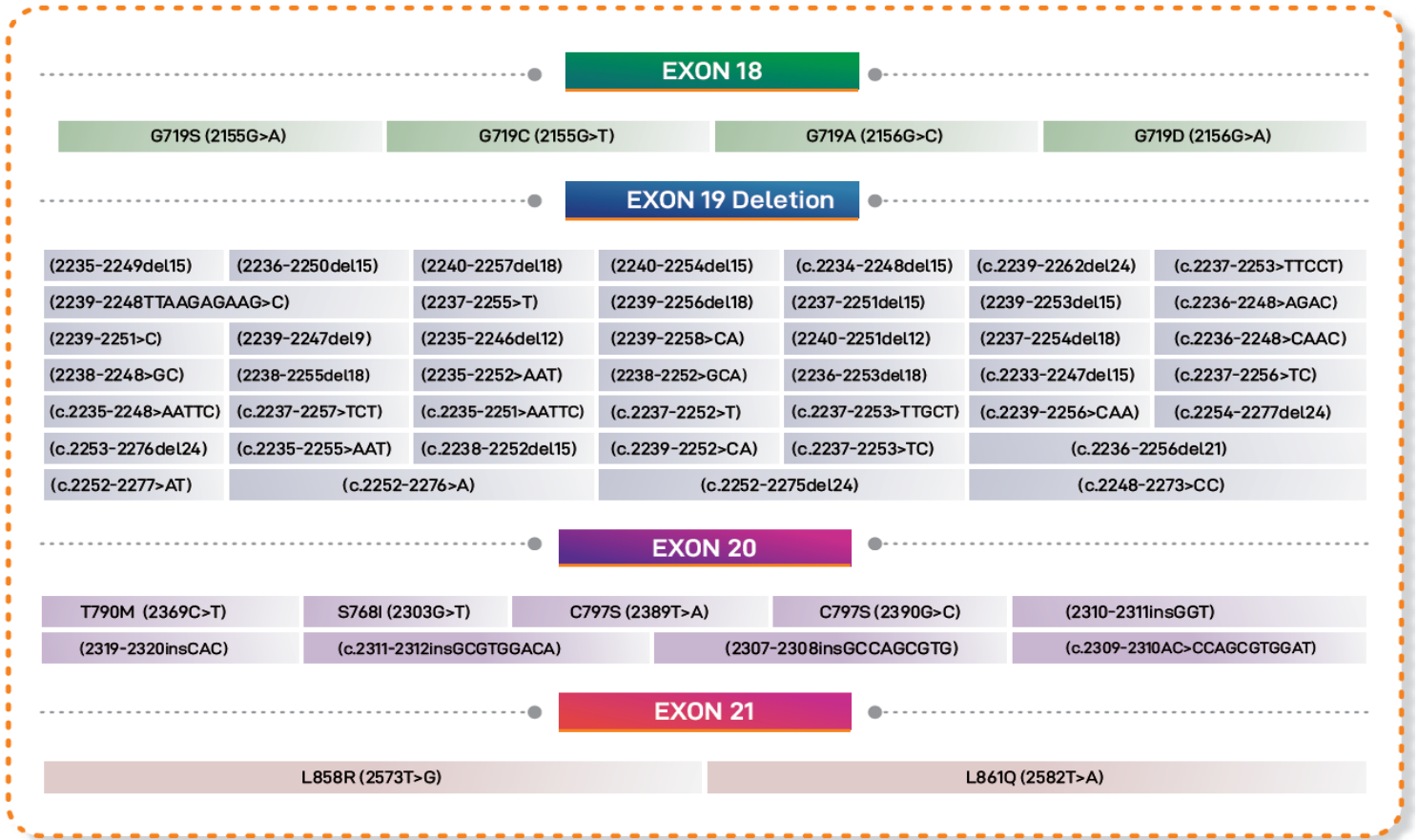
TECHNICAL SPECIFICATIONS

- Selective Amplification of DNA containing mutation with nested ARMS PCR
- Kit detects most prevalent EGFR mutations (19-del, S768I, G719X, L858R, L861Q & ex20ins) including T790M and C797S, the presence which correlates with resistance to first, second & third line of TKIs.
- Compatible Instruments – Applied Biosystems™ 7500 series, Applied Biosystems™ QuantStudio® series, Rotor-Gene Q, Bio-Rad CFX96, CFX384, Roche - LightCycler® 480/480 II and COBAS z 480

PRODUCT HIGHLIGHTS:

- Sample Type – DNA extracted from Formalin Fixed Paraffin-Embedded (FFPE) tissue and Liquid Biopsy
- Target Regions – Detects 59 different mutations of exon 18, 19, 20 & 21
- LoD – Sensitive to detect up to 1%-5% mutation in EGFR gene with input of 3-5ng of DNA

MUTATIONS DISTRIBUTION IN TRUPCR® EGFR KIT



ORDERING INFORMATION

Cat. No.	Description	Size
3B1311	TRUPCR® EGFR Mutations Detection Kit	24 Reactions
3B1312	TRUPCR® EGFR Mutations Detection Kit	48 Reactions

REFERENCES

- Joy, R.A., Thelakkattusserry, S.K., Vikkath, N. et al. Somatic mutation detection efficiency in EGFR: a comparison between high resolution melting analysis and Sanger sequencing. *BMC Cancer* 20, 902 (2020). <https://doi.org/10.1186/s12885-020-07411-1>
- D'Souza G, Dhar C, Kyalanoor V, et al. High frequency of exon 20 S768I EGFR mutation detected in malignant pleural effusions: A poor prognosticator of NSCLC. *Cancer Reports*. 2020;3:e1262. <https://doi.org/10.1002/cnr2.1262>

