

## EGFR Mutation Analysis

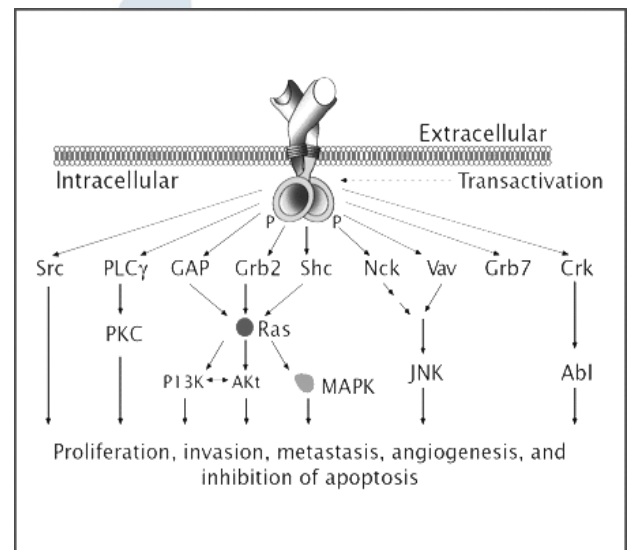
### EGFR Mutations and Cancer

Epidermal growth factor receptor (EGFR) is a membrane protein that plays a central role in transmitting signals that promote cell growth and proliferation. Its tyrosine kinase (TK) domain activates several downstream effectors that lead to activation of the Ras-Raf-MAPK pathway. Overexpression and oncogenic mutations that constitutively activate the TK domain of EGFR have been found in various solid tumors. Additionally, excessive activation of EGFR has been shown to be associated with advanced stages of cancer and a poor prognosis.

### Testing Procedure

EntroGen's EGFR mutation analysis kit is a real-time polymerase chain reaction (PCR)-based assay that uses mutant-specific primers to identify the presence of EGFR mutations. The testing procedure involves three (3) simple steps, which can be completed in approximately 2 hours from isolation of DNA to test results:

- Isolation of DNA from tumor biopsies, paraffin-embedded sections (FFPE), or fresh frozen tumors
- PCR setup with reagents included in the kit
- Amplification (8 reactions per sample) and detection using a real-time PCR instrument



### Specifications

EntroGen's EGFR mutation analysis kit detects the following EGFR mutations:

#### **Exon 18**

G719A - 2156G>C  
G719S - 2155G>A  
G719C - 2155G>T  
G719D - 2156G>A

#### **Exon 20**

T790M - 2369C>T  
S768I - 2303G>T  
2307-2308 ins GCCAGCGTG  
2319-2320 ins CAC  
2310-2311 ins GGT

#### **Exon 19**

2235-2249 del 15  
2235-2252>AAT del 18  
2236-2253 del 18  
2237-2251 del 15  
2237-2254 del 18  
2237-2255>T del 19  
2236-2250 del 15  
2238-2255 del 18  
2238-2248>GC del 11

#### **Exon 19 (continued)**

2238-2252>GCA del 15  
2233-2247 del 15  
2234-2248 del 15  
2235-2246 del 12  
2235-2248>AATC  
2235-2251>AATC  
2235-2252>AAT  
2236-2248>AGAC  
2236-2248>CAAC  
2236-2256 del 21  
2237\_2251>TTC  
2237-2252>T  
2239-2247 del 9  
2239-2256 del 18  
2239-2248>C del 10  
2239-2258>CA del 20  
2240-2251 del 12  
2240-2257 del 18  
2240-2254 del 15  
2239-2251>C del 13  
2237-2253>TC  
2237-2253>TTCCT

#### **Exon 19 (continued)**

2237-2253>TTGCT  
2237-2256>TC  
2237-2256>TT  
2237-2257>TCT  
2238-2252 del 15  
2239-2252>CA  
2239-2253 del 15  
2239-2256>CAA  
2239-2257>T  
2239-2262 del 24  
2246-2260 del 15  
2248-2273>CC  
2252-2275 del 24  
2252-2276>A  
2252-2277>AT  
2253-2276 del 24  
2254-2277 del 24

#### **Exon 21**

L858R - 2573T>G  
L861Q - 2582T>A

\* Expansion kit available for E709, L858M, and L861R mutations.

## Limitations

EntroGen's *EGFR* mutation analysis kit requires 40-80 nanograms of genomic DNA (5-10 nanograms per reaction) and can detect a mutation load of less than 1%. This sensitivity greatly depends on the extent of fragmentation and quality of the isolated DNA.

## Equipment and Materials

EntroGen's *EGFR* mutation analysis kit requires a real-time PCR instrument capable of detecting FAM and VIC fluorescent probes.

This test includes reagents required for the PCR amplification/detection, as well as validated reaction controls. Columns and reagents for DNA isolation are not included.

## Intended Use

EntroGen's *EGFR* mutation analysis kits are available for Research Use Only (RUO) in the United States and for In Vitro Diagnostic use (CE-IVD) in Europe.

## Ordering Information

Product Name	Cat. No.
EGFR 59 Mutation Detection Kit for Real-Time PCR - 52 Reactions	EGFR-RT52
EGFR Expansion Kit	EGFRX-RT52